Statement on IRS Notice of Proposed Rulemaking and Notice of Public Hearing on Taxable Medical Devices

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Good Morning.

I am Tyler Wilson, president and CEO of the American Association for Homecare. My organization is the national trade association that represents manufacturers which produce medical equipment, products and supplies designed for and intended for use by individuals in their homes. The Association also represents the companies that take these products, broadly known as "home medical equipment" from the manufacturers and furnish it directly to Medicare beneficiaries and other purchasers.

We appreciate the opportunity to comment about the proposed IRS rule on taxable medical devices.

The proposed rule suggests criteria for manufacturers to use in determining whether the sale of a medical device is a “taxable event” and, if so, whether it fits within the retail exemption. My Association has some concerns about how the proposed rule would classify types of devices and supplies that would fall under the retail exemption.

The Agency proposes to establish a two-pronged analysis that would require manufacturers to consider:
1) First, is the device is regularly available for retail purchase and use by individual consumers who are NOT medical professionals?
2) Second, is the device designed for consumers in a non-medical setting?

Let me say from the outset that home medical equipment and products, by its very nature, are items designed for and regularly available to individual consumers for their purchase and use in a non-medical setting.

While some of the items require a physician's prescription before they can be purchased (and this is particularly true if Medicare or private insurance is going to reimburse for the item), we agree with the proposed rule that the presence of or need for a prescription should not be a factor in determining whether the exemption applies. The amended IRS Code provisions require only that a device be "generally purchased by the general public at retail for individual use."

The proposed rule includes a regulatory safe harbor that explicitly applies to certain home medical equipment: that is – supplies used with home medical equipment and devices classified by the FDA as "over the counter."

If a device does not fit within the safe harbor, the proposed rule sets forth a series of factors to indicate whether the device meets the two-prong test mentioned earlier – again (1) first, is the item regularly available for purchase and use by individual consumers at retail and (2)

is it designed and intended for use by consumers in a non-medical setting or instead for use in a medical facility by a medical professional.

The American Association for Homecare believes that all home medical equipment, devices and supplies fall within the retail exemption. For this reason, we would argue that the proposed regulatory safe harbor is too narrow and that it should be expanded to include a "bright-line" test that explicitly includes all such items and supplies within a regulatory safe harbor.

If the Agency declines to expand the "safe harbor" provision, the Association recommends that the regulatory language be revised to clarify that the list of criteria used as part of the two-prong analysis is NOT exhaustive or conclusive or to be rigidly applied. In other words, devices or supplies that fail to meet one of the factors should not, without further analysis, trigger the application of the tax if other criteria are satisfied.

The salient criteria for defining home medical equipment, devices and supplies under the Social Security Act closely align with the criteria a device must meet in order to qualify for the retail exemption. The Association recommends that IRS adopt this definition as a bright-line test of whether a device is "designed and sold for individual use."

Home medical equipment, devices and supplies are also "regularly available for purchase and use by individual consumers who are not medical professionals." Typically, the companies have at least one retail location that serves walk-in customers. In fact, Medicare's Supplier Standards for Durable Medical Equipment (DME) are requirements that focus on a home medical equipment company's consumer (non-medical professional) customers. The Supplier Standards require the company to have a physical facility with certain attributes and features consistent with typical retail businesses:

- A location with at least 200 square feet;
- In a venue accessible to the public; and

- Staffed and open to the public at least 30 hours a week;
- With a permanent sign that is visible from the street and displaying posted hours with a publicly listed phone number.

For purposes of doing business with Medicare, companies supplying home medical equipment and devices are subject to the same standards that Medicare applies to retail outlets such as chain drug stores and independent pharmacies.

The statutory test is whether the device is generally available to the general public for purchase at retail, not whether the devices are sold by a company that also sells products that are not medical devices. Individual consumers may purchase or rent most home medical equipment from various types of retail operations – a company that specializes in such products or a chain drug store or a small independent pharmacy, or, in the case of many products through other consumer retail purchasing

channels. No one type of distribution channel should be given more weight than the others.

Even a sale of a technologically advanced piece of medical equipment should qualify as a sale at retail by virtue of the fact that it is sold to the end user, a private consumer, for personal use. These products are all sold on an individual basis, one HME device or supply at a time.

The proposed regulatory safe harbor is too narrow because it includes some categories of home medical equipment but not others. For example, the safe harbor includes enteral nutrients, equipment and supplies, presumably because Medicare pays for enteral formulas on a purchase basis. While the Association agrees that enteral formulas, equipment, and supplies should fall within the safe harbor for all of the reasons we identified above, we disagree that that Medicare Part B payment rules provide an appropriate rationale for including or excluding devices from the exemption. Using a payment

category as a shortcut for the analysis established under the Code would incorrectly exclude from the exemption devices and supplies that otherwise meet the criteria.

There appears to be no supportable rationale for explicitly including some home medical equipment and products, like enteral nutrition equipment and supplies, under the safe harbor but not including others like hospital beds or other rental items like PAP (positive airway pressure) respiratory devices, nebulizers, and home oxygen equipment.

We recommend that the Agency expand the safe harbor to include all HME devices and supplies. However, because all HME devices and supplies also qualify for the exemption under the proposed two-pronged test, our alternative recommendation is that IRS clarify how the factors under the test would apply to HME devices and supplies, especially respiratory HME devices and supplies.

The final rule should also clarify that respiratory HME devices such as those used in home oxygen therapy, nebulizers, positive airway pressure (PAP) devices, and the like fall within the exemption. The proposed rule excludes them from the exemption because they are classified as “anesthesiology devices” under FDA regulations. The Agency’s reliance solely on the FDA classification does not take into account that respiratory home medical devices and supplies would otherwise satisfy the multi-factor test to qualify for the exemption.

The Association suggests that the Agency remove subsection (E) (in section § 49.4191-2 (b) (2) (ii)) which relies on a Medicare payment category to determine whether an HME device or supply fits within the exemption. As is the case with the blanket use of an FDA device classification to exclude HME from the exemption, using a Medicare payment category as a factor for exclusion would impose the tax on a device or supply that would otherwise qualify for the exemption under the two-pronged test.

The frequent and substantial servicing category for rented devices is very narrow and currently applies to only a few home medical devices including certain home-use ventilators. It would be factually and legally incorrect to apply subsection (E) to exclude home oxygen therapy devices, nebulizers, PAPs, and other such respiratory modalities from the retail exemption because the frequent and substantial payment category does not apply to these devices and because respiratory HME devices and supplies qualify for the exemption under the two-pronged test.

Conclusion

To summarize, the Association believes that all HME devices and supplies are devices that are “generally purchased by the general public at retail for individual use” and, as such, should be subject to a regulatory safe harbor. The Social Security Act defines HME devices and supplies in a way that places them within the retail

exemption because they are “designed and sold for individual use.”

Furthermore, if IRS does not expand the safe harbor, then criteria for the retail exclusion [§48.4191-2 (b) (ii) (D) (1) and (E)] are too broad. Subsection (D) would exclude from the retail exemption respiratory devices classified as anesthesiology devices by the FDA and subsection (E) would exclude certain HME, presumably also respiratory devices such as ventilators, based on their Medicare payment category. The Agency should not rely solely on the FDA device category to exclude home oxygen therapy devices and other respiratory technologies from the retail exemption. This FDA device category is too broad and its application to these types of technologies incorrectly suggests that they are designed and intended for use by medical professionals in medical settings rather than by consumers in their homes. Similarly, it is incorrect to rely exclusively on the application of a Medicare payment category in determining whether a device fits the retail exemption.

Finally, if the Agency declines to expand the safe harbor, we recommend that it clarify how it would apply the two-pronged multi-factor test to HME devices and supplies. Specifically, the Association recommends that you revise the regulatory language to clarify that the list of criteria [under proposed 26 CFR § 48.4919-2 (b) (2)] is not exhaustive or conclusive. The final rule should clarify that the IRS will not rigidly apply the factors identified under the rule for establishing that an HME device falls within the retail exemption. The final rule should clearly state that the fact a device or supply fails to meet one factor should not be used to summarily exclude it from the exemption without further analysis, if other criteria are satisfied.

Thank you.