Caring that Feels Right at Home

Via Electronic Mail

January 21, 2010

Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Dept. of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Daniel Levinson
Inspector General
Office of Inspector General
U.S. Dept. of Health and Human Services
330 Independence Ave SW
Washington, DC 20201

Dear Acting Administrator Frizzera and Inspector General Levinson:

We are writing to express our serious concerns with an aspect of the Office of Inspector General for the Department of Health and Human Services' (OIG) Updated Special Fraud Alert on Telemarketing by Durable Medical Equipment (DME) Providers (the "Fraud Alert"), which your office published in the January 14, 2010, *Federal Register*.[1] As you may know, the American Association for Homecare (AAHomecare) is strongly in favor of measures to eliminate fraudulent or abusive practices from the Medicare DME benefit, including violations of the telemarketing prohibitions under §1834(a)(17) of the Social Security Act. However, we are very troubled by the assertion in the Fraud Alert that the DME providers who contact beneficiaries to effectuate a physician's verbal or written order violate §1834(a)(17), exposing the providers to exclusion from the program as well as potential liability for false claims if they submit Medicare claims arising from those contacts.

AAHomecare is the national trade association for health care providers, equipment manufacturers, and other organizations in the homecare community. AAHomecare members serve the medical needs of Americans who require oxygen equipment and therapy, mobility assistive technologies, medical supplies, inhalation drug therapy, home infusion, and other home medical products, services, and supplies in the home. The association's membership reflects a broad cross-section of the homecare community, including home medical equipment providers of all sizes operating approximately 3,000 locations in all 50 states.

The new policy announced in the Fraud Alert leaves virtually every Medicare-enrolled DME provider open to liability for false claims. Requiring DME providers to have a beneficiary's written authorization before contacting the beneficiary to deliver DME ordered by his/her physician could compromise the beneficiary's health and is also impractical and unworkable. **We request that you rescind this aspect of the Fraud Alert for the reasons we discuss below.**

[1] 75 Fed. Reg. at 2105 (January 14, 2010)

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I. Contacting the Beneficiary Based on a Physician's Verbal or Written Order Does Not Constitute a Prohibited Telephone Solicitation

When a provider receives an order from the physician and then, acting responsibly, contacts the beneficiary by telephone to obtain information and coordinate delivery of the item, that telephone contact has in fact been solicited by the physician, on behalf of the patient. It is therefore not an unsolicited telephone contact prohibited by the statute.

Nearly all DME items and services are furnished to beneficiaries in their homes in response to a written or verbal order communicated initially by the physician to the DME provider who then contacts the beneficiary to arrange for delivery of the item. Exceptions to this longstanding and widespread practice include retail transactions and items that are delivered to a beneficiary at the time he/she is being discharged from a hospital. Telephone contact with a beneficiary based on a physician's order is fundamentally different from the telemarketing activities that Congress addressed when it enacted §1834(a)(17) of the Social Security Act. The provider's communication, first with the physician and then with the beneficiary, is essential to ensuring that the beneficiary receives a DME item that is both medically necessary and appropriate for his/her condition. Limiting access to DME to only those instances where the beneficiary initiates the contact with the DME provider could at best delay services for which the beneficiary's need typically is urgent, or at worst, result in substandard care.

Importantly, when a beneficiary initiates the request for DME with the provider, there is a risk that the beneficiary desires an item primarily for his personal convenience rather than for a medical need. Medicare payment for DME requires that a beneficiary's physician consider clinical or functional measures that establish medical necessity for the DME item. When the physician communicates the order directly to the DME provider, he or she has already determined that the item is medically necessary. Clearly, this is preferable to the alternative scenario in which the beneficiary first contacts the DME provider, then having learned from the provider that Medicare payment rules require him/her to have a physician's order, the beneficiary contacts his/her doctor to request that order.

Many beneficiaries in need of DME do not have a medical background and/or are in such poor health that they would not be able to effectively communicate their needs for specific DME items. The current practice facilitates the exchange of clinical information between providers, which many beneficiaries could not communicate effectively. Very often, a beneficiary has an urgent need for the DME item such that the item must be delivered within a narrow window of time. This is typically the case for beneficiaries who need oxygen therapy. Likewise, beneficiaries may need a hospital bed when they are discharged from an inpatient facility. Even less complex equipment such as walkers must be promptly delivered so that the beneficiary can be discharged home. In each of these examples, the DME provider must (i) collect the clinical information that establishes medical necessity before initiating service to the beneficiary, and (ii) contact the beneficiary to schedule the delivery. In most or all such instances, the physician or other clinician has discussed the need for the equipment with the beneficiary and the range of available and recommended suppliers, and he/she has secured the beneficiary's implicit consent to facilitate the order with a particular DME provider.

Many beneficiaries also would not be able to effectively communicate the clinical information needed to determine whether they meet Medicare coverage criteria. Consequently, if the beneficiary is required to initiate the call to the provider, then the provider would most likely have to contact the doctor following the beneficiary's initial call to obtain additional information. This process can be time consuming and confusing depending on the sophistication of the beneficiary or caregiver entrusted to make the call and the availability of the physician's staff to confirm the order, thus delaying what should have been "prompt" treatment given the beneficiary's condition.

II. Congress Did Not Intend to Restrict Necessary Communication Between DME Providers and Beneficiaries

When Congress enacted the prohibition on unsolicited telemarketing,[2] it was targeting a specific abusive marketing practice that was prevalent at the time, and which Congress believed increased Medicare spending for medically unnecessary medical equipment. Specifically, Congress was addressing high pressure telephone sales "cold" calls targeting Medicare beneficiaries:

> The Subcommittee found that there is a substantial problem involving DME companies who engage in high-pressure sales techniques, usually by telephone, to induce Medicare beneficiaries to purchase equipment that they neither want nor need. These companies often make misrepresentations regarding Medicare, frequently telling beneficiaries that they will not have to pay any part of the cost of the equipment they order.
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> HOUSE REPORT NO. 102-431 H.R. REP. 102-431, 49 -50 (1992)

In contrast, longstanding Medicare policy recognizes and permits DME providers to dispense DME in response to a physician's verbal order for the item.[3] Typically, the physician communicates the order directly to the provider who, in turn, initiates the intake and assessment process based on a written confirmation of the physician's verbal order, which is later ratified by

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[2] *See* 42 U.S.C. §1395m(a)(17) which prohibits unsolicited telephone contacts of beneficiaries by suppliers unless one of three exceptions are present. The statute states as follows:

A supplier of a covered item under this subsection may not contact an individual enrolled under this part by telephone regarding the furnishing of a covered item to the individual unless 1 of the following applies:

> **(i)** The individual has given written permission to the supplier to make contact by telephone regarding the furnishing of a covered item.
>
> **(ii)** The supplier has furnished a covered item to the individual and the supplier is contacting the individual only regarding the furnishing of such covered item.
>
> **(iii)** If the contact is regarding the furnishing of a covered item other than a covered item already furnished to the individual, the supplier has furnished at least 1 covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

[3] Chapter 5, Medicare Program Integrity Manual (PIM), 100-8, available at: http://www.cms.hhs.gov.

the physician's signature and date.[4] The communication between the provider and the physician's office ensures that the order is accurately conveyed to the DME provider and promotes the timely delivery of services consistent with the beneficiary's medical need. Because DME providers may not bill Medicare for the item until they have a written order from the physician, the Medicare program is protected from any improper utilization or other abusive practices.[5]

With the exception of a handful of specific items that require a written order prior to delivery to the beneficiary, the Centers for Medicare and Medicaid Services' (CMS) policy has recognized the value in permitting DME providers to begin servicing beneficiaries based on the physician's verbal order. Otherwise, beneficiaries in need of life-sustaining medical equipment such as oxygen therapy would be required to wait for the equipment until the DME provider receives a written order from the physician.[6]

This practice is fundamentally different from the "high-pressure sales techniques" that concerned Congress. In this case, the order for DME is given *after* the physician has determined that a beneficiary has a medical need for the item. Section 1834(a)(17) addresses the scenario in which a beneficiary, having learned about a DME product as a result of a "cold" sales call, asks his doctor for an order for the item.

III. Regulations Implementing §1834(a)(17) Do Not Restrict a DME Provider's Ability to Contact Beneficiaries In Order to Effectuate a Physician's Order for DME

The preamble to the supplier standards implementing the telemarketing prohibitions addressed whether it was permissible for DME providers to contact beneficiaries based on a *referral* by a physician. CMS specifically did *not* address whether DME providers can communicate directly with a beneficiary to effectuate an order placed by his or her physician. The preamble to the October 11, 2000, final rule establishing additional supplier standards stated:[7]

> *Comment*: One commenter suggested that we add an exception to this standard. Specifically, the commenter suggested that we permit telephone contact if the supplier receives a referral from a medical professional involved in the patient's care.
>
> *Response*: While this may be reasonable in some situations, we find it problematic in that it may have unintended consequences as a loophole by allowing suppliers to purchase "referrals" (client lists) from medical professionals.
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> 65 Fed. Reg. at 60372.

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[4] *Id*.
[5] *Id*. OIG Compliance Guidance for DMEPOS Suppliers, 64 Fed. Reg. 36368 (June 6, 1999).
[6] In 2004, CMS proposed requiring a written order for all DME prior to delivery to the beneficiary. In response to public comments CMS did not finalize that proposal. CMS did require, however, a written order prior to delivery for power mobility devices. *See* Medicare Program; Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles; 71 Fed. Reg. 17021 (April 5, 2006).
[7] 65 Fed. Reg. at 60372.

CMS' concern in the 2000 rulemaking was that DME providers would interpret the term "referral" so broadly that it would encompass unsavory and illegal practices such as the sale of a physician's patient lists to DME providers.[8] We believe that there is an appropriate and obvious distinction between physician "orders," which are made after a physician's determination of medical necessity, and physician "referrals," which *arguably* could include orders as well as a broader range of physician requests. Physicians give orders for DME only after determining that the item is medically necessary. Our goal is to ensure that DME providers can initiate telephone communication with a beneficiary in response to the physician's verbal or written order for DME so that the beneficiary receives timely and appropriate DME items and services.

IV. Conclusion

In summary, when a DME provider contacts a beneficiary pursuant to the confirmation of the physician's verbal order, it is not engaging in telemarketing or unsolicited telephone contacts. These activities are fundamentally different. In the former, the physician has examined the beneficiary and made a determination of medical need for the DME. Congress did not intend to prohibit legitimate communication between the DME provider and the beneficiary once a physician has determined that a beneficiary requires an item of DME, and we do not believe that the OIG intends to do so either. Consequently, we request that you immediately revise the Fraud Alert so as to permit communication between a DME provider and a beneficiary in order to effectuate a physician's order for DME.

We would like to request a meeting with the appropriate staff within the OIG to discuss how our concerns can best be addressed. AAHomecare's Walt Gorski, Vice President of Government Relations, will be contacting you to arrange a meeting. He can be reached at 703-535-1894.

Sincerely,

Tyler Wilson,
President & CEO, AAHomecare

CC: Kimberly Brandt, CMS
James Cannatti III, OIG

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[8] The sale of protected health care information is unequivocally illegal under the privacy provisions of Health Insurance Portability and Accountability Act of 1996 as amended by the [HITECH of 2009]