



Via Electronic Submission

June 3, 2011

Donald Berwick, MD
Administrator, Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Medicare & Medicaid Services (CMS) Medicare Program; Revisions to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers Safeguards [CMS-6036-P2] RIN 0938-AQ57¹

Dear Administrator Berwick:

The American Association for Homecare (AAHomecare) submits these comments in response to the proposed rule cited above. The Centers for Medicare and Medicaid Services (CMS) has published the proposed rule to revise the durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) supplier standards that went into effect last year.

AAHomecare is the primary national association representing the interests of a broad range of DMEPOS suppliers that is representative of the industry across the United States. AAHomecare members include manufacturers and suppliers that make or furnish DMEPOS items that Medicare beneficiaries use in their homes. Our members are proud to be part of the continuum of care that assures that Medicare beneficiaries receive cost-effective, safe and reliable home care products and services in their homes. By virtue of our longstanding representation of DMEPOS suppliers in Washington and beyond, we are uniquely qualified to comment on the proposed rule.

The proposed rule amends the current DMEPOS supplier standards in two important ways. First, the rule revises the prohibition on “direct solicitation” of beneficiaries and reinstates an earlier standard based on the statutory prohibition on unsolicited telephone contacts to beneficiaries. CMS also proposes to revise the rules on DMEPOS supplier subcontracting arrangements, allowing suppliers greater latitude to enter into these arrangements.

AAHomecare agrees with the preamble, which states that CMS is not deviating from its goal of strengthening the supplier standards. The Agency published the proposed rule to address the day-to-day, operational “realities” that suppliers confront in providing quality care while maintaining access for beneficiaries. CMS also intends to clarify its interpretation of certain provisions of the supplier standards

¹76 Fed. Reg. 18472 (Monday, April 4, 2011).

to ensure that the standards protect against fraud, waste, and abuse while preserving access to services for Medicare beneficiaries.

AAHomecare supports the revisions CMS has proposed. We agree that the current standard prohibiting “direct solicitation” of beneficiaries is too broad, making it difficult for compliant suppliers to operate their businesses and respond to the care expectations of beneficiaries and those healthcare professionals who rely on DMEPOS suppliers to expedite their patients’ care at home. Likewise, the current supplier subcontracting rules are difficult to apply to many common DMEPOS contracting arrangements. Our comments below highlight areas we believe require additional clarification in light of the proposed rule. We discuss these specific issues in greater detail below.

I. PROHIBITION ON MAKING UNSOLICITED TELEPHONE CONTACTS TO BENEFICIARIES

We agree with the proposed revisions to the current standard prohibiting “direct solicitation” of beneficiaries. The scope of the current rule goes beyond the statutory prohibition on unsolicited telephone contacts² to encompass otherwise legitimate communication between suppliers and beneficiaries, including the types of useful communication that might occur during in-person encounters at community health fairs or similar venues, via a supplier’s legal advertising activities, and, most notably, during the actual referral process when a hospital discharge planner or treating physician refers the patient to a DMEPOS supplier for services and products.

Importantly, CMS has interpreted the current standards to prohibit suppliers from contacting beneficiaries for the purpose of filling their doctor’s order for DMEPOS without first obtaining their written permission for the call. This unrealistic interpretation cannot be implemented when patients are discharged from hospitals or see their physician and those referral sources expect the patient’s in-home delivery to be performed within two to four hours of the referral by phone or fax, not to mention all of the other Medicare and secondary insurance coverage verification and compliance documents that must be retrieved from the referral source and/or the patient during that critical time window. These interactions are best described as “care coordination,” not telemarketing. Care coordination is an expectation of the Medicare DMEPOS Supplier Standards, the Medicare Quality Standards for DMEPOS, other standards/rules that pertain specifically to the Medicare DMEPOS competitive bidding program and the proposed regulations associated with Accountable Care Organizations. This provision has proved unworkable for suppliers and is not supported by any reasonable interpretation of the current

²See 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.

standards.³ Consequently, we support CMS' decision to reinstate the supplier standard in effect before CMS finalized the current rule. AAHomecare wants to emphasize, however, that CMS must apply the "telemarketing" prohibition in a way that is consistent with what Congress intended when it prohibited traditional, unsolicited telemarketing directed at beneficiaries.

That is, Congress intended to prohibit high-pressure telephone sales, or "cold" calls, targeting Medicare beneficiaries. Cold calling is a specific abusive marketing practice that was prevalent almost two decades ago in 1992 when the law was passed. At the time, Congress believed that cold calling increased Medicare spending for medically unnecessary medical equipment:

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.

HOUSE REPORT NO.102-431 H.R. REP. 102-431, 49 -50 (1992).

The statutory prohibition on telemarketing to beneficiaries was never intended or understood to prohibit the legitimate and necessary communication that occurs when the supplier calls a beneficiary after receiving the referral to coordinate his/her safe and timely discharge from the hospital to his/her home, schedule the delivery of DME that his or her doctor ordered, or discuss other needs with the patient. In this context, the supplier's telephone call to the beneficiary cannot reasonably be characterized as the type of "cold call" Congress intended to address but again can be better classified as "care coordination."

It is worth noting that the supplier's call to the beneficiary in the circumstances discussed above is not "unsolicited." Indeed, the physician is acting on the beneficiary's behalf in contacting the supplier and the beneficiary is therefore in fact, through his/her physician, soliciting the supplier's contact.

In the past, CMS has attempted to distinguish among the various scenarios that can occur when the supplier calls the beneficiary to fill the doctor's order at the doctor's request with the goal of identifying the types of calls that might constitute prohibited telemarketing.⁴ For example, CMS has stated that if a beneficiary expects "a" supplier's (any supplier's) call, then the supplier is not engaged in prohibited

³AAHomecare supports the revisions to the rule prohibiting direct solicitation of beneficiaries under the proposed rule. However, we note that the current standards do not prohibit suppliers from contacting a beneficiary to fill a doctor's prescription without first getting the beneficiary's written permission as CMS contends. Specifically, the standards define "direct solicitation" as:

[D]irect contact, which includes, but is not limited to, telephone, computer, e-mail, instant messaging or in-person contact, **by a DMEPOS supplier or its agents to a Medicare beneficiary without his or her consent for the purpose of marketing the DMEPOS supplier's health care products or services or both.**

42 CFR 424.57 (emphasis supplied).

Calling a beneficiary to fill his/her doctor's prescription is clearly outside the definition of "direct solicitation" under the standards because the contact is not for the purpose of "marketing the DMEPOS supplier's health care products or services. . ." under any reasonable interpretation of the regulation.

⁴CMS Telemarketing Frequently Asked Questions, February 2010

telemarketing when he/she calls the beneficiary to fill the doctor's order. This distinction is artificial and creates uncertainty for the many different scenarios that occur when a supplier calls a beneficiary and he or she did not expect, or simply does not remember due to being ill or overwhelmed by the prospects of a hospital discharge or new treatment/therapy at home, that a supplier would call.

Moreover, if not arbitrary, then the distinction is simply not useful. Whether or not the beneficiary expects "a" supplier to call him/her does not change the underlying nature of the call, *i.e.*, to coordinate and schedule the delivery of DMEPOS that the doctor has ordered based on the beneficiary's individual medical need. These calls are fundamentally different from those Congress intended to prohibit. In this case, the doctor has examined the beneficiary and made a determination of medical need for the DME. A contrary interpretation is impracticable and would delay care that the doctor has determined is medically necessary and potentially result in increased costs to the Medicare program and beneficiaries in the form of protracted hospital stays or emergency room visits due to a delay in the start of care.

Congress did not intend to prohibit legitimate communication between the supplier and beneficiary once a physician has determined that a beneficiary requires an item of DME; and we do not believe that CMS should do so either.⁵

With this in mind, AAHomecare has developed the following FAQs based on the Association's understanding that the telemarketing prohibition does not reach calls from a supplier to a beneficiary to implement the doctor's order for medically necessary DME. We request that CMS confirm whether our interpretation of the proposed rule is correct in each of the scenarios below.

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- 1. Q.** A physician determines that her patient, a Medicare beneficiary, requires oxygen and discusses this with the patient. The physician orders the oxygen and the supplier receives the order through the physician's electronic medical record (EMR) system. The supplier calls the beneficiary to arrange for the delivery of the oxygen. Is the supplier in this example violating the supplier standards?
- A.** *No. The supplier contacted the beneficiary for the purpose of filling the doctor's order for a medically necessary item, oxygen. The doctor is acting on behalf of the beneficiary when he or she places the order. The physician also discussed the need for the oxygen with the patient. Consequently, it is expected that the beneficiary would be aware that a supplier would contact him/her to arrange for the delivery. The supplier would still be expected to comply with all other CMS policies and documentation requirements such as obtaining oxygen testing results, the oxygen Certificate of Medical Necessity (CMN), etc.*

⁵ The preamble makes the following statement with respect to its intent in promulgating the current rule, suggesting that CMS recognizes the difference between legitimate and abusive communications with beneficiaries:

The purpose [of the August 27, 2010 final rule] was to inhibit the direct, coercive, and targeted solicitation of our nation's senior citizens. We are concerned that these solicitations and subsequent purchases can be fraudulent or abusive in nature, which may result in monetary increases in health care costs and further drains on the Medicare Trust Fund.

76 Fed Reg. at 18474.

- 2. Q.** The physician sees the next patient who arrives with her daughter because she has mild dementia and also qualifies for oxygen due to her underlying COPD. The physician discusses the beneficiary's need for oxygen with the daughter and places the order with the supplier using the EMR. The supplier receives the order and contacts the beneficiary to arrange delivery of the oxygen. When the supplier calls, the beneficiary is at home alone and was not expecting a supplier's call. Did the supplier in this example violate the supplier standards?
- A.** *No. The supplier in this example is filling a doctor's order for a medically necessary item. The beneficiary in this example lacks the capacity to understand what the doctor ordered and so could not have expected to receive a call from a supplier. However, the physician discussed the need for oxygen with the patient's caregiver or surrogate who consented to the oxygen prescription on the beneficiary's behalf. Had the caregiver/surrogate been with the beneficiary when the supplier called, it is expected that she would have anticipated a call from an oxygen supplier. If the beneficiary had the capacity to understand what the doctor had ordered (which she did not in this example), presumably, she too would have expected a call from an oxygen supplier.*
- 3. Q.** The doctor's next patient is seen by the physician assistant (PA). After appropriate evaluation and testing, the PA concludes that the patient, a beneficiary, needs to start on oxygen. While the patient is still in the examining room, the PA steps out to discuss this conclusion with the doctor and the doctor agrees. The PA renews the beneficiary's prescription for Metformin, but forgets to discuss the prescription for oxygen with him/her. The PA notes the oxygen prescription in the record and the office staff calls the referral in to the supplier, expecting the oxygen to be delivered within four hours of the referral. The supplier, in turn, calls the beneficiary to verify benefits and arrange for delivery. The beneficiary was not expecting a supplier to call. Assume the PA is authorized under the state practice act to order oxygen. Did this supplier violate the supplier standards?
- A.** *No. The supplier in this example is filling a doctor's order for a medically necessary item. This is not the type of unsolicited telephone contact prohibited under the supplier standards because the purpose of the call is to coordinate care and fill a doctor's order, not to market the supplier's products or services on an unsolicited basis. Even though the beneficiary in this example was not expecting a call from a supplier, the PA acted on behalf of the beneficiary when he/she gave the order for oxygen, and the contact was not for the purpose of marketing a product or service to the beneficiary. The supplier would still be expected to comply with all other CMS policies and documentation requirements such as obtaining oxygen testing results, the oxygen CMN, etc.*
- 4. Q.** A doctor orders a CPAP device for a Medicare beneficiary, but the order does not include the interface (mask) to use with the device. The doctor contacts the supplier with the referral and his/her order and the supplier calls the beneficiary to schedule delivery. The beneficiary was aware that a supplier would call him/her to schedule the delivery of the CPAP. The supplier also informs the beneficiary that he/she will need an interface in order to meet his physician's treatment plan and actually use the device correctly -- an item the beneficiary had not expected to discuss and which the doctor did not order. Subsequently, the supplier contacts the doctor to get an order for the interface. The supplier has not previously furnished a covered item to this beneficiary. Did the supplier violate the supplier standard?
- A.** *No. The supplier in this example is filling a doctor's order for a medically necessary item. The beneficiary must be informed about the need for a CPAP interface because the CPAP will not*

function without one, rendering the doctor's order for the CPAP meaningless. Even though the supplier has not previously furnished an item to the beneficiary and the doctor had not ordered an interface, the supplier in this example did not make an unsolicited telephone contact to the beneficiary because he discussed an item that was essential for the CPAP device, an item the doctor ordered, to function properly.

5. Q. As part of a promotional campaign, a supplier rents a booth at a local hospital's COPD fair to display equipment and provide information to the public. Members of the public complete a sign-up sheet with their contact information if they want the supplier to followup with them individually. The following week, the supplier contacts the people who filled out sign-up sheets, some of whom are Medicare beneficiaries. Did this supplier violate the supplier standards?
- A. *No. The supplier in this example contacted individuals, including Medicare beneficiaries, who requested in writing that the supplier contact them with more information. In other words, the beneficiaries who completed sign-up sheets gave the supplier their written consent to the call.*

II. SUBCONTRACTING FOR LICENSED SERVICES

The proposed rule would also amend the supplier standards with respect to the rules on DMEPOS subcontracting. The current standards prohibit suppliers from contracting for licensed services unless state law permits the subcontracting arrangement. In contrast, the proposed rule would revise the standard to permit subcontracting "unless expressly prohibited by state law." In other words, the proposed rule states the converse of the standard currently in place. AAHomecare concurs with CMS' rationale for revising this standard. The proposed revision is straightforward compared to the current standards and would be easier for suppliers to operationalize in daily practice.

In order to assist suppliers in understanding the scope of their obligations under the proposed subcontracting provisions, AAHomecare requests that CMS respond to the questions that follow. We are compelled to share with you that there continues to be confusion about the services and activities that may be subcontracted as well as which individuals and entities may furnish services under contract with a supplier.

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1. A supplier is enrolled with the National Supplier Clearinghouse (NSC) as an "oxygen supplier." The state requires anyone who dispenses oxygen to be licensed by the state pharmacy board. The supplier is not licensed by the state pharmacy board for dispensing oxygen. It furnishes oxygen by subcontracting with a licensed supplier to furnish oxygen on its behalf. Does this supplier meet the requirements of the supplier standards?
 2. In the above example, assume the supplier furnishes oxygen and is licensed by the state pharmacy board to dispense oxygen. The supplier furnishes stationary oxygen to Medicare beneficiaries, but subcontracts with another supplier who is licensed to furnish liquid oxygen and refills of portable oxygen. Is the supplier in compliance with the supplier standards?
 3. The supplier in the example above subcontracts with respiratory therapists (RTs) to perform oxygen set-ups, patient education, patient monitoring and other follow-up. Assume that the state does not require that a licensed RT perform these services. Is the supplier in violation of the supplier standards?
 4. Assume that the state in example number 3 above requires that licensed RTs perform CPAP set-ups. Assume that state law does not address whether a supplier can subcontract with an RT to

perform CPAP set-ups. In this example, can the supplier use contract RTs who are licensed to perform the set-up?

III. OTHER SUPPLIER STANDARDS

As we noted above, AAHomecare supports the proposed revisions to the current supplier standards. We note, that once the proposed rule is finalized, the following FAQ on the NSC's website should be revised as we suggest below in red font:

Supplier Standard 7

Supplier locations are now required to be a minimum of 200 square feet, with exceptions for ~~state-licensed~~ **certain** orthotic and prosthetic personnel providing custom-fabricated orthotics or prosthetics in private practice.

This exemption will NOT apply to any other supplier type, **but does apply to** ~~nor will it apply to~~ any orthotist or prosthetist that is ~~not~~ state licensed, **or who practices in a state that does not offer state licensure for orthotic or prosthetic personnel** ~~even if the state does not provide/require licenses.~~

Finally, we request that CMS clarify the supplier standard that addresses the location of the supplier's clinical records. The NSC addressed this issue in an FAQ on its website. We suggest that CMS clarify the response as indicated in red below:

- Q. Could you confirm that it is permissible to use an off-site, third-party (e.g. [v]endor or third party biller) to store records if they could be retrieved quickly?
- A. It is not permissible to use an off-site third party to store **current patient** records even if they could be retrieved quickly. **However, archived records can be stored off-site. Suppliers' archiving policies should, at a minimum, conform to existing state, federal or accreditation standards.**

IV. CONCLUSION

Overall, AAHomecare is encouraged to see that CMS has considered the practical realities of a DMEPOS supplier's operations and caring for patients in its proposed revisions to the current supplier standards. We support the changes CMS has proposed and request that CMS clarify the issues we highlighted in our questions above.

Thank you for the opportunity to submit these comments. Please feel free to contact me at (703) 535-1894 if you have any questions or I can be of further assistance.

Sincerely,



Walt Gorski
Vice President for Government Relations