



Via Electronic Submission

March 25, 2008

Kerry Weems
Acting 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
<http://www.cms.hhs.gov/eRulemaking>

Re: Medicare Program; Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Enrollment Safeguards; Proposed Rule [CMS-6036-P] RIN 0938-AO90¹

Dear Acting Administrator Weems:

The American Association for Homecare (AAHomecare) submits the following comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed rule establishing additional durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier standards. AAHomecare is the national association representing the interests of DMEPOS suppliers. AAHomecare members include a cross section of manufactures 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 standing as a representative of DMEPOS suppliers, we are uniquely qualified to comment on the proposed rule.

According to the preamble, the proposed rule is one component of a larger strategy to ensure that only legitimate suppliers enter the Medicare program. Other pieces of this strategy include the implementation of a national competitive bidding program, which will reduce the number of suppliers who can furnish DMEPOS to Medicare beneficiaries; the implementation of a requirement that all suppliers obtain a \$65,000 surety bond for each national provider identifier (NPI) number; and revisions to CMS' contract with the National Supplier Clearinghouse (NSC) that require the NSC to conduct more frequent on-site visits. CMS is also conducting enrollment

¹ 73 Fed. Reg. 4503 (January 25, 2008).

demonstrations in Los Angeles and South Florida. The Agency is proposing this rule in the belief that the other initiatives will not eliminate fraud from the program.

Since the first supplier standards were published in 1992, CMS has revised and expanded the standards so that the original seven supplier standards now number 25. Yet, CMS continues to chase fraudulent entities that enter the program. In Florida and California, the Office of Inspector General for the U.S. Department of Health and Human Services (OIG), the NSC, CMS and the U.S. Department of Justice (DOJ) have uncovered so-called DMEPOS suppliers that were not open for business during their posted business hours, had no inventory, or simply did not exist at the location the NSC had on record for the supplier. Presumably, the fraudsters had applied for Medicare billing numbers and passed an on-site inspection as all new suppliers are required to do, calling into question CMS' oversight over the contractors responsible for managing this benefit.

We understand the impulse to address fraud by adding new supplier standards and making the existing ones even more prescriptive than they already are. These efforts, however, are mostly redundant now that CMS requires that all new suppliers be accredited. Moreover, the proposed standards make it difficult for legitimate suppliers to respond to the prevailing business climate while maintaining the quality of their services. As an organization, we support efforts to eliminate fraud from the DMEPOS benefit, but we oppose adopting overly prescriptive standards that have proven to be only modest deterrents to criminals yet create operational inefficiencies for suppliers and can result in less access for beneficiaries.

Instead, CMS should ensure that all new suppliers undergo a rigorous on-site inspection and are accredited before receiving a Medicare billing number. We also encourage CMS to hold its contractors accountable. Finally, we note that many of the changes CMS is proposing are significant and suppliers will need adequate time to organize their businesses to comply. Any of the changes CMS adopts will require an implementation period of at least one year. We discuss these issues in further detail in our comments below.

I. BACKGROUND

A. The First Supplier Standards

Historically, getting paid for DMEPOS was as easy as submitting a bill to a Medicare carrier. Because the Medicare program did not have any DMEPOS supplier standards, suppliers could submit an invoice along with whatever identifying information a carrier requested and be reasonably assured of getting paid. In 1991, in response to concerns about unscrupulous suppliers abusing the program, the Ethics and Treatment of Home Medical Equipment Act of 1991 (H.R. 2534) was introduced with the support of the DMEPOS industry. The bill would have required CMS (then HCFA²) to promulgate certification standards for DMEPOS suppliers and would have granted deemed status for any suppliers accredited by the Joint Commission on the Accreditation of Healthcare Organizations.

² HCFA was the acronym for the Health Care Financing Administration.

The following year, in 1992, CMS issued a rule with the first supplier standards.³ From the outset, supplier stakeholders and the Agency were at odds over the best approach to the standards. The Agency did not fully appreciate suppliers' concerns about potential abuse by unscrupulous entities. In response to a comment suggesting that CMS conduct random site visits, CMS responded as follows:

We believe that self-certification is sufficient for almost all suppliers, especially since a false report to the government could constitute a serious offense. The regional carriers will investigate suppliers with which we experience problems and about which we received complaints.

57 FR 27290 at 27296.

Surprisingly, the new standards did not require suppliers to have a physical service location or meet other basic indicia of an ongoing business such as complying with applicable state licensing requirements, maintaining a commercial general liability insurance policy, or having a dedicated business telephone number. According to CMS, these standards were unnecessary:

We agree that every supplier should have a physical facility and personnel. Since both a street address and an employer identification number or Social Security number will be required for every supplier on the disclosure of ownership form, we do not believe that it is also necessary to make physical facility and personnel a standard.

We do not believe it is necessary to require proof of liability insurance. We do not wish to interfere in the way suppliers conduct their business any more than is absolutely necessary. We also feel that such a provision might prevent some small, local suppliers from providing DMEPOS to Medicare beneficiaries.

57 FR 27290 at 27297.

CMS also dismissed calls for more comprehensive standards requiring on-site inspections and quality and equipment management plans:

³ *Medicare Program; Carrier Jurisdiction for Claims for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues Involving Suppliers, and Criteria and Standards for Evaluating Regional DMEPOS Carriers*; 57 Fed. Reg. 27290 (June 18, 1992). The rule required suppliers to certify that they met the following standards:

In response to orders which it receives, fills those orders from its own inventory or inventory in other companies with which it has contracted to fill those orders or fabricates or fits items for sale from supplies it buys under a contract; Is responsible for delivery of Medicare covered items to Medicare beneficiaries; Maintains and repairs directly or through service a contract with another company, items it has rented to beneficiaries; Honors all warranties expressed or implied under applicable State law; Accepts returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted or sold) from beneficiaries; Answers any question or complaint a beneficiary has about the item or use of the item that was sold or rented to him or her, and refers beneficiaries with Medicare questions to the appropriate carrier; and Discloses consumer information to each beneficiary with whom it does business which consists of the suppliers to which it must conform.

Routine on-site inspections would be extremely expensive. We do not believe they would be relevant to the types of business standards in this regulation.

We do not agree that a supplier quality assessment plan is relevant and should be required, nor do we agree that an equipment management plan is necessary. We believe that acceptance/rejection of such plans would be undue interference in the way suppliers do business.

57 FR 27290 at 27297.

B. The 1994 Social Security Act Amendments

Congress required CMS to correct shortcomings in the standards in 1994. Under the Social Security Act Amendments of 1994, Congress mandated CMS to require that suppliers have a physical service location at an appropriate site, maintain proof of liability insurance, and comply with all state and federal licensure and regulatory requirements in order to receive payment from Medicare.

It is astonishing that the Medicare program did not require suppliers to maintain an appropriate physical service location until January 1, 1996, the effective date of the 1994 amendments.⁴ By that time, there were widespread accounts of fly-by-night operations that billed Medicare fraudulently then vanished.⁵ CMS admitted that 32 out of 36 suppliers in Miami were not legitimate businesses.⁶ Although the NSC had been established and was processing supplier number applications, it did not verify background information or conduct on-site inspections.⁷ CMS tried new initiatives to curtail fraud, including Operation Restore Trust, and, at the urging of legitimate suppliers, finally began a program of on-site inspections.

In the meantime, Congress acted again to require CMS to enhance the supplier standards. With the industry's support, the Balanced Budget Act of 1996 (BBA) included a provision that would have required suppliers to obtain a \$50,000 surety bond to enroll in Medicare. The BBA also mandated CMS to promulgate standards specific to oxygen. Although CMS published a proposed surety bond regulation, CMS did not finalize that rule,⁸ and the Agency never published proposed oxygen standards as required by the BBA. On October 11, 2000, CMS again

⁴ *Medicare Program Additional Supplier Standards*, 60 Fed. Reg. 63440 (December 11, 1995).

⁵ General Accountability Office (GAO), *Medicare Spending, Modern Management Strategies Necessary to Curb Billions in Unnecessary Payments* (GAO/HEHS-92-210, September 1995) ("GAO Report").

⁶ See Chapter 1, *Medicare and Medicaid Fraud and Abuse*, Alice G. Gosfield, citing CMS Clamps Down on DME Suppliers, Requiring Recertification, Surety Bonds, 2 BNA' Health Care Fraud Report 44 (1998).

⁷ GAO Report.

⁸ *Medicare Program Additional Supplier Standards*, 63 Fed. Reg. 2926-01 (Tuesday January 20, 1998). CMS recently published a proposed rule that would require a \$65,000 surety bond for each of a supplier's NPIs. *Medicare Program; Surety Bond Requirement for suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)*, 72 FR 42001(August 1, 2007). AAHomecare submitted comments on the proposed rule on September 28, 2007. We reiterate the point we made in our comments, a surety bond requirement as onerous as the one proposed by CMS should be imposed only on new suppliers who have no track record with the Medicare program.

published new supplier standards in the hopes of creating even higher hurdles to keep out fraudulent “suppliers,” which by then appeared to be firmly entrenched in the program.⁹

C. Quality Standards and Accreditation

With the announcement of the “Wheeler Dealer” initiative in 2003, it became clear that CMS, which had been slow at first to address fraud through the supplier standards, had failed in its subsequent efforts to expand and enforce the standards. Under the Medicare Modernization Act of 2003 (MMA), Congress directed CMS to take a different approach to DMEPOS supplier enrollment. Rather than continuing to focus on shoring-up ineffective business standards, the MMA required CMS to develop quality standards that would be administered through accrediting organizations selected by CMS. In order to receive payment for a Medicare covered item, suppliers must be accredited.

CMS has designated accrediting bodies responsible for surveying and certifying that the supplier meets the DMEPOS quality standards. Surveyors are credentialed individuals with education or experience in the operation of DMEPOS suppliers. Our members report that it takes at least four months to prepare for the accreditation survey. The survey itself is far more comprehensive than an NSC on-site inspection and poses a significant hurdle to anyone whose intent is merely to churn Medicare claims. Accreditation is a giant step towards eliminating the incentives that make the DMEPOS benefit a magnet for fraud.

II. COMMENTS

A. Accredited Suppliers Need Flexibility to Operate Efficiently

Although we see the value in having reasonable supplier standards, we are very concerned that the proposed standards dictate to suppliers how they should manage their businesses. Accredited suppliers must be able to respond to changes in the business climate in order to maintain the quality of their services. This includes the ability to centralize and consolidate functions such as warehousing, customer service, and record retention. Similarly, accredited suppliers should have control over their hours of operation and the status of their workforce to meet the demands of the communities in which they operate. We believe that changes to the standards pertaining to suppliers’ physical service location, contracted services, hours of operation and business telephone are redundant for accredited suppliers inasmuch as the quality standards already include comprehensive business standards. We provide specific comments on the standards below.

1. State Licensure

a) The Proposed Prohibition on Suppliers’ Contractual Arrangements is Contrary to Currently Accepted Business Practices for Medicare Providers and Suppliers

⁹ *Medicare Program: Additional Supplier Standards*, 65 Fed. Reg. 60 366-60 378 (October 11, 2000).

AAHomecare supports the requirement that suppliers comply with all state and local laws and regulations that pertain to their business, including professional licenses and certifications. However, the proposed regulation significantly expands the current standards by requiring suppliers to furnish directly through employees any item or services for which a state requires a license. For example, if a state requires that respiratory therapists set-up oxygen patients, the supplier would be required to furnish that service directly through an employee rather than under arrangements with a subcontractor. It is our understanding that the NSC has tried to impose this requirement on suppliers for several years although there has not been a legal basis for enforcing it.¹⁰ Even the statutory authority that CMS references in support of the proposed rule would not compel such a requirement,¹¹ and CMS has not provided any empirical basis or other evidence to support the need for this standard.

The use of contract personnel is an accepted business practice throughout the health care community. Hospitals, skilled nursing facilities, home health agencies, and pharmacies use contract personnel to meet staffing ratios established by law or regulation. This practice allows for the efficient and timely delivery of quality services to patients and allows health care providers to manage their workforce cost effectively.¹² It is unclear to us why CMS would single-out DMEPOS suppliers to impose such a burdensome operational requirement now that CMS has quality standards and accreditation as tools to deter unscrupulous or shoddy suppliers. While we are aware that CMS has encountered scenarios involving “shell” suppliers that contract with one or two licensed individuals to generate fraudulent billings to Medicare, we believe that accreditation addresses these unacceptable practices through the quality standards, including those on Administration, Financial Management, and Human Resources Management.¹³

CMS has also failed to consider the negative impact that this proposal will have on the cost of and beneficiary access to certain types of DMEPOS, such as home oxygen therapy. Our members include manufacturers of medical gases who assist DMEPOS suppliers with the furnishing of oxygen, oxygen equipment, and oxygen supplies to their patients. Beneficiaries

¹⁰ In February of 2006, in response to a Paperwork Reduction Act review of the CMS-855S form, AAHomecare submitted comments on proposed changes to the form that required suppliers to furnish directly, through W-2 employees, professional services requiring state licensure.

¹¹ CMS provides the following statutory bases: (i) Sections 1102 and 1871 of the Social Security Act (the “Act”); (ii) Sections 1814(a), 1815(a) and 1833(e) of the Act;¹¹ (iii) Section 1834(j)(1)(A) of the Act; (iv) Section 1842(r) of the Act; (v) Section 1862(e)(1) of the Act; (vi) Section 4313 of the Balanced Budget Act of 1997; (vii) Section 31001(i)(1) of the Debt Collection Improvement Act of 1996; and Section 936(j)(1)(A) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

¹² Hospitals contract with physicians and other licensed professionals to provide licensed services as hospital services “under arrangements.” See 42 C.F.R. §§ 409.10, 412.50, 413.106, & 411.354; Medical Benefits Manual 30.1, 230.6. Similarly, skilled nursing facilities may furnish services “under arrangements.” See 42 C.F.R. §483.75. In these instances the Medicare program does not dictate to providers how they must organize their businesses, but holds them accountable for the services furnished under arrangements with contractors.

¹³ The Joint Commission on the Accreditation of Healthcare Organizations explicitly recognizes contracting for licensed services when the supplier complies with state licensing requirements and remains responsible for the services provided by the contractor. Joint Commission standards require that a supplier to have a written agreement for subcontracted services and that its leadership staff approve of the sources for the contracted services. Suppliers remain responsible for the quality of the services furnished under contract and must evaluate the subcontracted services to ensure that the level of quality meets its standards, *See* Joint Commission Standard LD 1.30.

who do not have access to DMEPOS suppliers in their community may have access to oxygen when suppliers subcontract with oxygen manufacturers to furnish these services. The proposed standard would increase the staffing costs of furnishing oxygen to these patients and create unnecessary hurdles to access for these services even when state laws or regulations would permit the supplier to furnish oxygen under contractual arrangements.¹⁴

b) The Proposed Standard Would Limit Suppliers' Ability to Subcontract Services under Competitive Bidding

The regulations governing implementation of the national competitive bidding program for DMEPOS explicitly allow suppliers to engage subcontractors to furnish DMEPOS products and services. Suppliers who submit bids must agree to provide every product included within a product category subject to bidding. This means that a supplier that bids on the oxygen product category must be able to furnish every modality of oxygen and each of the oxygen equipment technologies identified in the request for bids (RFB). Likewise, winning bidders must agree to service every beneficiary within a competitive bidding area. Because not all suppliers may currently be capable of meeting one or both of these requirements, CMS has explicitly permitted them to subcontract services subject to competitive bidding.

As with other services furnished “under arrangements” and recognized by CMS, the subcontractor has no recourse against the Medicare program or beneficiaries; it must look solely to the winning bidder for compensation for its services. The Medicare program precludes all enrolled suppliers and providers from contracting with excluded entities. Consequently, bidders may not contract with any individual or entity excluded from a federal health care program. Beyond imposing this requirement, CMS will not regulate the contractual arrangement. CMS looks solely to the winning bidder who will be responsible for the quality of the subcontractor’s services.¹⁵ These provisions implicitly recognize that the requirement for suppliers to meet

¹⁴ For example, the Florida Medicaid program explicitly permits suppliers to contract with a respiratory therapist (RRT) to furnish oversight of patients requiring oxygen. Specifically, a supplier must furnish these services through an employed practitioner or registered nurse (RN) or under arrangements with such a professional, provided the contract meets the following standards:

To be considered a valid contract between a durable medical equipment/medical supply services provider and a CRTT, RRT, or RN to provide oxygen services for the purposes of the Medicaid program, the contract must meet the following criteria:

- be a written document;
- be dated;
- be signed by both parties;
- specify the term of contract;
- specify the amount of consideration (payment) that will be paid to the contractor by the DME company;
- state that consideration paid to the contractor is the sole responsibility of the contracting parties;
- specify that the CRTT, RRT, or RN will provide services and meet all requirements of this section in this handbook; and
- be accompanied by evidence of current professional licensure of the CRTT, RRT, or RN who will be providing oxygen services.

Chapter 2, Florida Medicaid DME/Medical Supply Services Coverage and Limitations Handbook.

¹⁵ The preamble to the final rule states:

eligibility criteria (which include Medicare enrollment and accreditation) adequately protects the program when suppliers furnish services under this arrangement.

CMS's decision to permit winning bidders to subcontract services is also consistent with current supplier standards 4 and 12, which permit suppliers to contract with another company for inventory necessary to fill orders and for delivery of items to Medicare beneficiaries, respectively. Although CMS is proposing to revise standard 12 to clarify that a supplier is solely responsible for meeting the standard, the preamble states that suppliers may continue to subcontract these services but will be held accountable for ensuring that they are carried out properly, just as program rules would require for all services furnished under a contractual arrangement.

The proposed revisions to standard 1, however, would restrict suppliers from subcontracting any services that require a state licensure, even when state law would otherwise permit the supplier to furnish the service under arrangement with another individual or entity. This requirement will no doubt limit the ability of some suppliers to participate in competitive bidding. This is especially true with respect to the oxygen product category inasmuch as many suppliers currently outsource the furnishing of some oxygen modalities and oxygen equipment. We do not believe that this is an outcome that CMS intends. Consequently, we request that CMS eliminate proposed revisions to standard 1.

2. Physical Service Location

a) Physical Service Location

AAHomecare agrees that all suppliers must maintain a physical service location on an appropriate site, but the Association believes that CMS should not dictate how suppliers manage their business functions. CMS must consider the many ways in which legitimate, accredited suppliers have organized their operations and permit flexibility in the standards to accommodate those business needs. These include the need to consolidate and centralize functions such as customer service and intake, record retention, billing, warehousing and distribution functions. For example a supplier could establish small service locations that may not be fully functioning facilities, but are supported by centralized distribution centers and customer service centers. Beneficiaries may walk up to the service location, but beneficiary calls are directed to a call center.

At the same time, facilities that are not open to beneficiaries such as closed pharmacies should not be required to be "accessible to beneficiaries" inasmuch as, by definition, these are not service locations intended for beneficiary access. Similarly, facilities that function solely as centralized call centers, warehouses or distribution centers should not be required to obtain

We will not evaluate subcontractors to determine if they meet the accreditation, quality, financial, and eligibility standards because a subcontractor to a contract supplier cannot itself be a contract supplier and cannot submit claims under the Medicare DMEPOS Competitive Bidding Program.

supplier numbers. We also counsel CMS not to impose specific requirements for facility size because facility size will depend on the product lines and other business needs of the supplier.

b) Posted Hours of Operation

We suggest that CMS eliminate the proposed requirement that suppliers update the NSC when they change their hours of operation. It is sufficient to require suppliers to post their hours of operation. The NSC has a large backlog of applications and already has a hard time keeping up with other, more important, changes of information.

c) Signage

It should be sufficient if the supplier's business signage complies with any applicable zoning requirements, which may limit the sign's size or location. Additionally, if an on-site inspector determines that a supplier is not in compliance with standard 7 because of its signage, the supplier should have an opportunity to correct the problem before its supplier number is revoked, assuming the supplier's physical service location is otherwise adequate.

3. Business Telephone

Proposed standard 9 would prohibit exclusive use of call forwarding to cell phone numbers, answering services, or faxes. We do not interpret this standard to preclude the use of centralized call centers as we described above and request that CMS explicitly clarify this. Suppliers that organize their business in this fashion typically have calls to local branches forwarded to a customer service center that has access to all relevant beneficiary records. This standard also poses problems for very small suppliers who may not have call centers and must rely on call forwarding when staff must be away from the service location. The current standards allow suppliers to use call forwarding and voicemail or answering services, but they do not permit exclusive use of such modes of communication. This at least gives smaller suppliers some flexibility to respond to the demands of their businesses while maintaining compliance with the standards.

Regardless of the size the company, suppliers also need the ability to respond to emergencies that affect their telephone systems. For example, if a phone cable is down, suppliers may be forced to route calls to cell phones or other facilities. Accredited suppliers must have emergency preparedness plans, and in the case of power failures or similar situations, alternative means of routing calls are part of the contingency plans that suppliers follow.

It also would be appropriate for CMS to give suppliers an opportunity to demonstrate that they maintain a primary business telephone consistent with the standard. We are aware of instances where, because of a telephone company omission, the supplier number does not appear in a public directory. In these situations, the supplier should be able to produce an invoice from the telephone company to demonstrate compliance with the standard, assuming the supplier otherwise meets Medicare enrollment standards.

4. Prohibition on Sharing a Practice Location with Another Supplier

Proposed supplier standard 29 would prohibit a supplier from sharing a practice location with another supplier. The scope of this prohibition is unclear when the proposed regulation is read together with the preamble. Language in the preamble calls into question the widespread practice of maintaining DMEPOS consignment closets with physicians and other health care providers. This practice serves to facilitate access to medical equipment for patients who may have an immediate need for an item in order to safely transition from one health care setting to the home. The OIG has considered this practice in the past and concluded that it does not present a risk under the anti-kickback regulations as long as no remuneration flows between the supplier and the other health care provider sharing a practice location.¹⁶

The practice of maintaining consignment closets does not constitute “sharing a practice location” or “co-mingling of inventory” inasmuch as the supplier must comply with supplier standard 7 requiring that it maintain a physical service location at an appropriate site. The DMEPOS items in the consignment closet with a health care provider continue to be the supplier’s inventory, but the items are available for patients who have an immediate need for DMEPOS such as oxygen or a wheelchair to safely transition from one care setting to the home. The supplier remains responsible for complying with all the supplier standards, including the requirement to document that the beneficiary received the item and ensuring that the beneficiary receives proper instruction on the use of the item.

Some suppliers may offer multiple product lines organized as separate businesses. While the businesses may have separate physical addresses, they might share warehouse facilities and other business functions with each other. Again, we believe that overly prescriptive standards that dictate a supplier’s business structure are unnecessary now that all new suppliers must be accredited in order to enroll in the program.

CMS must also consider that suppliers have organized their operations to meet the standards currently in effect. If CMS imposes changes that require suppliers to acquire new space for their physical service locations, it must allow sufficient time for an orderly transition. Note that some suppliers will also have to terminate current lease agreements in order to acquire the new space. All of the changes proposed to this standard will be costly for suppliers to implement. Some may choose to convert their physical service locations to warehouse facilities; others may close the locations all together.

5. Minimum Hours of Operation

Consistent with our comments above, we urge CMS to reconsider standard 30 which would require suppliers to remain open a minimum of 30 hours a week. It is a widespread practice among all suppliers – both large and small – to have part-time hours for some locations. The impact of staffing costs for these small locations will be significant, and many suppliers will opt to close these branches. Importantly, suppliers establish small locations with very limited staff and part-time hours in mostly rural communities where a larger branch may be too far away to

¹⁶ OIG Advisory Opinion, 02-4 (April 26, 2002). The OIG stated that a DMEPOS supplier could place portable oxygen in a hospital for the use of patients being discharged to the home.

sustain frequent deliveries to the area. Suppliers may also furnish services “by appointment,” as a means of accommodating their patients who may desire scheduling outside of normal business hours.

We urge CMS to move away from an outdated retail model of DMEPOS suppliers. Suppliers are accredited health care entities that comprise an important component of the continuum of care. The services and therapies that can be safely furnished in the home are increasingly sophisticated, requiring an array of credentialed and professional staff. Accredited suppliers should have flexibility to operate on schedules that meet their business needs and the needs of their communities. Without the opportunity to operate part-time service locations, suppliers will close these facilities, reducing access for beneficiaries. We understand CMS’ concern about suppliers that post unduly restrictive hours of operation, but reiterate that prescriptive standards such as this one are unnecessary for accredited suppliers.

Finally, we note that many of these part-time locations have very limited staff. There may be times when the location is unattended because the lone employee is making a delivery. Currently, in case the NSC arrives for a site visit, suppliers post the time they would return and the NSC comes back to perform the site visit at that time. We recommend that CMS continue to allow this practice.

B. Prohibition on Unsolicited Telephone Contact of Beneficiaries

The proposed revisions to standard 11 significantly expand on the existing prohibition on suppliers’ unsolicited telephone contacts with beneficiaries.¹⁷ Although CMS characterizes proposed standard 11 as a “clarification” of the current standard, the proposed revision is so broad that it would preclude necessary communication between suppliers and beneficiaries and limit suppliers’ lawful advertising and marketing activities. Under proposed standard 11, a DMEPOS supplier “may *only* contact a beneficiary when supplying a Medicare covered item and *only when one or more of the following applies*:

- (i) The individual has given written permission to the supplier to contact them concerning the furnishing of a Medicare-covered item that is to be rented or purchased;
- (ii) The supplier has furnished a Medicare-covered item and the supplier is contacting the individual to coordinate delivery of the item;
- (iii) If the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.”

A literal interpretation of the proposed rule would prohibit a supplier from contacting a beneficiary to arrange for delivery of an item of DME pursuant to a physician’s verbal or written order unless one of the exceptions in the proposed rule applied. This places the supplier in a “chicken or the egg” dilemma because a permissible contact under the standard assumes that the

¹⁷ 42 C.F.R. § 424.57(c)(11).

supplier “*has furnished*” a covered item to the beneficiary before the contact takes place. The proposed rule also would prohibit email, internet, or in-person contacts between suppliers and beneficiaries if the supplier has not furnished a covered item to the beneficiary within the preceding 15 months unless the beneficiary has given written permission for the contact. As long as suppliers are engaging in otherwise lawful promotional activities, these limitations exceed CMS’ authority under the statute and impede beneficiaries’ right to learn about the products and services that may be available to address their health concerns.

1. CMS Must Allow Necessary Communication Between Suppliers and Beneficiaries

When Congress enacted the prohibition on unsolicited telemarketing,¹⁸ 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.

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

In contrast, longstanding Medicare policy recognizes and permits suppliers to dispense DMEPOS in response to a physician’s verbal order for the item.¹⁹ Typically, the physician communicates the order directly to the supplier 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

¹⁸See 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.

¹⁹ Chapter 5, Medicare Program Integrity Manual (PIM), 100-8, available at: <http://www.cms.hhs.gov>.

the physician's signature and date.²⁰ The communication between the supplier and the physician's office ensures that the order is accurately conveyed to the supplier and promotes the timely delivery of services consistent with the beneficiary's medical need.

The beneficiary, however, retains the right to request that the physician contact a different supplier or to designate a supplier of his choosing. Importantly, the verbal order is given *after* the physician has determined that a beneficiary has a medical need for the item. Moreover, for the vast majority of DME items, suppliers deliver the item to the beneficiary based on the written confirmation of the verbal order alone. Because suppliers 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.²¹

With the exception of a handful of specific items that require a written order prior to delivery to the beneficiary, CMS policy has recognized the value in permitting suppliers to begin servicing beneficiaries based on the physician's verbal order. Otherwise, beneficiaries in need of life-sustaining medical equipment such as oxygen would be required to wait for the equipment until the supplier receives a written order from the physician.²²

In the preamble to the final supplier standards published on October 11, 2000, CMS addressed whether it was permissible for suppliers to contact beneficiaries based on a *referral* by a physician. CMS specifically did *not* address the issue that concerns us here: that suppliers must communicate directly with a beneficiary to effectuate an order placed by his or her physician. The preamble to the October 11, 2000, final rule for DMEPOS supplier standards stated:²³

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.

65 Fed. Reg. at 60372.

We hope that CMS draws an appropriate distinction between physician "orders" and physician "referrals," which includes orders but may also include a broader range of physician requests. Our goal is to ensure that suppliers can initiate telephone or in-person communication with a beneficiary (as would be the case when DME is delivered to a hospital) in response to the physician's verbal or written order for DME. In summary, when a supplier contacts a beneficiary

²⁰ *Id.*

²¹ *Id.* OIG Compliance Guidance for DMEPOS Suppliers, 64 Fed. Reg. 36368 (June 6, 1999).

²² 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 PMDs. *See* Medicare Program; Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles; 71 Fed. Reg. 17021 (April 5, 2006).

²³ 65 Fed. Reg. at 60372.

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 because 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 supplier and beneficiary once a physician has determined that a beneficiary requires an item of DME, and we do not believe that CMS intends to do so either. Consequently, we request that CMS revise this standard to explicitly permit communication between a supplier and beneficiary to effectuate a physician's order for DMEPOS.

2. CMS Cannot Restrict Otherwise Lawful Advertising and Promotional Activities

Further, the telemarketing prohibition passed by Congress does not prohibit in-person contacts between suppliers and beneficiaries. CMS exceeds its authority by prohibiting such contacts under proposed standard 11.²⁴ The new regulation would curtail otherwise beneficial communication between beneficiaries and the supplier community.²⁵ Under proposed standard 11, suppliers would risk losing their supplier number by participating in community health fairs, education programs targeting beneficiaries, and other public interest activities that may be sponsored by or held in support of patient advocacy groups. We recommend that CMS eliminate the prohibition of in-person contacts under standard 11.

CMS must also clearly state what it means by "coercive response" internet advertising. We have been unable to find a definition for that term in our research. We agree that suppliers should comply with applicable laws governing internet communication such as those that prohibit spam email, but we disagree that CMS can prohibit suppliers from engaging in otherwise lawful internet advertising.²⁶ Importantly, we are hampered in our ability to comment on this issue because we do not understand what conduct CMS intends to preclude when it refers to "coercive response" internet advertising. We recommend that CMS specify the conduct it intends to prohibit under this standard and allow the public an opportunity to submit additional comments on this issue.

²⁴ Unlike the FDA which has explicit statutory authority to regulate advertising for products it regulates, *see, e.g. Pennsylvania Employees Benefit Trust Fund v. Zeneca, INC*, 499 F. 3d 239 (3rd Cir. 2007), Congress has not explicitly authorized CMS to regulate suppliers' promotional activities other than the authority under the telemarketing prohibition in § 1395m (a) (17).

²⁵ Even assuming, without conceding, that CMS has authority to regulate this type of commercial speech, the prohibition on suppliers' promotional activities under standard 11 is too broad and interferes not only with suppliers' right to engage in commercial speech, but also with beneficiaries' "right to know" about products and services available from DMEPOS suppliers. *Thompson v. Western States Medical Center, Et. Al.*, 535 U. S.357 (2002), (holding that restrictions on soliciting prescriptions for and advertising compounded drugs under the Food and Drug Modernization Act of 1997 (FDMA), amounted to unconstitutional restrictions on commercial speech).

²⁶ Limits on internet advertising were addressed by Congress in 2003 under the CAN-SPAM Act (Controlling the Assault of Non-Solicited Pornography and Marketing Act), Pub. L. 108-187, codified at 15 U.S.C. §§ 7701 *et. seq.* The Act establishes requirements for those who send commercial email, spells out penalties for spammers and companies whose products are advertised in spam if they violate the law, and gives consumers the right to ask e-mailers to stop spamming them. The law, which became effective January 1, 2004, covers email whose primary purpose is advertising or promoting a commercial product or service, including content on a Web site. The Federal Trade Commission (FTC) and the Federal Communications Commission (FCC) have been tasked by Congress to oversee these forms of advertising.

C. Other Standards

1. Delivery of Items to the Beneficiary

Our interpretation of this standard based on language in the preamble is that CMS will continue to allow subcontracting for delivery. Please confirm that our understanding is correct. We request that the standard state this explicitly.

2. Tax Delinquencies

We agree that suppliers should not have outstanding tax delinquencies, but the Association requests that CMS expand on this standard to permit suppliers to demonstrate that they are current on their tax obligations in the event that the jurisdiction has mistakenly reported a delinquency. Suppliers should also be permitted to pay any outstanding amounts before their supplier number is revoked.

3. Retention of Documentation

We believe that most reputable suppliers already have comprehensive document retention policies for medical necessity information, including physician orders. We recommend that CMS revise this standard to require that suppliers retain the documentation from the date of service, not the date that the claim was paid.

4. Liability Insurance

CMS proposes clarifications to standard 10, requiring suppliers to obtain and maintain “comprehensive liability insurance.” We believe that the terminology, “comprehensive liability policy” is an outdated term and should be replaced with “Commercial General Liability Insurance” policy, consistent with current terminology in the insurance industry. Our suggestion is that CMS replace the phrase “Comprehensive Liability” with “Commercial General Liability” for additional clarity.

In addition, we believe that the reference to the term “incident” would be more accurately defined as “occurrence.” We assume that the intent of the revised language is to ensure that the insurance policy covers claims made by the customer against the supplier and its employees, and not that the policy covers the actual customer. Please confirm our understanding of this aspect. Consequently, we suggest that you adopt the following language for accuracy and clarity:

We are proposing to revise this provision to specify that the DMEPOS supplier has a Commercial General Liability insurance policy in the amount of at least \$300,000 per occurrence that covers both the supplier's place of business and employees of the supplier against claims made by the customer and ensures that insurance policy must remain in force at all times.

Further, while we appreciate the intent to allow self-insurance, we are confused about the statement that “this would not preclude the use of self-insurance to demonstrate compliance with

the comprehensive liability insurance policy as long as CMS or the NSC can verify the policy and its coverage provisions with an independent underwriter.” A self-insured entity would not have involvement from an independent underwriter. Inasmuch as self-insured companies are likely to be among the larger suppliers, we recommend that CMS or the NSC should consider a requirement that the supplier demonstrates that the business is financially viable. The provision of audited financial statements, such as a 10K or 10Q establishing the net worth of the supplier is at \$300,000 or greater, may be sufficient. Certainly, it should not be multiples of that number.

III. CONCLUSION

AAHomecare sincerely appreciates the opportunity to submit these comments. As we have stated many times in the past, we support efforts to rid the Medicare program of fraudsters that pose as DMEPOS suppliers. In the process, however, CMS should consider the needs of legitimate suppliers for flexibility in organizing their businesses. Accredited suppliers need freedom to utilize advances in technology in order to increase efficiencies in their operations. CMS should be cautious about adopting standards that limit business innovation and instead allow accredited suppliers the ability to respond to changes in the business climate.

With this in mind, we urge CMS to require all new suppliers to undergo a rigorous on-site inspection and fully implement accreditation before making changes to the standards. In particular, we urge CMS to eliminate the prohibition on subcontracting services under standard 1 and to clarify proposed standard 11 to explicitly permit communication between suppliers and beneficiaries to initiate services ordered by a physician and to allow suppliers to engage in otherwise lawful promotional activities, including those that involve in-person, internet, and email communications. Likewise, we urge CMS to not impose minimum hours of operation on suppliers, and request that you revise the other standards consistent with our comments above. Finally, to the extent CMS makes any changes to the standards, we strongly recommend a transition period of at least one year to allow suppliers adequate time to come into compliance with the new requirements.

AAHomecare is available at your convenience to discuss these issues with you in greater detail. Please feel free to contact AAHomecare’s Walt Gorski at (703) 535-1894 if you have any questions.

Sincerely,

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

Tyler Wilson
President
American Association for Homecare