May 7, 2012

VIA COURIER AND ELECTRONIC MAIL

Courier's Desk
Attn: CC:PA:LPD:PR (REG-113770-10)
Internal Revenue Service
1111 Constitution Ave, N.W.
Washington, DC 20224

RE: Notice of Proposed Rulemaking and Notice of Public Hearing on Taxable Medical Devices (77 *Fed. Reg.* 6,028 [Feb. 7, 2012].)

Dear Sir/Madam:

The Federation of American Hospitals ("FAH"), the American Hospital Association ("AHA"), the Catholic Health Association of the United States ("CHA"), the Healthcare Supply Chain Association ("HSCA"), and the Association for Healthcare Resource & Materials Management ("AHRMM") appreciate the opportunity to submit these comments in response to the Internal Revenue Service's ("IRS") Notice of Proposed Rulemaking and Notice of Public Hearing on Taxable Medical Devices, referenced above. This letter builds upon our earlier comments on this subject in a letter dated March 28, 2011.

In summary, the IRS should implement the device tax in a manner that recognizes the "shared responsibility" commitment from a broad group of key health care stakeholders, including medical device companies, to bring forward long-needed national health reform through passage of the Patient Protection and Affordable Care Act ("ACA"). Given their commitment to the goals of ACA, medical device companies should not be permitted to sidestep their ACA financial contribution by passing through the tax to their customers, including hospitals. As the ACA appears to permit device companies to deduct the tax from their income for federal tax purposes, to allow device companies also to pass through the tax to their customers, would provide a financial benefit that could leave device companies in a better financial position than before the ACA was enacted.

We support the facts and circumstances test with regard to the retail exemption, but it could be enhanced by providing additional guidance. Finally, we urge the IRS to interpret the terms ”manufacturer,” “importer,” “use” to exclude activities regarding packaging and sterilizing devices for use in surgery kits to avoid improper treatment of hospitals and other healthcare providers as “manufacturers” or “importers,” and also the potential for double taxation of certain devices. We also seek clarification as to whether hospitals could be considered “importers” for the purpose of the medical device tax.

I. Background

The ACA imposes on sales of “taxable medical devices” made after December 31, 2012 by a manufacturer, producer, or importer a tax equal to 2.3 percent of the price for which these devices are sold. (*See* Internal Revenue Code (“IRC”) § 4191.) Section 4191 defines “taxable medical devices” as those devices intended for humans, exempts certain specific types of medical devices, and provides the IRS with authority to exempt “any other medical device determined by the Secretary to be of a type which is generally purchased by the general public for individual use.” This authority provides a “retail exemption” to the medical device tax.

The undersigned organizations believe it is important for the IRS to understand the proper context under which the medical device tax was enacted and the tax’s importance in the overall financing structure of the ACA. The ACA provides coverage and access to health care services for mostly all Americans, thereby addressing an uninsured crisis that has reached a critical juncture in this country, and is costing the health care system, through employers, providers, insurers and individuals, billions of dollars per year. The ACA also provides delivery reforms that are designed to contain health care costs and to improve the way health care services are delivered.

A. “Shared Responsibility” Is a Core Element of Healthcare Reform

A broad array of health care stakeholders supported the goals of this important, new public health policy, many through reductions in federal insurance payments as part of a “shared responsibility” strategy to create a better health care system. For the nation’s hospitals, this means a contribution of $155 billion over 10 years, largely through reductions in Medicare payments.

The concept of “shared responsibility” for funding and implementing healthcare reform, among all population segments and affected economic interests, was a core element of the legislative bargain from the very beginning. Senator Max Baucus, Chair of the Senate Finance Committee and a key figure throughout the legislative process that resulted in the enactment of ACA, sent a letter to President Obama on November 6, 2008, immediately after the election, stating his intent to present his plan to move forward with health care reform early in the new administration. In the letter Senator Baucus stated, “These proposals will be built on the key principles that I have identified as essential to successful reform…..Shared Responsibility:

Individuals, employers, and the government must all play a part in the creating and funding of a new health care system. I intend to enumerate specific roles and opportunities for all to share the burden."[1]

The "shared responsibility" for "funding of a new health care system," as described in Sen. Baucus's letter, included a revenue contribution from the medical device industry in the initial drafts of the legislation. For example, the Senate Finance Committee's September 9, 2009 white paper, "Framework for Comprehensive Health Reform," included a proposed "manufacturer's fee" on medical device makers, described as follows: "an annual fee of $4 billion would be imposed on the medical devices manufacturing sector beginning in 2010. The fee would be allocated by market share."[2] This proposal evolved and was ultimately included in the final legislation as the 2.3 percent medical device manufacturers excise tax in IRC § 4191.

Thus, there is no doubt that medical device manufacturers, along with all other healthcare sectors, are expected to make a financial contribution to health care reform. As noted above, the hospital sector's contribution of $155 billion over 10 years, largely through reductions in Medicare reimbursements, is its component of "shared responsibility," and other providers are providing similar contributions. Medical device companies are part of the supply chain for health care providers. Thus, these companies do not receive federal health insurance program payments directly, so the option of reducing direct payment was not available to Congress to fulfill the device industry's financial commitment. Instead, a medical device tax was enacted as the proper way for medical device companies to contribute financially to the better health care system envisioned in the ACA.

Consistent with the legislative intent that medical device manufacturers along with all other healthcare sectors contribute to the cost of healthcare reform, the IRS and Treasury Department should assure that device manufacturers themselves – not their customers – contribute to "shared responsibility" by bearing the economic effect of the 2.3 percent device excise tax, and not passing this through to providers, like hospitals, which thereby increases their total contribution to health reform.

For all of these reasons, the undersigned organizations believe the IRS should implement the medical device tax in a way that ensures medical device companies honor their financial commitment to promote a better health care system. We urge the IRS to reflect in the final rule policies that properly address the context in which the tax was enacted, and that in implementing this new authority, the IRS should set policy that ensures medical device companies pay directly their financial commitment under the tax.

---

[1] Letter available online at Finance Committee website, finance.senate.gov/newsroom/chairman/release/?id=b7fe3588-4028-4484-b0fd-f4c90632db36.

[2] A link to the September 9, 2009 "Framework" paper is at finance.senate.gov/newsroom/chairman/release/?id=cd42e3c9-62af-41de-9ad9-8acba8aee97a. The medical device manufacturers fee is described on page 18 of the paper.

II. The Device Tax Should Not Provide a Windfall for Medical Device Companies

In addition to the concern noted above, we also are concerned that the device tax could be implemented in a way that would actually result in a windfall for device companies, and that such an outcome could actually leave these companies in a better financial position than they were before the ACA became law. This is clearly not what Congress intended.

More specifically, as purchasers of medical devices, hospitals and group purchasing organizations are concerned that medical device companies will eventually pass through this entire tax to their customers. This strategy would allow device manufacturers to sidestep their responsibilities, while increasing the financial commitment of other stakeholders, including hospitals. From a systemic perspective, this would actually increase (not decrease) the cost of health care and would likely negatively impact patients and employers through higher insurance premiums and cost sharing.

We strongly believe it would be inappropriate and fundamentally unfair for device companies to reap this type of unintended benefit, especially given the "shared responsibility" commitment made by many health care stakeholders that led to passage of the ACA. Below, we offer policy recommendations that would prevent this windfall from occurring.

III. The IRS Should Explicitly Prohibit The Pass-Through of the Tax to Purchasers.

In general, the IRC does not permit a manufacturer to seek a refund of an excise tax on any grounds unless it can certify that the tax was not included in the price of the article sold to customers, or that it has repaid the tax to the customer or obtained its consent to seek a refund. (*See* IRC § 6416(a)(1).) If medical device companies are allowed to deduct the amount of the tax from income, we believe that deduction is tantamount to a refund and should trigger the pass-through prohibitions noted above.

The proper policy for the medical device tax would be to *prohibit* device manufacturers from passing the tax through to their purchasers. This approach will afford manufacturers the benefit of reducing their income by the amount of the tax through a deduction, but will also require them to pay the tax in a manner consistent with their "shared responsibility" commitment to support the passage of the ACA.

We believe the IRS should require medical device manufacturers to follow the same certification procedures already in place for refunds, in order to require direct accountability from the device companies regarding their business practices. The most effective way to implement this legislative intent is to require device manufacturers to certify on their Form 720 excise tax returns that they have not included the tax as a component of the price of their

products, and therefore have not passed the tax through to their customers.[3] We believe this is appropriate public policy, and reflects the true intent of Congress in establishing the "shared responsibility" network of stakeholders that made passage of the ACA possible.

A. Certifying No Pass-through on the Tax Return Is a Congressionally Approved Approach

An important benefit of implementing the no-pass-through rule by having device manufacturers make a certification on their excise tax returns is that Congress has approved this type of procedure in very similar excise tax contexts. Under IRC § 6416(a)(1), in order for a manufacturer to claim a refund of an overpayment of a manufacturers excise tax, the manufacturer must prove that it –

(i) Has repaid the tax to any purchaser who originally paid the tax as part of the purchase price; or

(ii) Has obtained the consent of the purchaser to receive the refund (usually by agreeing to reimburse all or part of any refund to the purchaser; or,

(iii) Never "included the tax in the price of the article."

Under applicable Treasury regulations, the manufacturer seeking a refund makes this showing by "submit[ting] with the [refund] claim a statement, supported by sufficient evidence," that one of those factors has been met. (Treas. Reg. § 48.6416(a)-3(a)(2).) Like all tax returns and other tax submissions, the refund claim must be signed under the penalties of perjury. (See IRC § 6065.)

Therefore, the procedure we are suggesting – that a manufacturer liable for the medical device excise tax must include a statement with its Form 720 excise tax return that it has not included the tax in the price of any medical device – is identical in concept to the kind of statement already required by law to support excise tax refund claims. It would be no more complex, difficult or burdensome for medical device manufacturers to make this certification than it is to file refund claims under current law. Adopting this kind of Congressionally-approved statement procedure would be an easy and effective way to implement the legislative intent that the medical device tax not be passed through to device purchasers.

[3] As stated in our March 28, 2011 comments, the undersigned organizations' position should not be read as precluding manufacturers from properly accounting for the cost of the tax as a business expense or otherwise. We take no position on how manufacturers should account for the tax. What we do say is that allowing manufacturers to escape the tax by passing it through directly to their customers is inconsistent with the legislative intent underlying healthcare reform.

B. Precluding Pass-through Does Not Make the Excise Tax a Nondeductible "Penalty"

As noted above, FAH, AHA, CHA, HSCA and AHRMM take no position on, and are not urging any restriction on, how medical device manufacturers account for the device tax. Our proposal is simply that device manufacturers not be allowed to include the tax as a component of the price of their products. That means that the manufacturers will be paying the excise tax themselves, and they may be able to deduct it as a business expense if otherwise allowed by generally applicable tax rules.

In particular, the medical device excise tax is not one of the specialized taxes or fees enacted in ACA that are specifically treated as nondeductible. New section 4980H of the IRC imposes excise taxes and penalties on large employers that do not provide minimum essential health insurance coverage for their employees. New section 4980I imposes an excise tax on certain high-cost employer-sponsored health insurance coverage (so-called "Cadillac plans"). In addition, the ACA imposes separate, new fees on branded prescription drug manufacturers and importers, and on health insurance issuers. All those taxes, penalties and fees are nondeductible by law for income tax purposes.[4] In contrast, no provision of law makes the medical device excise tax nondeductible.[5] We take no position on, and recommend no new restrictions on, how device manufacturers account for the medical device excise tax.

C. Precluding Pass-through Of Medical Device Tax Raises No Legal or Constitutional Concerns

The limited jurisprudence on anti-pass-through provisions indicates that the IRS and Treasury Department have the authority to require device manufacturers not to pass through the tax to purchasers as a component of the sale price of medical devices.

In *Hawkins v. United States*, 544 F. Supp. 39, 41 (S.D. Ohio 1982), the court observed that the IRS had promulgated regulations precluding corporations from carrying certain tax credits back to years in which they could be passed through to S Corporation shareholders. Although the case was decided on different grounds, there is no suggestion that the IRS lacked authority to disallow S Corporation shareholders to utilize such credits even though there was no specific statutory authorization for the regulations for precluding the pass-through. Disallowing the pass-through of tax benefits to shareholders is similar in principle to disallowing the pass-

---

[4] See IRC § 275(a)(6) (non-deductibility of taxes paid under Chapter 43 of Internal Revenue Code, which contains §§ 4980H, 4980I). See also JOINT COMM. ON TAX'N, TECHNICAL EXPLANATION OF THE REVENUE PROVISIONS OF THE "RECONCILIATION ACT OF 2010," AS AMENDED, IN COMBINATION WITH THE "PATIENT PROTECTION AND AFFORDABLE CARE ACT" (JCX-18-10, Mar. 21, 2010), at pages 86, 91 (non-deductibility of prescription drug fees and health insurance provider fees).

[5] See JCX-18-10, *supra* note 4, at pages 137-39 (Joint Committee explanation of medical device excise tax, with no suggestion it is nondeductible).

through of an excise tax to purchasers. Thus, this case supports the authority of the IRS and Treasury Department to take the action we recommend.

In *Shell Oil Co. v. N.Y. State Tax Comm'n*, 91 A.D.2d 81; 90-95, 458 N.Y.S.2d 938, 944-47 (App. Div. 1983), the Appellate Division of the New York State Supreme Court considered a New York State gasoline tax law that prohibited oil companies from including the tax as part of the price of gasoline sold to consumers – similar to the anti-pass-through rule we are recommending for the medical device tax. The court held that this *state* law anti-pass-through provision violated the Interstate Commerce Clause of the U.S. Constitution, specifically because it forced citizens of other states in which the oil companies operated to bear the burden of a tax imposed by New York. This was the only constitutional problem discussed by the court.

It is important to recognize that, since the medical device tax and the proposed anti-pass-through regulation are *federal* tax requirements imposed on all device manufacturers nationwide, there is no Commerce Clause concern whatsoever. Thus, the only court decision to deal squarely with the constitutional status of an anti-pass-through provision raised no constitutional problem that would impact a *federal* tax law or regulation, and supports the ability of the IRS and Treasury Department to preclude pass-through of the medical device tax to purchasers.

IV. Facts and Circumstances Approach for Retail Exemption is Appropriate, But Could Be Enhanced with Additional Guidance

Internal Revenue Code § 4191(b)(2) specifically exempts from the 2.3 percent medical device tax: (1) eyeglasses, (2) contact lenses, (3) hearing aids, and (4) devices that the IRS determines "to be of a type which is generally purchased by the general public at retail for individual use." This provides a broad grant of authority to the IRS to use the so-called retail exemption to exclude from the tax appropriate medical devices that are for personal use.

The undersigned parties support the IRS's proposal to use a "facts and circumstances" approach for evaluating whether a device would be eligible for the retail exemption. The rule includes a safe harbor which provides certainty in the identification of certain categories of taxable medical devices that the IRS would consider to be "of a type generally purchased by the general public at retail for individual use." For devices in categories that fall outside the safe harbor, the agency lays out several factors that are relevant to this determination, but clarifies that other facts and circumstances in addition to those listed may also be relevant.

The Proposed Rule's examples also are helpful in demonstrating how a "facts and circumstances" determination should be made. We support this approach for its flexibility and believe it to be preferable to one in which the IRS would promulgate a regulatory list of exempt medical devices, which would quickly become outdated and would be cumbersome to keep up. To keep up with the fast-changing nature of the medical device industry, the undersigned parties also urge the agency to provide, in an on-going manner, additional guidance regarding the application of the retail exemption via revenue procedures or other rulings, as appropriate.

V. The Terms "Manufacturing," "Importing," and "Use" Should Be Interpreted to Exclude Hospital Activities Related to Packaging and Sterilization of Surgery Kits

We understand that the IRS is making an effort to apply existing excise tax principles to the device tax as it develops guidance, including the exception to the tax for taxable products sold for "further manufacture" under Code section 4221 and the tax on the "use" of a taxable product under section 4218. We are concerned about the potential tax treatment related to the packaging and sterilization of surgery kits by hospitals. The Proposed Rule refers to kits as "two or more different medical devices, or a combination of medical devices and other items, packaged in a single bag, tray, or box for the convenience of the user." Under the Proposed Rule, this determination is based on whether the kit itself is listed as a device with the Food and Drug Administration ("FDA"). If the kit itself is listed, then the kit is a separate taxable device and the excise tax applies to the entire sale price of the kit (including the portion of the price attributable to any items in the kit that are not taxable medical devices).

In general, "kitting" involves combining a group of products (some of which are taxable medical devices) and sterilizing these products as needed for use. In the hospital context, the products are purchased by the hospital and are then sterilized and put into custom surgery kits for use by the hospital. The assembly and sterilization of these kits is not a device manufacturing process, and the IRS should explicitly clarify that kit assembly and sterilization do not cause a hospital to be a "manufacturer" (or "importer") subject to the medical device tax. [6] Also, not excluding hospital-assembled kits could result in some products being taxed twice.

The undersigned organizations firmly believe that the appropriate point of distribution at which the excise tax should be imposed is the sale of the devices that make up the "kit," rather than on the kitting process of the hospital. Without clear guidance, the issue of what constitutes a "manufacturing" process is likely to arise. In addition, under certain circumstances the excise tax is triggered by the "use" of a taxable medical device and would then be subject to tax as if the manufacturer had sold the device. We urge the IRS to clarify in its guidance that these types of activities do not trigger the device tax.

Once a hospital has purchased a medical device, any processes it uses to prepare for the most effective and safest use of the device should not constitute "manufacturing" for purposes of the medical device tax. There is no indication that Congress intended to impose this tax on hospitals when performing these functions. The IRS should define or interpret the term "manufacture" and an "importer" in a way that ensures that these types of processes do not subject hospitals to the tax.

This approach would be consistent with the FDA's treatment of hospital kitting. Because hospital-sterilized kits are not offered for "commercial distribution," hospitals are not required to register as device establishments under FDA rules. (*See* 21 C.F.R. §807.20.) In assembling

[6] The "importer" concern is also the subject of Section VI of this comment letter, below.

these special kits, hospitals are clearly doing so for their own use, and not for commercial distribution.

Even when similar kits are commercially distributed, the FDA categorizes "kit assemblers" separately from device manufacturers for purposes of registration and listing.[7] The FDA does not require premarket clearance of "convenience kits" made up of cleared components when the assembler is able to reasonably conclude that its sterilization process does not significantly affect the safety and effectiveness of any of the kit's components.[8]

Excluding the kitting and sterilization process from the scope of "manufacturing," "importing," or "use" for purposes of the medical device tax will be the most reasonable policy to administer and will reduce the likelihood that some products are taxed twice, once when sold to the hospital and a second time when the hospital "kits" the device. While the exemption in IRC Code section 4221 for sales for "further manufacture" is designed to prevent double taxation, a clear policy that ensures that such "kitting" is not manufacturing will be more consistent with current distribution practices, easy to administer, and will help ensure that the tax is imposed only once on a product. We urge the IRS, therefore, to clarify that such processes do not constitute either "manufacturing," "importing," or "use" of a taxable medical device.

VI. Clarification Sought on Whether a Hospital Could be Subject to the Excise Tax as an Importer

The application of existing excise tax principles to the medical device tax gives rise to another area of concern for hospitals. The Proposed Rule explains that under the excise tax regulations the term "manufacturer" includes an "importer" of a taxable device (see 26 CFR 48.0-2). As noted above, the excise tax can be triggered by a manufacturer's use of the device. Some hospitals purchase medical devices for their own use from foreign suppliers. In addition, the excise tax regulations also indicate that when a third party imports a taxable item on behalf of a "beneficial owner" the beneficial owner may be deemed the importer and be liable for the tax upon sale or use of the article in the United States. Hospitals frequently purchase medical devices through group purchasing organizations (GPOs), which may obtain the devices from overseas sources.

Given that the hospital industry has no experience with the excise tax legal regime, there is a high degree of confusion about whether and when a hospital might be liable for the excise tax in connection with a medical device obtained from a foreign source either directly or through

---

[7] *FDA Website: Who Must Register, List and Pay the Fee*, at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm#manufacturer.

[8] *Convenience Kits, Interim Regulatory Guidance*, FDA, May 20, 1997, at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080217.pdf.

a GPO. We are concerned that, if the regulations could be interpreted to impose the tax on hospitals, hospitals do not have in place the processes necessary to meet this obligation. We also would question whether this would be an appropriate application of the regulation, given the history and intent of the medical device tax. We request that the IRS provide additional guidance on this issue, including a notice and comment period before making a determination that hospitals would be liable for the excise tax as importers under the regulations.

* * * * * * * *

The undersigned parties appreciate the opportunity to comment on the Notice. If you have any questions or need additional information, please contact Jeff Micklos of the Federation of American Hospitals at (202) 624-1521.

Sincerely,

Charles N. Kahn III
President & CEO
Federation of American Hospitals

Rick Pollack
Executive Vice President,
Advocacy & Public Policy
American Hospital Association

Michael Rodgers
Senior Vice President
Public Policy and Advocacy
The Catholic Health Association of
the United States

Curtis Rooney
President
Healthcare Supply Chain Organization

Deborah Sprindzunas
Executive Director
Association for Healthcare Resource & Materials Management

cc: Stephanie Bland, Internal Revenue Service
Jeanne Ross, U.S. Department of the Treasury