



Via Electronic Submission

May 7, 2012

The Honorable Timothy F. Geithner
Secretary, Department of Treasury
Attention: CC:PA:LPD:PR (REG-113770-10)
Internal Revenue Service
1111 Constitution Avenue, NW
Washington, DC 20224

**Re: Comments on IRS Notice of Proposed Rulemaking and Notice of Public Hearing,
Taxable Medical Devices [REG-113770-10]¹**

Dear Secretary Geithner:

The American Association for Homecare (AAHomecare) submits the following comments in response to the Internal Revenue Services' (IRS) request for comments on the above captioned proposed regulation. The proposed rule would implement amendments to the Internal Revenue Code (Code) under the Patient Protection and Affordable Care Act (ACA) that impose an excise tax on the sale of certain medical devices by the manufacturer, producer, or importer of the medical device. The law excludes eyeglasses, contact lenses, hearing aids, and "any other medical device that is generally purchased by the general public at retail for individual use" (the retail exemption). The proposed rule would provide guidance on the types of devices and supplies that would fall under the retail exemption.

AAHomecare represents manufacturers and companies that furnish durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that are intended and designed for use by individuals in their homes or in other settings that serve as their homes such as assisted living facilities and group homes. Throughout these comments, we will refer to DMEPOS as "home medical equipment" (HME) and supplies. "HME" is a term of art in the in the homecare sector because "HME" and supplies more accurately describe the products HME businesses sell. In light of our members' expertise and experience, AAHomecare is uniquely qualified to comment on the proposed rule.

¹ Department of the Treasury Internal Revenue Service, Taxable Medical Devices, 77 Federal Register 6028 (February 7, 2012).

Specifically, the proposed rule sets forth 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. The Agency proposes to establish a two-pronged multi-factor analysis that would require manufacturers to consider: i) whether the 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.

According to the rule, the fact that a device requires a prescription would not be a factor in determining whether the exemption applies. AAHomecare agrees that the need for a prescription is not a relevant factor. The amended Code provisions require only that a device be “generally purchased by the general public at retail for individual use.”² The two-pronged test correctly recognizes that, to qualify for the exemption, the key questions are: i) is the device available to consumers at retail; and ii) is it designed and intended for use by consumers in a non-medical setting?

The proposed rule also includes a regulatory safe harbor that explicitly applies to certain items of HME: supplies used with HME and devices classified by the Food and Drug Administration (FDA) as over the counter (OTC). If a device does not fit within the safe harbor, the proposed rule sets forth a series of factors to indicate whether a device is: i) regularly available for purchase and use by individual consumers; and ii) primarily for use in a medical institution or office by a medical professional.³

Generally, AAHomecare agrees that the proposed two-pronged multi-factor test would be useful in determining whether a device fits within the retail exemption. However, AAHomecare believes that all HME devices and supplies fall within the exemption because they are regularly available for individual purchase and use by consumers and are designed primarily for consumers, not medical professionals, to use in their homes and communities. As a result, the rule should go further and include a “bright-line” test that would explicitly include all HME devices and supplies within a regulatory safe harbor.

In the event that the Agency declines to follow this approach, AAHomecare 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. In other words, the final rule should clarify that the IRS will not rigidly apply the factors under the two-pronged test to summarily exclude an HME device or supply from the exemption. The fact that a device or supply fails to meet one of the factors should not, without further analysis, trigger the application of the tax if other criteria are satisfied.

² 26 U.S.C. § 4191(b)(2).

³ 26 CFR §48.4191-2 (b) (2) (i) and (ii), proposed.

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 HME devices and supplies would otherwise satisfy the multi-factor test to qualify for the exemption. Clearly then, respiratory HME devices should not be excluded from the exemption without first performing this analysis.⁴

I. HME Devices and Supplies Are Designed for and Regularly Available to Individual Consumers for Their Purchase and Use in a Non-medical Setting

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). Under the Code, the Secretary can exempt from the definition of “taxable medical device” “any other medical device determined by the Secretary to be of a type which is generally purchased by the general public at retail for individual use.” In making this determination, the proposed rule would have manufacturers consider: i) whether the 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.

HME devices and supplies are medical devices intended for human use as defined under §201h of the FFDCA. Consequently, HME devices are taxable devices as defined under the Code unless they fall within the retail exemption to the tax. AAHomecare believes that all HME devices and supplies fall within the retail exemption to the tax because they “are designed and sold for individual use,” as contemplated by Congress.⁵ In fact, the salient criteria for defining HME devices and supplies under the Social Security Act (Act) align closely with the criteria a device must meet in order to qualify for the retail exemption. The Act states that that these devices are: “determined to be *necessary on the basis of the individual’s medical and physical condition . . . used in his home* (including an institution used as his home . . .) [. . .] **whether furnished on a rental basis or purchased** . . . [.]”⁶ AAHomecare recommends that IRS adopt this definition as a bright-line test of whether a device is “designed and sold for individual use.”

HME devices and supplies are also “regularly available for purchase and use by individual consumers who are not medical professionals.” Predominately, HME companies have at least one retail location that serves customers in person. The Medicare DMEPOS Supplier Standards

⁴ The Agency acknowledges this point by its reference to the Joint Committee on Taxation’s Technical Explanation (Technical Explanation) of the ACA, which states “The exemption for such items is not limited by the device class as defined under section 513 of the Federal Food Drug and Cosmetic Act.” 77 Fed Reg. at 6029.

⁵ The Technical Explanation emphasizes that “items would only be exempt if they are generally designed and sold for individual use.”

⁶ 42 U.S.C. §1395x.

focus on an HME company's consumer customers by requiring the company to have a physical facility that is: at least 200 square feet; on an appropriate site; in a location accessible to the public; staffed and accessible during posted hours of operation; open to the public at least 30 hours a week; has a permanent sign that is visible from the street; and has a publicly listed phone number, among other requirements.⁷ Importantly, for purposes of doing business with Medicare, HME companies are subject to the same standards that Medicare applies to retail outlets such as chain drug stores and independent pharmacies.

The fact that HME devices and supplies may be sold by companies that sell only these products should not be a factor that excludes them from the exemption. 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.⁸ Individual consumers may purchase or rent most HME devices and supplies directly from an HME company, a chain drug store or an independent pharmacy, or through other consumer retail purchasing channels such as the Internet. Even a cursory search for HME devices and supplies on Amazon.com, a popular consumer shopping website, very quickly locates hundreds of HME products that are marketed to and available for purchase by individual consumers. The vendors in many cases also sell any number of other household products and electronics including gas grills, stereo receivers, and watches. However, the scope of a seller's inventory should not be a factor in deciding whether the exemption applies because HME and supplies are readily available for purchase by individual consumers through multiple retail purchasing channels such that no one type of distribution channel should be given more weight than the others.⁹

Moreover, HME companies furnish devices to the individual end user consistent with the traditional legal definition of a "retail" sale. *Black's Law Dictionary* defines a retail sale as: "[t]he sale of goods or commodities to ultimate consumers, as opposed to the sale for further distribution or processing." Other excise tax provisions under the Code likewise define a sale at retail as a "sale for purposes other than resale after manufacture, production, or importation."¹⁰ Logically, a sale of even a technologically advanced HME device or supply would qualify as a sale at retail because it is sold to the end user, the ultimate consumer. These products are all sold on an individual basis, one HME device or supply at a time.¹¹

⁷ 42 CFR § 424.57.

⁸ AAHomecare believes that the proposed rule is too restrictive in describing "retail businesses" as ones that also "sell items other than medical devices" and recommends that IRS remove this language.

⁹ See for example, the Amazon storefront for JDS Enterprises, (attached), available at: http://www.amazon.com/s/qid=1335199254/ref=sr_pg_2?ie=UTF8&me=AF40AZNRPA46C&rh=&page=2; and http://www.amazon.com/s/qid=1335198664/ref=sr_pg_1?ie=UTF8&me=AF40AZNRPA46C&rh=&page=1.

¹⁰ See 26 U. S. C. § 4002(a), 4011(a)(repealed) and 4052(a)(1).

¹¹ Note that not all HME devices are immediately re-sold to a Medicare beneficiary. Some transfers of wheelchairs or other "capped rental" HME devices from a retailer to a Medicare beneficiary are not a "sale" as that term is defined in Article II, section 2-106(1) of the Uniform Commercial Code in the sense that, under the rules applicable under the Medicare program, the Medicare beneficiary does not take title to the "capped rental" device until the device has been rented for 13 months. Therefore, while Medicare payment rules require rental payments for a while, eventually the HME device subject to Medicare payment rules end up as a sale. See Social Security Act §

Consequently, AAHomecare believes that all HME devices and supplies as defined under the Act fall within the scope of the retail exemption. HME devices and supplies are: i) regularly available for purchase¹² and use by individual consumers who are not medical professionals; and ii) are intended and designed for use by individual consumers in their homes and communities, not medical institutions. By definition, HME devices and supplies are intended for use in an individual consumer's home. HME devices and supplies are intended and designed primarily for consumer end users, not medical professionals, and, as such, differ in their size, user interface, and operating instructions, among other features.

Together, these factors support AAHomecare's conclusion that the proposed regulatory safe harbor is too narrow because it includes some categories of HME devices and supplies but not others.¹³ For example, the safe harbor includes enteral nutrients, equipment and supplies, presumably because Medicare pays for enteral formulas on a purchase basis. AAHomecare agrees that enteral formulas, equipment, and supplies should fall within the safe harbor for all of the reasons we identified above. However, 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 for the exemption under the Code.¹⁴

In the case of enteral nutrition, it is true that enteral formulas are commonly available in supermarkets, but enteral pumps and related supplies paid for under Medicare Part B are more commonly available through the other consumer purchasing channels we described above such as HME companies, chain drug stores and independent pharmacies, and the Internet. Moreover, while Medicare pays for the formula as a purchase, it pays for equipment like

1834(a)(7)(A)(i)(I), 42 U.S.C. § 1395m(a)(7)(A)(i)(I). While certain existing excise taxes already present in the Internal Revenue Code apply to both sales and certain leases or rentals, the language of the Reconciliation Package apparently would apply only to "sales." Importantly, under state sales tax laws, the rental of an item to an end user is considered a sale of the device for sales tax purposes; therefore, it would not be unreasonable to say even for the rental program there is a retail purchase during the rental period.

¹² Under the statutory definition, the payment mechanism by which an individual acquires a device does not determine whether the device or supply is HME. The statute clearly states that a device is HME if it is used by individuals in their homes, regardless of whether the device is rented or purchased.

¹³ It is also worthwhile to point out that proposed § 48.4191-2 (b) (iii) (D) (5) provides that supplies "necessary for the effective use of DME" as described under applicable Medicare manuals fall within the safe harbor. Application of subsection (D) (5) to HME devices and supplies that do not fall explicitly within the safe harbor gives rise to the anomalous result that a cannula or mask used with home oxygen devices, PAP devices, or nebulizers is exempted from the tax while the device that makes the supply necessary might be a "taxable device" that does not qualify for the retail exemption.

¹⁴ We also note that the reference to 42 CFR § 411.351 to define enteral nutrients, equipment, and supplies is confusing. §411.351 identifies the items and services that fall under the Stark law prohibitions to physician self-referrals. The application of the Stark law to these items should not be relevant to whether they fit within the retail exemption.

enteral pumps on a rental basis.¹⁵ As a result, there appears to be no supportable rationale for explicitly including some HME devices and supplies like enteral nutrition, equipment, and supplies under the safe harbor but not including others like hospital beds or other rental HME devices and supplies like PAP 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.

II. Respiratory HME Devices and Supplies Are Designed for and Regularly Available to Individual Consumers for Their Purchase and Use in a Non-medical Setting

A. IRS Should Not Exclude a Device from the Retail Exemption Based on an FDA Classification

AAHomecare believes that under the statutory definition for HME devices and supplies, the application of proposed §48.4191-2 (b) (ii) (D) (1) and (E) to HME respiratory devices is too broad. Subsection (D) would exclude from the retail exemption respiratory devices classified as anesthesiology devices by the FDA under 21 CFR Part 868, 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 under Part 868 to exclude home oxygen therapy devices, PAP devices, nebulizers, 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.

We recommend instead that the regulatory safe harbor explicitly apply to HME devices used in home oxygen therapy, nebulizers, PAP devices, and other respiratory modalities for the reasons we discussed above. In the alternative, because these devices satisfy all of the factors identified under the two-pronged test, they should at least be subject to this analysis rather than summarily excluded from the exemption based on their FDA classification.

HME respiratory devices are vastly different from respiratory equipment used in hospitals and other institutions. Hospital inpatients receive oxygen *via* the hospital's bulk compressed oxygen system through cannulas and masks connected to the system through the wall. Other respiratory modalities either also connect to the compressed gas reservoir or, like invasive ventilators, have interfaces and other design features intended for use by medical professionals. In contrast, respiratory HME devices such as stationary and portable oxygen

¹⁵ 42 CFR. §414.104.

concentrators used in the delivery of home oxygen therapy, nebulizers, PAP devices, and similar respiratory HME devices are designed to be used in an unstructured home environment by consumers, most of whom are disabled or elderly and who lack medical knowledge.

Typically, stationary concentrators plug into a home electric outlet, while portable oxygen concentrators operate from a variety of power sources and are popular among individuals who travel because they are lightweight and are approved for use onboard commercial flights. Respiratory HME devices also include lightweight, portable oxygen systems that have small oxygen tanks that are easily portable and are typically used with home transfilling systems. Generally, all of these products have been featured in direct-to-consumer advertising and can be purchased directly by consumers at HME retail locations, chain drug stores and community pharmacies, and through the Internet. Importantly, the devices' interface, operating manual, and other features are designed for the consumer end user.

It is also useful to note that FDA itself recognizes that its current classification system inadequately addresses the rapid transition of care to the home environment. In recent years, the Agency has started a "Home Use Device" initiative to bring together manufacturers, patient representatives, and clinicians to discuss issues pertaining specifically to devices intended for use by consumers in their homes. Importantly, the FDA has defined a "home use devices" as a "medical device intended for users in any environment outside of a professional healthcare facility."¹⁶ Among other factors, the FDA and manufacturers agree that home use devices are used in an unstructured care environment by consumers who may be disabled, chronically ill, elderly, or cognitively impaired and that all of these factors affect the devices' design including, most importantly, their durability, size, user interface, and operating instructions.

B. IRS Should Not Exclude a Device from the Exemption Based on a Medicare Payment Category

AAHomecare also suggests that the Agency remove subsection (E) as a negative factor under proposed § 49.4191-2 (b) (2) (ii). Subsection (E) 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 exclude¹⁷ HME from the exemption, using a

¹⁶ See Home Health and Consumer Devices, available at:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/default.htm>.

¹⁷ We note that use of the FDA classification to *exclude* devices from the retail exception results in a broad exclusion of products that would otherwise fit the exception. However, we agree with the Agency's use of Subpart D of 21 CFR part 890 (Physical Medicine Devices) to *include* wheelchairs and ambulatory products with the retail exception. §48.4191-(b) (2) (i) (C), proposed. Consistent with our discussion throughout these comments, it is important to emphasize, that ambulatory devices and wheelchairs qualify for the exemption under both the Code provision and two-pronged test in the proposed regulation. Likewise, seating and positioning cushion and backs used with wheelchairs and other mobility devices qualify for the exemption under the Code or the proposed two-pronged test.

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 HME devices including certain home-use ventilators. Moreover, as we discussed above, whether an HME device or supply falls into a specific payment category is determined by CMS under its discretion to administer the program.¹⁸ Thus, whether a device falls within the retail exemption would be determined by what could be an arbitrary administrative action rather than by whether the device or supply falls within the exemption under the Code or satisfies the two-pronged test. Finally, 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.

III. FDA Should Clarify How It Would Apply the Multi-factor Test to All HME Devices and Supplies

AAHomecare believes that IRS should expand the regulatory safe harbor to include all HME devices and supplies rather than limiting it to the products and supplies listed in the proposed rule. However, if the Agency declines to take this approach, we recommend that it clarify how it would apply the two-pronged test to other HME devices and supplies. Specifically, you should revise the regulatory language to state clearly that the fact that a device or supply fails to meet one of the factors does not, without further analysis, trigger the application of the tax if other criteria are satisfied.

IV. Conclusion

To summarize, AAHomecare 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.” The statute explicitly defines HME devices and supplies as equipment “determined to be *necessary on the basis of the individual’s medical and physical condition . . . used in his home* (including an institution used as his home . . .) [. . .] **whether furnished on a rental basis or purchased** . . . [.]”¹⁹ HME devices and supplies are rented or sold by HME companies to the individual consumer end user in a transaction that can be fairly characterized as a “retail sale.” Moreover, HME companies have many features in common with retail outlets

¹⁸ For example, in 2006 CMS removed noninvasive positive pressure ventilators from the frequently serviced payment category, reclassifying them as respiratory assist devices and placing them in the capped rental payment category. 71 Fed. Reg 4519 (January 27, 2006).

¹⁹ 42 U.S.C. §1395x.

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such as chain drug stores and independent pharmacies, including a physical location that: is accessible to the public; has a permanent, visible sign; has posted hours of operation; and must be open for business for a minimum of 30 hours a week. When viewed as a whole, these factors strongly support our request that IRS expand the regulatory safe harbor to include all HME devices and supplies.

Further, if IRS does not expand the safe harbor, then §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 under 21 CFR Part 868 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 under Part 868 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, AAHomecare 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. In other words, 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.

AAHomecare appreciates the opportunity to submit these comments. We intend to attend and present at the public meeting on May 16, 2012, and will be submitting a separate request for the hearing. We also request that opportunity to discuss these issues in person with your staff prior to the public hearing. AAHomecare will follow-up with you to schedule a convenient time for us to meet.

Sincerely,

A handwritten signature in cursive script, appearing to read "Walter Gorski".

Walter Gorski

Vice President of Government Affairs

American Association for Homecare