



*Caring that Feels Right at Home*

January 7, 2011

The Honorable Timothy F. Geithner  
Secretary, Department of Treasury  
1500 Pennsylvania Avenue, NW  
Washington, DC 20509

**Re: Comments on Guidance for the Excise Tax on Medical Devices (Notice 2010-89)**

Dear Secretary Geithner:

The American Association for Homecare (AAHomecare) is pleased to submit the following comments regarding the implementation of the new excise tax on medical devices imposed by section 4191 of the Internal Revenue Code (Code). Section 4191 was added by section 1405 of the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029, 1064-1065 (the Act), in conjunction with the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119. The statutory language imposes an excise tax on the sale of any “taxable medical device” by the manufacturer, producer, or importer of the device in an amount equal to 2.3 percent of the sale price, beginning in 2013. The provision provides exemptions for eyeglasses, contact lenses, hearing aids, and 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.

**AAHomecare believes that Durable Medical Equipment (DME) and supplies should be exempt from the new excise tax on medical devices. It is our opinion that the statutory language and Congressional intent validate our position.** AAHomecare appreciates the opportunity to provide important information on this matter and looks forward to working with you and your staff as the guidance for the excise tax on medical devices is developed.

AAHomecare is the only national trade association representing every line of medical equipment and services within the homecare community. The Association represents health care providers and manufacturers who serve the medical needs of Americans who require durable medical equipment, supplies, and services such as diabetes therapy and other supplies, oxygen equipment and therapy, sleep therapy technologies, mobility assistive technologies, inhalation drug therapy, home infusion, and other home medical equipment, therapies, services, and supplies in their homes. Our membership reflects a

cross-section of the homecare community, including national, regional, and local providers. With approximately 500 member companies at 3,000 locations nationwide, AAHomecare and our members are committed to advancing the value of quality health care services furnished to patients in their homes.

For the purpose of the comments AAHomecare is submitting, references to Home Medical Equipment (HME) are to be defined and treated the same as DME and supplies. HME is a term of art for the homecare sector.

### **Medical Device Tax Statutory Language**

The Act includes a provision requiring an excise tax on the sale of a “taxable medical device” equal to 2.3% of the price of the device. The tax is imposed on any sale by a “manufacturer, producer or importer” of the device. Under the law, a “taxable medical device” is any medical device as defined in section 201(h) of the Federal Food, Drug and Cosmetic Act (FFDCA). As a general rule, HME items, which include wheelchairs, canes, crutches, walkers, home care beds, bath safety aids, commodes and oxygen devices, meet the definition of a “device” as used in the FFDCA.

Under the Act, the Secretary of Treasury 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.” Thus, in order to be exempt from the tax, the Secretary must determine that the device is generally purchased (a) by the general public; (b) at retail; and (c) for individual use. AAHomecare believes that sales of HME should be exempt from the definition of “taxable medical device” because of the exemption in section 4191(b)(2)(D) of the Internal Revenue Code.

The following is the policy rationale for AAHomecare’s position.

### **HME Meets Statutory Requirement for Exemption**

Items of HME include items such as canes, crutches, walkers, commodes, bath safety items, wheelchairs, respiratory devices, home care beds and other items that individuals with acute or chronic conditions use to enable them to get around their home and community, and generally be more self-reliant. HME items help people recover or convalesce in their homes rather than in more expensive institutional settings. HME is the general industry term for these products. Please note that under the Medicare program, the term “durable medical equipment” (or “DME”) is used to define the items under the Medicare Part B benefit. All HME items are classified by the FDA as Class I or Class II medical devices. AAHomecare is not aware of any HME items that are classified by the FDA as Class III devices.

#### **(a) “Generally Purchased By the Public”**

HME items are “generally purchased by the general public.” The intent of the sponsors throughout the entire health care reform process has been that the tax, or fee, should

apply to medical devices such as scalpels, diagnostic equipment, and other items used “in connection with providing a health care service,” in the words of the House bill. Such items used in connection with providing a health care service are not generally purchased by the general public; they are purchased by hospitals, medical offices, physician practices, and other health care providers. Although it is true that some HME items will be purchased by health care providers, the Association believes that the phrase “generally purchased” provides the Secretary of the Treasury with enough flexibility to determine that the sale of an item of HME is “generally purchased by the general public,” and thus should be excluded for the medical device tax.

Individuals can purchase HME items at retail establishments such as a local retail pharmacy, a local HME retailer, or a Wal-Mart. There are a wide variety of firms that sell (and/or rent) HME items. Some firms focus on mobility devices such as canes, walkers, crutches, manual and/or power wheelchairs. Other firms focus on respiratory items such as oxygen concentrators and portable oxygen systems. And some firms carry a comprehensive inventory of HME items, including the previous items and other items such as home care beds, bath safety items and commodes. Regardless of the array of HME devices they carry, HME firms share the common characteristic of selling HME directly to consumers for the consumers’ own use.

While individuals purchase HME items from an HME retailer, similar items may also be purchased in large quantities by a health care institution such as a hospital or nursing home. For purposes of implementation of this exemption, the Association believes that HME items are purchased more often by individuals than by institutions. Also, in many instances (for example, home care beds), the product purchased and used by the consumer in his/her home will be a different product than a similar product purchased and used by patients in a health care institution.

AAHomecare has conducted research regarding the term “generally purchased” and have found no health care example where the government defined that term. The closest verbiage we have found is in the Medicare program, and its interpretation of the similar term “usually.” The Medicare Program provides limited benefits for outpatient prescription drugs. The program covers drugs that are furnished “incident to” a physician’s service provided that the drugs are not “usually” self-administered by the patients who take them. Section 112 of the Benefits, Improvements & Protection Act of 2000 (BIPA) redefined this exclusion to drugs “not usually self-administered by the patient.”

For the purposes of applying this exclusion, the Centers for Medicare and Medicaid Services (CMS) defined the term “usually” to mean more than 50 percent of the time for all Medicare beneficiaries who use the drug.<sup>1</sup> Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from coverage and the contractor may not make any Medicare payment for it. Further, Merriam-Webster’s online dictionary identifies the word “generally” as being synonymous with “usually.” AAHomecare, therefore, recommend that the IRS employ a definition for the term

---

<sup>1</sup> See CMS Manual System, Pub. 100-02, Transmittal 91, June 20, 2008.

“generally purchased by the public” similar to how CMS has defined the term “usually.” Any medical device that is purchased by an individual at least 50% of the time should therefore be exempt from the excise tax.

#### **b) “Purchased At Retail”**

The criterion for exclusion requires that the item of HME be of a type that is generally purchased “at retail.” Other excise-tax provisions already present in the Internal Revenue Code define a sale “at retail” as a “sale, for a purpose other than resale, after manufacture, production, or importation.”<sup>2</sup> This definition is consistent with the common legal definition of a retail sale, as used in most state sales-tax laws (sales taxes generally apply to sales “at retail”) and as set forth in Black’s Law Dictionary: “[t]he sale of goods or commodities, as opposed to the sale for further distribution or processing.” It seems clear that a sale of even a technologically advanced item of HME, such as a power wheelchair, would qualify as a sale at retail, even if the sale does not occur in a retail store, because it is a sale to the end user, the ultimate consumer.<sup>3</sup> These products are all sold on an individual basis, one wheelchair or other HME item at a time. Further, certain HME items, such as complex power wheelchairs, are actually manufactured to the specifications of the particular consumer to meet his/her specific medical needs. If such items are “generally” sold to the end user, then sales of such items may be eligible for this exemption. (Based on the precise wording of the statute, a particular sale of an item need not be a retail sale in order to qualify for the exemption, so long as Treasury has determined that the item is “of a type” generally sold at retail.)

Further, state licensure laws support the notion that HME is generally sold at retail. While not all states require HME firms to be licensed, many do. There are approximately 22 states that require firms that sell home medical items to be licensed in order to sell to consumers in the state.<sup>4</sup> States that require HME firms to be licensed generally require them to operate out of an appropriate physical facility with a business number, with visible posted signs, and in a location that is accessible to the public.

---

<sup>2</sup> See Internal Revenue Code sections 4002(a), 4011(a)(repealed) and 4052(a)(1).

<sup>3</sup> Note that not all items of DME are immediately re-sold to a Medicare beneficiary. Some transfers of a wheelchair or other “capped rental” items of DME 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” item until the item has been rented for 13 months. Therefore while Medicare payment rules require rental payments for a while, eventually the HME item subject to Medicare payment rules end up as a sale. See Social Security Act § 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 item 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.

<sup>4</sup> States requiring HME firms to be licensed include: AL, AR, CA, DC, FL, ID, IL, IN, KS, LA, MD, MS, NC, NV, OH, PA, PR, SC, TN, TX, VA, VI

While state licensure requirements vary somewhat, common themes include having an “appropriate” physical location where consumers can shop during normal business hours.<sup>5</sup> Following are relevant excerpts from some state license requirements:

- California’s licensure law calls an HME firm a “home medical device retailer,” and requires these firms to include “an area, place or premises from which...home medical devices and home medical device services are sold, fitted or dispensed at retail.” (See California Code of Regulations, Title 22, Section 51000, <http://www.dhcs.ca.gov/provgovpart/Pages/DurableMedicalEquipmentApplicationPackage.aspx>)
- The South Carolina DME Provider Manual states that the provider must have a physical retail business location in South Carolina or within 25 miles of the South Carolina border. (See: <http://www.scdhhs.gov/internet/pdf/manuals/dme/SECTION%202.pdf> )
- Ohio requires HME firms to maintain a facility that is appropriate to lease or sell HME (See Ohio Revised Code Title 47, Chapter 4752 “Home Medical Services,” and Ohio Administrative Code Chapter 4761:1)

Finally, Medicare enrollment requirements for HME suppliers require the firms to operate out of retail locations. In order to qualify for a Medicare HME billing number, a firm must comply with 32 Medicare Supplier standards.<sup>6</sup> Among the requirements are that the location (a) maintain a physical location on an appropriate site; (b) be in a location that is accessible to the public; (c) be accessible and staffed; (d) have a permanent visible sign; (e) have posted hours of operation; and (f) be open to the public at least 30 hours per week. These criteria are typical practice patterns of any retail business. (See 42 CFR §424.57(c) for complete list of Medicare DME Supplier Standards.)

### **(c) “For Individual Use”**

A medical device meets the exclusion of subparagraph (D) if it is of a type that is generally sold for individual use. It seems obvious that items of HME would satisfy the exclusion requirement as they are used by individuals. The definition of HME in the Social Security Act supports this common understanding of HME as it references “individuals” and “patients” as users of the equipment multiple times.<sup>7</sup>

Consumers often purchase HME items “out-of-pocket,” while in many instances a third party payor (such as Medicare, Medicaid, or a private health insurance payor) pays for the

---

<sup>5</sup> The National Supplier Clearinghouse, a Medicare contractor, maintains a database and link to DME state laws and regulations at: <http://www.palmettogba.com/palmetto/statelicensure.nsf/WY?OpenView>

<sup>6</sup> The standards are codified at 42 C.F.R. Sec §424.57(c).

<sup>7</sup> For example, the Social Security Act defines “durable medical equipment” as items used by an “individual,” and determined to be necessary based on the “individual’s” medical and physical condition (Social Security Act 1861(n)).

item under the person's health insurance policy. In all of these circumstances, the purchase is for use by the individual consumer.

### **Intent of Congress to Exempt HME from Medical Device Tax**

In addition to meeting the statutory requirement for exemption, AAHomecare believes that it was not the intent of Congress to subject HME items to the medical device tax. When discussing the accusation that the medical device tax was a "wheelchair tax", Speaker Pelosi responded in a myth and fact sheet –

“In providing health insurance to 36 million more Americans, this legislation will improve patient access to medical devices and bring significant financial benefit to the medical device industry. The bill raises \$20 billion over ten years to help cover the cost of expanding insurance through an excise tax on an industry that will generate an estimated \$1.5 trillion in revenue over that time period. Sales of wheelchairs and other medical devices to individuals are exempt from the tax; the tax only applies to sales of medical devices to health care institutions, such as hospitals. “<sup>8</sup>

A major justification for the medical device tax came from the health care reform law's requirement that more Americans be covered by health insurance. Members of the Senate Finance Committee reasoned that, since more Americans will have insurance, more will receive medical procedures, so medical device manufacturers will see an increase in sales. Scott Mulhauser, a spokesman for Senator Max Baucus said,

"Revenues to the device manufacturing industry will go up as insurance coverage expands, and this fee will ensure the industry helps contribute to the reform effort as it benefits."<sup>9</sup>

AAHomecare believes that this justification is another indicator that it was the intent of Congress to exempt HME from the tax. The increased health care coverage provided in the Patient Protection and Affordable Care Act will not increase sales volume for the HME sector. HME items that are manufactured by medical device companies are predominantly provided to seniors and disabled patients by HME providers for use in the patient's home. This is unlike many of the other types of medical devices subject to the tax that are utilized by hospitals, physicians, and other health care providers to treat patients in a facility. Because HME is utilized by patients who are predominately covered by federal government programs, an expansion of health care coverage is unlikely to significantly increase HME spending or result in windfall profits to HME manufacturers.

### **Conclusion**

As explained above, **AAHomecare believes that HME items should be exempt from the new excise tax on medical devices. It is the Associations opinion that the statutory**

---

<sup>8</sup> <http://www.speaker.gov/newsroom/factcheck?id=0133>

<sup>9</sup> [http://www.msnbc.msn.com/id/32974002/ns/politics-health\\_care\\_reform/](http://www.msnbc.msn.com/id/32974002/ns/politics-health_care_reform/)

**language, as well as the Congressional intent validates our position.** AAHomecare appreciates the opportunity to provide this important information and looks forward to working with you and your staff as the guidance for the excise tax on medical devices is developed.

If you have questions about the Association's position, please contact Jay Witter at (703) 535-1884 or [jayw@aahomecare.org](mailto:jayw@aahomecare.org).

Sincerely,

A handwritten signature in black ink that reads "Tyler J. Wilson". The signature is written in a cursive, flowing style.

Tyler J. Wilson  
President