Medical Device Tax: Examination of Dec. 2012 IRS Rule and Impact on DME

On December 5, 2012, the Internal Revenue Service (IRS) published a final rule implementing a new 2.3 percentage point excise tax on the sale of certain medical devices by the manufacturer, producer, or importer of the device. The device tax is required under the Affordable Care Act (ACA) as one of the funding mechanisms for the health reform law. Eyeglasses, contact lenses, hearing aids, and "any other medical devices that are generally purchased by the general public at retail for individual use" (the retail exemption) are exempted from the tax by statute. The Final Rule provides guidance on the types of devices that fit within the retail exemption. Click here to view the Final Rule.

The rule establishes a two-pronged "facts and circumstances" test to determine whether a device qualifies for the exemption. Manufacturers must consider: i) whether a device is regularly available for purchase and use by individual consumers who are not medical professionals; and ii) whether the design of the device demonstrates that it is not primarily intended for use in a medical institution or office or by a medical professional. The IRS specified a number of positive and negative factors that are relevant to the analysis under each prong of the test. These factors are "nonexclusive." In other words, a device may nonetheless qualify for the exemption based on a factor that is not on the list and despite the presence of a negative factor. **Thus, whether a device will be exempt from the tax will require the manufacturer to balance the pertinent facts and circumstances and make a determination based on the "totality" of the facts in light of the factors the IRS believes are relevant.**

The final rule includes a number of examples that apply this analysis to DMEPOS items, including portable concentrators, manual and powered wheelchairs, and hospital beds. In each case, the Agency concludes that these devices would not be subject to the tax. To understand the implications of the Final Rule for their specific businesses, manufacturers and distributors should consult a tax advisor.

I. OVERVIEW OF THE REGULATION

A. Safe Harbor Provision

A "taxable medical device" is any medical device intended for human use as defined in section 201(h) of the Federal Food, Drug and Cosmetic Act (FFDCA). Consequently, all devices are taxable devices unless they fall within the retail exemption to the tax. The final rule carves out a "safe harbor" for devices the IRS believes fall within the retail exemption without further analysis. The safe harbor includes:

(i) Devices identified under the FDA's Over-the-Counter Tests database;

(ii) Devices described as "OTC" or "over the counter" devices in the relevant FDA classification regulation heading;

(iii) Devices described as "OTC" or "over the counter" devices in the FDA's product code name, the FDA's device classification name, or the product code name, the FDA's device classification name, or the "classification name" field in the FDA's device registration and listing database;

(iv) DMEPOS items payable on a purchase basis under Medicare Part B and that are one of the following types of devices:

a) prosthetic and orthotic devices that do not require implantation or insertion by a medical professional;
b) parenteral and enteral nutrients, equipment, and supplies;
c) customized items;
d) therapeutic shoes;
e) supplies necessary for the effective use of DME.

The Agency did not extend safe harbor protection to all DMEPOS devices. However, devices that are outside the safe harbor may nonetheless qualify for the exemption through application of the facts and circumstances analysis described in more detail below. The final rule includes examples to demonstrate how the safe harbor criteria apply to specific devices. One example clarifies that the safe harbor includes glucose monitors and test strips because they are in the FDA's online OTC test database. Lancets are also in the safe harbor because they are "supplies necessary for the effective use of DME" as specified by CMS in its payment manuals.

B. Two Pronged Multi-Factor Analysis

Devices that do not explicitly fall within the safe harbor may qualify for the retail exemption under the two prong multi-factor test. The final rule specifies both positive and negative factors that the IRS considers relevant to the analysis. However, as stated above, these factors are not exclusive of each other. A device might qualify for the exemption based on factors that are not specified in the rule. Moreover, no one factor is given greater weight than another because the factors are non-exclusive. This means that a device may qualify for the exemption despite the presence of a negative factor if, under the "totality" of the "facts and circumstances," the device is one that is generally purchased by the general public "at retail for individual use." One significant benefit of this approach is that manufacturers and their tax advisors will have considerable flexibility in determining whether a particular device qualifies for the exemption.

The first prong of the test is whether the device is "regularly available for purchase and use by individual consumers who are not medical professionals." The factors in this analysis are designed to show whether individuals with no medical training can readily purchase and use a type of device. Generally, an affirmative response to one of the factors under this prong would be positive and would support a conclusion that the device qualifies for the exemption. The following factors are relevant to the analysis under the first prong of the test:

(A) Whether consumers with no medical training can buy the device in person, over the telephone, or over the Internet, through retail businesses such as drug stores, supermarkets, or medical supply stores and retailers that primarily sell devices (for example, specialty medical stores, durable medical equipment, prosthetics, orthotics, and supplies [DMEPOS] suppliers and similar vendors);

(B) Whether consumers with no medical training can use the device safely and effectively for its intended purpose with little or no training from a clinician;

(C) Whether the device is a Physical Medicine Device under applicable FDA classifications.

The second prong of the test is whether the device is "primarily for use in a medical institution or office or by a medical professional." An affirmative response to a factor under the second prong would suggest

that the device is designed for institutional use or use by a medical professional. Affirmative responses to factors under this prong of the test would weigh against a determination that a device qualifies for the exemption. The following factors are relevant to the analysis under the second prong of the test:

(A) Whether the device must be implanted, inserted, operated, or otherwise administered by a medical professional;

(B) Whether the cost to acquire, maintain, and/or use the device requires a large initial investment and/or ongoing expenditure that is not affordable for the average individual consumer;

(C) Whether the device is a Class III;

(D) How the FDA classifies the device;

(E) Whether the device is a DMEPOS item payable exclusively on a rental basis under the frequent and substantial servicing payment category for Medicare Part B.

In response to comments submitted by AAHomecare, the IRS clarified that neither a device's Medicare payment category nor its FDA classification would summarily exclude the device from the retail exemption. Instead, the Medicare payment category or FDA classification would be one of several factors to consider in light of all the positive and negative factors identified in the final rule. Importantly, the IRS agreed with AAHomecare that specialty medical stores or DMEPOS suppliers were retail businesses through which individual consumers with no medical training could purchase devices. Consequently, the fact that a consumer obtained the device from a DMEPOS supplier or other medical supply business is a positive factor that would tend to support a finding that a device qualifies for the exemption.

II. APPLYING THE FACTORS UNDER THE TWO PRONGED TEST

The final rule includes 15 examples that apply the criteria under the rule to various medical devices. Five of the examples address DMEPOS items—glucose monitors, mechanical and powered wheelchairs, portable oxygen concentrators, urinary ileostomy bags, and home use AC powered adjustable beds. In each of these five examples, the IRS concluded that retail exemption applied either because the device was in the safe harbor or because the device is regularly available for purchase by individual consumers in retail outlets (including medical specialty stores and from DMEPOS suppliers) and are generally such that the consumer can use it with little or no training from a medical professional.

In general, the Agency's analysis focuses on whether, on balance, one set of factors (favorable or unfavorable) outweighs the other. In other words, because the rule gives equal weight to all the factors, the analysis requires a determination of whether there are more favorable than unfavorable factors (or *vice versa*) such that the device would qualify for the exemption. For example, the IRS concluded that portable oxygen concentrators are exempt from the tax because they satisfied more positive than negative factors. The Final Rule states as follows:

> Individual consumers who are not medical professionals can regularly purchase the portable oxygen concentrators in retail pharmacies, medical specialty stores, or DME suppliers, as well as over the Internet. In addition, individual consumers can use the portable oxygen concentrators safely and effectively for their intended medical purpose with minimal or no training from a medical professional. Further, although the portable

> oxygen concentrators are classified by the FDA under a category described in paragraph (b)(2)(ii)(D) of this section, they do not need to be implanted, inserted, operated, or otherwise administered by a medical professional, do not require a large investment and/or ongoing expenditure, are not Class III devices, and are not ''items requiring frequent and substantial servicing.''
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> Thus, the *portable oxygen concentrators have* ***multiple factors*** under paragraph (b)(2)(i) of this section *that tend to show they are regularly available for purchase and use by individual consumers* ***and only one factor*** *under paragraph (b)(2)(ii) of this section that tends to show they are designed primarily for use in a medical institution or office or by medical professionals.* Based on the totality of the facts and circumstances, the portable oxygen concentrators are devices that are of a type that are generally purchased by the general public at retail for individual use.

The IRS takes a similar approach in each of the DMEPOS device examples in the Final Rule. Its analysis for mechanical and powered wheelchairs concludes that there are multiple factors that "tend to show that they are regularly available for purchase by individual consumers and ***at most only one factor*** . . . that tends to show they are designed primarily for use in a medical institution or office or by medical professionals."

It is unclear, however, how manufacturers should reconcile the factors in situations where the negative and positive factors are equal. In other words, because the Final Rule apparently treats all factors as having equal weight, there might be devices which do not definitively fall within one category or the other. Although we are not currently aware of devices for which this might be true, this is a point about which AAHomecare members should be aware.

III. CONCLUSION

In summary, the approach in the Final Rule appears straightforward to apply and gives manufacturers and their tax advisors the flexibility to consider factors in their analysis that were not specified in the regulation. However, this approach could also lead to ambiguous results in situations where the positive and negative factors for a given device are equal. In this scenario, the positive and negative factors would presumably cancel out each other because all of the factors are weighed the same. This may be an issue that requires further clarification from IRS and Treasury based on the input the Association receives from its members.