Business Newswire Release

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National Association of Dental Laboratories Legal Analysis Determines that the IRS proposed rule will not subject most products made by domestic dental laboratories to the new federal Medical Device Excise Tax

Tallahassee, FL: The National Association of Dental Laboratories, the trade association representing the interests of nearly 10,000 dental laboratories in the United States has put forth a legal analysis that indicates that most finished devices made in a dental laboratory setting will not be subject to the new federal Medical Device Excise Tax which goes into effect January 1, 2013.

Since Congress passed the Affordable Health Care Act in 2010, the NADL has worked diligently to educate the industry on the elements of the medical device excise tax requirements that may affect dental laboratories. When the law was first passed, there was perspective that due to the broad FDA definition of "medical device", devices made in the laboratory setting at that point of sale would be subject to the tax.

The Internal Revenue Service has recently published proposed rules relative to implementing the new law. NADL, through the work of its in-house legal review and the outside-counsel, has determined that the published IRS proposed rule does not subject most devices made in the domestic dental laboratory setting to the medical device excise tax.

This legal analysis is based on the definition of "taxable medical device" set forth in the proposed IRS rule. (See §48.4191-2) In order for a device to be subject to the new tax and considered a "taxable medical device", it must be a device listed that is required to be listed

as a device with the FDA. While many of the materials such as alloys or ceramics that are used to make dental restorations are devices that are listed with the FDA, a domestic dental laboratory that makes dental devices that are not required to be listed with the FDA will not have to register with the IRS and will not have to file quarterly Medical Device Tax returns.

The majority of dental devices made by domestic dental laboratories does not have an FDA product code and are not required to be listed with the FDA.

"This means that if the IRS adopts the Proposed Rule on taxable medical devices then domestically made crowns, bridges, dentures, veneers, and some orthodontic appliances will not be subject to the medical device tax at the point of sale from the dental laboratory to the dentist. This is very good news for many domestic dental laboratories and will save most domestic dental laboratories from the considerable cost of compliance and logistical burdens that most businesses in our industry would otherwise face beginning January 1, 2013" says Warren Rogers, CEO of Knight Dental Group, Oldsmar, FL and president of NADL.

"We are pleased with the proposed IRS definition, nonetheless, there are certain devices made in a dental laboratory setting that are required to be listed with the FDA and as a result will meet the IRS definition of a "taxable medical device". Those products include imported restorations made by foreign dental laboratories since those devices are required to be listed with the FDA. Sleep apnea devices and some dental implant devices made by domestic dental laboratories must also be listed with the FDA. Those dental laboratories that make devices that are required to be listed will be subject to quarterly IRS filing and remitting the 2.3% medical device tax beginning in 2013" says Eric Thorn, Esquire, NADL in-house counsel.

For domestic dental laboratories, they are likely to see the 2.3% device tax cost impact when they buy materials and equipment from dental manufacturers and suppliers, as most of the raw materials used by dental laboratories to make a completed dental device have an FDA product code and are required to be listed with the FDA. As a result those materials will be subject to the medical device tax.

Background

Dental Laboratories make crowns, bridges, dentures, dental implants, mouth guards and orthodontic devices such as retainers and sleep apnea devices and snore guards. The materials and components used to make these items (such as alloys, ceramic, resins, abutments, individual denture teeth, etc.) are listed with the FDA using FDA product codes.

With the exception of sleep apnea devices and snore guards, the devices that are domestically made by dental laboratories from the FDA listed and FDA product coded components are not required to be listed with the FDA and do not have any FDA product code. For example there is not a code for a porcelain-fused-to-metal crown or for a finished set of dentures or a completed dental implant.

While the FDA requires all establishments that manufacture medical devices to register with the FDA and requires these establishments to list the devices that they manufacture with the FDA pursuant to 21 CFR 807, dental laboratories are specifically exempted.
§ 807.65(i) exempts domestic dental laboratories from the FDA's device listing requirements.

However, if a dental laboratory undertakes certain activities, such as importing devices or manufacturing sleep apnea devices or snore guards, the dental laboratory will be required to register with the FDA and list those devices with the FDA using the applicable FDA product code(s). Imported crowns, bridges, dentures, dental implants, mouth guards and orthodontic devices such as retainers are required to be listed with the FDA and do have an applicable FDA product code.

It is important to note that the IRS definition of importer that applies to excise taxes is different from the FDA's importer definition. Under the IRS definition of "importer" the person who brings an article into the United States is only a nominal importer if they are not also the beneficial owner of the article. For example, if you engage a customs broker they are a nominal importer and the IRS deems the beneficial owner to be the importer, in this case which may be the U.S. dental laboratory that is selling the device for excise tax purposes.

See 26 CFR 48.0-2(a)(4) for the IRS definition of "importer."

Taxable Medical Device – IRS Guidance to date § 48.4191–2 Taxable medical device. (as currently proposed by the IRS)
(a) Taxable medical device—(1) In general. A taxable medical device is any device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, that is intended for humans. For purposes of this section, a device defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act 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 Federal Food, Drug, and Cosmetic Act and 21 CFR part 807, pursuant to FDA requirements. (emphasis added)

As stated in the IRS's commentary that was published in the preamble of proposed rule:

"Therefore, all devices that are listed under a single product code listing in conjunction with the FDA's device listing requirement are "taxable medical devices" unless they fall within an exemption under section 4191(b)(2). " 77 Fed. Reg. 25 (7 February 2012) p. 6029

The IRS clearly states that any device listed under a single FDA product code is a "taxable medical device". The IRS does not anywhere in the proposed rules or in the accompanying commentary or elsewhere indicate that anything other than a device that is required to be listed is a "taxable medical device".

FDA Dental Device Product Codes

In 21 CFR 872 the FDA has promulgated the 132 generic classifications of the dental devices intended for human use that are in commercial distribution. Each one of these generic classifications has one or more associated three-letter FDA product codes. There are 297 three letter FDA product codes that apply to dental devices.

21 CFR 872 - Dental device classifications:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=872

FDA Dental Device Product Codes:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?start_search=1&Submission_Type_ID=&DeviceName=&ProductCode=&DeviceClass=&ThirdParty=&Panel=DE&RegulationNumber=&PAGENUM=500&SortColumn=DeviceName

Dental device establishments that are required to register use these 297 FDA product codes in order to list with the FDA the devices they manufacture. There are no applicable FDA product codes for domestically made crowns, bridges, dentures, dental implants, mouth guards and orthodontic devices such as retainers.

Conclusion

Domestically made crowns, bridges, dentures, dental implants, mouth guards and orthodontic devices such as retainers are generally not required to be listed 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. Therefore, domestically made crowns, bridges, dentures, dental implants, mouth guards and orthodontic devices such as retainers are not "taxable medical devices" for the purposes of the Medical Device Tax.

PLEASE SHARE THIS ANALYSIS WITH YOUR OR LEGAL OR TAX ACCOUNTING PROFESSIONAL TO DETERMINE ITS APPLICABILITY TO YOU INDIVIDUAL BUSINESS ACTIVITIES.

NOTHING IN THIS ANALYSIS IS INTENDED AS OR SHOULD BE CONSTRUED AS OR RELIED UPON AS U.S. FEDERAL TAX ADVICE AND CAN NOT BE USED FOR THE PURPOSE OF AVOIDING ANY PENALTIES UNDER THE INTERNAL REVENUE CODE.

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