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May 7, 2012

Re: Proposed Taxable Medical Device Excise Tax Regulations
Reg-113770-10

Internal Revenue Service
CC:PA:LPD:PR (REG-113770-10)
Room 5203
P.O. Box 7604
Ben Franklin Station
Washington, DC 20044

Attention: Ms. Natalie Payne

Submitted electronically to http://www.regulations.gov (IRS REG-113770-10)

Dear Ms. Payne:

On behalf of the Premier healthcare alliance uniting more than 2,600 leading hospitals and health systems and 84,000-plus other healthcare sites, we appreciate the opportunity to comment on the Internal Revenue Service (IRS) proposed regulations that provide guidance on the excise tax imposed on the sale of certain medical devices under section 4191 of the Internal Revenue Code (the "Code"), enacted by the Health Care and Education Reconciliation Act of 2010 in conjunction with the Patient Protection and Affordable Care Act (ACA).

Premier is a performance improvement alliance using the power of collaboration to lead the transformation to high quality, cost-effective care. Owned by hospitals, health systems and other providers, Premier maintains the nation's most comprehensive repository of clinical, financial and outcomes information and operates a leading healthcare purchasing network. A world leader in helping deliver measurable improvements in care, Premier has worked with the Centers for Medicare & Medicaid Services to improve hospital performance. Our comments primarily reflect the concerns of our owner hospitals and health systems related to the assembly of surgical kits by hospitals for their own use. As service providers, the members of our alliance have a vested interest in providing the most effective medical technology to patients at the best value. Premier previously provided comments on these issues in response to Notice 2010-89.

The proposed regulations provide that a taxable medical device is a device that is listed with the Food and Drug Administration (FDA). Hospitals and other healthcare providers are not subject to FDA requirements with respect to surgical kits assembled by the hospital or provider for their own use and therefore are not required to list their kits. Thus, under the proposed regulations, the device tax does not apply to a hospital kit. We believe this result is a proper interpretation of the statutory provisions. Because hospital kitting is a common practice, we request that an example to this effect be included in the final regulations.

Detailed discussion follows.

Description of hospital kitting

In general, "kitting" involves combining a group of products (some of which are taxable medical devices and some of which are not) 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 kits, also known as custom procedure trays (CPTs), for use by the hospital in its performance of medical procedures. Kits are packaged by hospitals and other providers for a wide variety of medical procedures, from the most routine involving a few medical devices (such as suture removal), to the most complicated involving several hundred medical devices (such as open heart surgery), and for all manner of procedures in between.

Convenience kitting provides various benefits to healthcare providers and patients, including increasing patient safety by ensuring that the medical devices needed for a medical procedure are all present and correctly chosen. Kitting also helps healthcare providers to organize their inventory efficiently, with all of the cost savings that entails.

Hospital convenience kits are not listed with the FDA and therefore are not taxable medical devices under the proposed regulations. The final regulations should include an example to this effect.

The proposed regulations define a taxable medical device as a "device that is listed as a device with the Food and Drug Administration (FDA) under section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR part 807, pursuant to FDA requirements."[1] The FDA's listing requirement hinges on "commercial distribution" of the product.[2] Because hospital-sterilized kits are not offered for commercial distribution, hospitals are not required to register as device establishments under FDA rules, nor are they required to list their kits.[3] Thus, kits prepared by

[1] Prop. Reg. §48.4191-2(a).
[2] See 21 CFR § 807.20(a).
[3] See 21 C.F.R. Part 807.

hospitals are not "taxable medical devices" within the meaning of the proposed regulations and section 4191(b) of the Code.

Because a hospital kit is not a taxable medical device, the sale of a taxable device by a manufacturer of that device to a hospital is not eligible for tax free treatment under the excise tax rules relating to "further manufacture" under Code section 4221. Rather, the excise tax attaches upon the sale of the taxable medical device by the manufacturer. For example, suppose a hospital purchases scalpels that are listed devices from a manufacturer. The hospital sterilizes the scalpels and combines them with other items into a CPT. The excise tax is imposed on the manufacturer when the scalpels are sold to the hospital. The creation and use of the CPT by the hospital is not a taxable event.

While we believe these results are clear under the proposed regulations, we request that an example to this effect be included in the final regulations. Kitting is common practice for hospitals and other healthcare providers and an example will provide greater clarity with respect to the tax.

The proposed regulations reflect congressional intent with respect to the device tax, which was to impose a tax on manufacturers of devices. Each part of the healthcare industry has a shared commitment and responsibility to pay for healthcare reform. The intent of the device tax is to raise revenues from manufacturers to cover their share of financing healthcare reform. Hospitals are already contributing their fair share, through policies that reduce hospital payment updates and Medicare and Medicaid disproportionate share hospital (DSH) payments and that penalize hospitals based on rates of readmissions and hospital-acquired conditions. In addition, we are concerned that the device tax will be transferred, at least in part, to hospitals that purchase taxable devices. **To this end, we urge the IRS to prevent device manufacturers from passing the tax on to providers by requiring, at the very least, that manufacturers certify that they have not included the tax in the price of their products on their requisite filing documents.** We believe that Congress did not intend to have hospitals and other providers absorb the device tax, nor did it intend for the device tax to be applied to kitting and sterilization processes performed by hospitals (possibly resulting in double taxation).

Conclusion

The proposed rule properly excludes kits assembled by hospitals and other health care providers from the definition of "taxable medical device" because such kits are not listed as devices with the FDA. Including an example in the final regulations confirming this result would be helpful and provide greater clarity.

In closing, Premier appreciates the opportunity to respond to the proposed rule on the medical device excise tax. Please do not hesitate to contact Blair Childs, senior vice president of public affairs, at 202.879.8009 or Blair_Childs@PremierInc.com if you would like to discuss further.

Sincerely,

Blair Childs
Senior Vice President, Public Affairs
Premier healthcare alliance