



March 28, 2011

VIA COURIER AND ELECTRONIC MAIL

Courier's Desk
Attn: CC:PA:LPD:PR (Notice 2010-89)
Internal Revenue Service
1111 Constitution Ave, N.W.
Washington, DC 20224

RE: IRS Notice 2010-89: Request for Comments Regarding the Excise Tax on Medical Devices

Dear Sir/Madam:

The Federation of American Hospitals, the American Hospital Association, the Catholic Health Association of the United States, and the Health Industry Group Purchasing Association appreciate the opportunity to submit these comments in response to Internal Revenue Service ("IRS") Notice 2010-89, 2010-52 I.R.B. 908: Request for Comments Regarding the Excise Tax on Medical Devices ("Notice").

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 enact long-needed national health reform through passage of the Patient Protection and Affordable Care Act ("ACA"). Given their commitment to the goals of ACA, device companies should be prohibited from 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 permit a financial "double-dip" that could leave device companies in a better financial position than before the ACA was enacted.

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 generally 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," which is known as the retail exemption.

Before responding to the Notice, we feel it is important to set a proper context regarding the medical device tax and its importance in the overall structure of ACA. The ACA provides coverage and access to health care services for all Americans, thereby addressing an uninsured crisis that has reached a boiling point in this country. 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 broad array of health care stakeholders was asked to support the goals of this important, new public policy, many through reductions in federal insurance payments as part of a “shared responsibility” strategy. For the nation’s hospitals, this means a ten-year contribution of \$155 billion, largely through reductions in Medicare payments.

As part of this strategy, Congress enacted the medical device tax as a means to ensure that the medical device industry also participated in the “shared responsibility,” given its place as a stakeholder and a beneficiary of health reform. Medical device companies are part of the supply chain for health care providers. Thus, these companies do not receive federal insurance payments directly, so the option of direct payment reductions 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 ACA.

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 remain mindful of the broad policy context in which the tax was enacted, and that in implementing this new authority, the Service should set policy that ensures medical device companies pay directly their financial commitment under the tax.

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

We are concerned that the device tax could be implemented in a way that allows medical device companies to avoid their financial commitment to the passage of ACA and instead transfers their financial responsibility onto others in the health care system, mainly hospitals. Further, we 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 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.

In addition, unless the IRS takes action, the device tax is likely to be interpreted to allow medical device companies to treat the tax as a deduction to their income for federal corporate tax purposes. In this case, the medical device companies would receive a double benefit, as they could pass through the tax to their customers through higher prices while being permitted to deduct the tax to reduce its income. This “double-dip” could place device companies in a better financial position

than they were prior to health reform, while transferring their financial commitment onto other health care stakeholders.

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” of 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 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 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. We urge the IRS to undertake notice and comment rulemaking on this issue that proposes that medical device manufacturers are required to bear the 2.3 percent tax themselves and not pass it through as an added cost to healthcare providers or, ultimately, to employers and patients through the cost of insurance.

One option to enforce this no-pass-through rule would be to require device manufacturers to certify on their federal excise tax returns that the tax was not included in the price of any taxable device sold to customers. 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 ACA possible.

IV. Devices Sold to Hospitals for Patient Use Should Be Included in the Retail Exemption

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.

To implement Congress's clear intent, the undersigned parties encourage the IRS to explicitly exempt devices sold to hospitals and other healthcare providers for the use of patients, as long as they are “of a type” often purchased at retail for personal use. This exemption should explicitly cover bandages, applicators, gloves and gowns, pregnancy and other diagnostic tests, and other

devices made available by healthcare providers to patients and utilized for the personal treatment or comfort of the patients themselves - basically, any medical item except mechanical, electronic or high-technology devices which the patients do not directly see or utilize.

We see no need for formal regulations to implement the "retail" exemption. The IRS "determination" of which devices are exempt need not, and should not, take the form of formal notice and comment regulations. Section 4191 does not require the issuance of regulations, and a rulemaking approach would be too cumbersome to keep up with the fast-changing medical device industry. Instead, we believe a regularly updated Revenue Procedure or other ruling would be more appropriate. The Joint Committee on Taxation explanation of section 4191 (JCX-18-10, page 138) notes that the IRS is expected to simply "publish a list" of exempt medical devices. We encourage the IRS to take a flexible and frequently updated approach to the retail exemption.

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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,



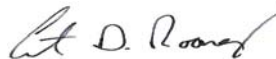
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