Tighter Enrollment Standards for Medical Equipment Suppliers

Details about the New Regulations and Their Implications

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On August 27, 2010, the Centers for Medicare & Medicaid Services (CMS) issued a final rule outlining a new regulation enhancing Medicare enrollment standards for suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The regulation adds several new standards and makes more stringent existing standards that suppliers must meet before being able to furnish equipment and supplies to Medicare beneficiaries. These rules may have applications for a number of DMEPOS providers and provider types. For example, they could impact operations of independent suppliers or suppliers located in larger facilities such as hospitals. In a CMS press release it was noted that these new standards are intended to “reduce fraud in Medicare and provide beneficiaries with additional assurance that they are being served by legitimate suppliers who meet Medicare’s standards.”

Further, on August 26, 2010, in a series of day-long summits, U. S. Department of Health and Human Services (HHS) Secretary Kathleen Sebelius and Attorney General Eric Holder held a summit in Las Vegas bringing together various stakeholders and interested parties to discuss ways to eliminate fraud within the U.S. health care system. In commenting on the new DMEPOS regulations, Secretary Sebelius noted that these tools support “continuing efforts to reduce Medicare fraud by helping ensure that only appropriately qualified suppliers are enrolled in the program.”

Key facts about DMEPOS include the following:

- In fiscal year (FY) 2007, the Medicare program spent more than $10 billion for DMEPOS supplies.
- In March 2008, there were 113,154 individual DMEPOS suppliers, but due to affiliations of some DMEPOS with chains, there were 65,984 unique billing numbers.
It was noted that approximately 20 percent of DMEPOS suppliers are located in rural areas and that the vast majority of them are small entities, based on Medicare reimbursement data only.

The largest concentrations of DMEPOS suppliers were located in five states (percentages are approximations): California (9 percent); Texas (7 percent); Florida (7 percent); New York (6 percent); and Pennsylvania (5 percent).

The intended objective of the regulatory additions and revisions to the DMEPOS supplier enrollment standards is to help ensure that only “qualified and legitimate” DMEPOS suppliers participate in Medicare. “All suppliers for these items, including those DMEPOS items prescribed by the beneficiary’s physician, from simple canes and walkers to complex power wheelchairs, oxygen supplies and equipment, and hospital beds now must meet these new standards.”

The following article outlines the new provisions of this final rule, which are included in the standards below.

**Obtaining Oxygen**

DMEPOS suppliers are now required to obtain oxygen from a state-licensed oxygen supplier (applicable only to those suppliers in states that require oxygen licensure).

**Ordering and Referring Documentation**

Ensure that DMEPOS continue, as they are required, to maintain ordering and referring documentation from physicians or non-physician practitioners. Here, the supplier must maintain such information, including the national provider identifier, received from a physician, nurse practitioner, physician assistant, clinical social worker, or certified nurse midwife, for seven years after the date of service. Such information should be maintained to assure DMEPOS suppliers that coverage criterion for an item has been met.

If the information in the patient's medical record does not adequately support the medical necessity requirement, then the supplier is liable for the dollar amount involved (unless a properly executed advance beneficiary notice of possible denial has been obtained). This particular provision may be critical to some DMEPOS suppliers and their current operations. This may require a review of existing operations to ensure that all necessary documentation is maintained in relation to an order.

**Prohibition on Sharing of a Practice Location**

DMEPOS suppliers are prohibited from sharing a practice location with any other Medicare supplier or provider. This prohibition is not applicable at a practice location that meets one of the following exceptions:

- where certain physician or non-physician practitioner furnishes items to his or her own patient as part of his or her professional service;
- where a physical or occupational therapist furnishes items to his or her own patient as part of his or her professional service; and
- where a DMEPOS supplier is co-located with and owned by an enrolled Medicare provider; the DMEPOS supplier must (1) operate as a separate unit; and (2) meet all other DMEPOS supplier standards.

A number of commenters raised concerns with regard to this exception when both businesses are owned by the same person or entity or the DME supplier is a separate unit located within or owned by a larger health care facility or hospital. CMS disagreed with commenters who stated that this exception should be culled around the basis of ownership alone.

Therefore, we have established exceptions to the sharing of space limitation found in § 424.57(c)(29). In § 424.57(c)(29)(ii)(C), we have established an exception for DMEPOS suppliers that have a practice location within a Medicare provider that is subject to the requirements specified in 42 CFR 489.2(b). This ex-
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ception will allow a hospital, home health agency (HHA), skilled-nursing facility (SNF), or other Part A provider that is enrolled in Medicare to co-locate with a DMEPOS supplier that is owned by that Part A provider and is a separate unit. It is important to note that these DMEPOS suppliers while owned by the Part A provider must still meet all of the other DMEPOS supplier standards in § 424.57 to obtain and maintain Medicare billing privileges.\textsuperscript{16}

Thus, DMEPOS suppliers may be enrolled within the same building owned by a hospital.\textsuperscript{17} A review, however, should be conducted to ensure that the DMEPOS supplier meets all applicable requirements.

**HOURS OF OPERATION**\textsuperscript{18}

DMEPOS suppliers must remain open to the public for at least 30 hours a week, with exceptions for physicians or licensed non-physician practitioners furnishing services to their own patient(s) as part of their professional service, and DMEPOS suppliers working with custom made orthotics and prosthetics. This provision is not applicable at a practice location where:

- certain physician\textsuperscript{19} furnishes items to his or her own patient(s) as part of his or her professional service;
- certain licensed non-physician practitioner\textsuperscript{20} furnishes items to his or her own patient(s) as part of his or her professional service; or
- DMEPOS supplier is working with custom made orthotics and prosthetics.

**MEDICARE OVERPAYMENT**\textsuperscript{21}

Previously, CMS had proposed to redesignate the current text of 42 CFR § 424.57(d) as paragraph (d)(1) and proposed adding a new paragraph that specified that “CMS, the NSC, or CMS designated contractor establishes a Medicare overpayment from the date of an adverse legal action or felony conviction (including felony convictions within the 10 years preceding enrollment or revalidation of enrollment) that precludes payment.”\textsuperscript{22}

Further, CMS proposed that any overpayment assessed by CMS or its designated contractor due to a failure to report this information would follow the existing rules governing Medicare overpayments.\textsuperscript{23} In response to a commenter stating that the term “adverse legal action”\textsuperscript{24} was vague, CMS added the definition for the term “final adverse action” to mean one or more of the following actions:

- a Medicare-imposed revocation of any Medicare billing privileges;
- suspension or revocation of a license to provide health care by any state licensing authority;
- revocation for failure to meet DMEPOS quality standards;
- a conviction of a federal or state felony offense\textsuperscript{25} within the last 10 years preceding enrollment, revalidation, or re-enrollment; and
- an exclusion or debarment from participation in a federal or state health care program.

CMS notes that if it is found that a supplier does not meet the applicable standard, then CMS can revoke a supplier’s billing privileges. Generally, the revocation is effective 30 days after the entity is sent notice of the revocation. Further, CMS or a CMS contractor may reopen all Medicare claims paid on or after the date of a final adverse action to establish an overpayment determination.\textsuperscript{26}

The final rule also clarified and expanded existing DMEPOS supplier enrollment requirements to establish and maintain billing privileges in the Medicare program. The following is a brief outline of revised current supplier standards.\textsuperscript{27}

**Licensure Requirements**\textsuperscript{28}

Under the new DMEPOS supplier requirements, new application certification standards must be met. The supplier must meet and certify in its application for billing privileges that it meets and will continue to meet certain standards. Specifically, that it will operate its business and furnish...
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Medicare-covered items in compliance with the following applicable laws:

- federal regulatory requirements that specify requirements for the provision of DMEPOS and ensure accessibility for the disabled;
- local zoning requirements; and
- state licensure and regulatory requirements; if a state requires licensure to furnish certain items or services, a DMEPOS supplier:
  - must be licensed to provide the item or service;
  - must employ the licensed professional on a full-time or part-time basis, except for DMEPOS suppliers who are (1) awarded competitive bid contracts using subcontractors to meet this standard; or (2) allowed by the state to contract licensed services; and
  - must not contract with an individual or other entity to provide the licensed services, unless allowed by the state where the licensed services are being performed.

In issuing the final rule, CMS added to the above noted language to clarify that DMEPOS must be licensed suppliers to provide licensed services. CMS specifically noted, “We believe that we are enrolling DMEPOS suppliers, not third party agents that subcontract their operations to suppliers that are not enrolled or cannot enroll in the Medicare program. Therefore, to ensure that only qualified suppliers are enrolled or maintain enrollment in the Medicare program, we maintain that a DMEPOS supplier must be licensed to provide licensed service(s) and cannot contract with an individual or entity to provide the licensed service(s).” It should be noted that contracting out licensed services and the W-2 employee provisions of this standard only apply when not addressed by state licensing requirements. CMS noted that “DMEPOS suppliers must meet all applicable State licensing requirements and that this standard will only apply when not addressed by State licensing requirements.”

Further, CMS responded to various comments. One commenter noted that the licensure requirement changes would result in “different Federal requirements for hospital-based DMEPOS suppliers based solely on the location of the supplier and further disadvantage hospitals because hospitals generally use independent contract to perform its services.” CMS responded that all DMEPOS suppliers — even those based at hospitals or operated by other providers — must meet state licensing requirements for the services they provide. “This change will enable CMS to verify that the supplier is meeting the applicable State licensing requirements for the services that it furnishes.”

**Physical Facility — Appropriate Site**

The DMEPOS must comply with a number of applicable physical facility requirements on an appropriate site. A DMEPOS must maintain a physical facility on an appropriate site that must meet all outlined standards. An appropriate site must meet existing criteria in addition to the new standards, which include the following:

- Except for state-licensed orthotic and prosthetic personnel providing custom fabricated orthotics or prosthetics in private practice, the site maintains a practice location that is at least 200 square feet beginning (1) September 27, 2010, for a prospective DMEPOS supplier; (2) the first day after termination of an expiring lease for an existing DMEPOS supplier with a lease that expires on or after September 27, 2010, and before September 27, 2013; or (3) September 27, 2013, for an existing DMEPOS supplier with a lease that expires on or after September 27, 2013.

- The site is in a location that is accessible to the public, Medicare beneficiaries, CMS, NSC, and its agents. (The location must not be in a gated community or other area where access is restricted.)

- The site is accessible and staffed during posted hours of operation.

- The site maintains a permanent visible sign in plain view and posts hours of operation. If the supplier’s place of business is located within a building com-
plex, the sign must be visible at the main entrance of the building, or hours can be posted at the entrance of the supplier.38

Except for business records that are stored in centralized locations, the site is in a location that contains space for storing business records (including the supplier's delivery, maintenance, and beneficiary communication records).39

The site is in a location that contains space for retaining the necessary ordering and referring documentation.40 This location may be the centralized location for all of the business records and the ordering and referring documentation of a multisite supplier. It may be a “closed door” business, such as a pharmacy or supplier providing services only to beneficiaries residing in a nursing home, that complies with all applicable federal, state, and local laws and regulations (which still must comply with all applicable requirements).41

CMS noted that the purpose and objective of establishing a minimum square footage requirement is necessary to avoid situations that have occurred in the past. Specifically, those DMEPOS suppliers that do not have a minimum square footage requirement have been determined to be fraudulent suppliers or have provided less than sufficient services to Medicare beneficiaries. In response to many concerns, CMS decided to establish the 200-square foot requirement rather than 500-square feet, which was determined to impose undue burden for some suppliers. Accordingly, CMS adopted the 200-square foot per practice location requirement.42

Further, CMS will establish a three-year phase-in period for those existing suppliers of DMEPOS who have signed leases, including long-term leases, on or before the date of the publication date of the final rule; however, this rule does not apply to suppliers of DMEPOS who have a pending enrollment application with the NSC. It is expected that prospective DMEPOS suppliers comply with this requirement as of the effective date of the regulation.43

DMEPOS suppliers located within larger complexes or hospital facilities should have appropriate information posted about services at the main entrance of the hospital.

On-Site Inspections44

The DMEPOS must permit CMS, the NSC, or their agents to conduct onsite inspections to ascertain supplier compliance with the requirements of this section. CMS clarified in the Federal Register that “it is necessary for all DMEPOS suppliers to be open during posted hours of operations. The revised language only clarifies who is authorized to conduct the onsite visit...[W]e believe that unannounced site visits are necessary to ensure that DMEPOS supplier is continually meeting the supplier standards in Sec. 424.57.” Further, CMS indicated “unannounced on-site visits to be a very effective tool in combating fraud and abuse and to protect the Medicare Trust Fund from unscrupulous suppliers. Moreover, CMS and our designated contractor, the NSC, have conducted unannounced on-site visits since 2000 to ensure compliance with those standards which only can be verified by visual inspection.”45

It also should be noted that if the NSC or its agents are unable to perform a site visit during a supplier's posted business hours, the NSC would deny billing privileges for prospective applicants or would otherwise revoke the billing privileges of the DMEPOS supplier(s) enrolled in the Medicare program.46 One commenter recommended that instead of revoking a supplier's billing privileges when a site visit cannot be conducted, the NSC should suspend billing privileges pending further investigation to determine if the entity is a legitimate supplier. CMS responded by stating that it does not have the statutory or regulatory authority to suspend billing privileges under those circumstances.47

Business Telephone Operations48

DMEPOS suppliers must maintain a primary business telephone that is operational at the appropriate site listed under the name of the business locally or toll-free for beneficiaries.
The revised rules prohibit the use of cellular phones, beepers, or pagers as the primary business telephone.

Calls must not be exclusively forwarded from the primary business telephone listed under the name of the business to a cellular phone, beeper, or pager.

Answering machines, answering services, facsimile machines, or a combination of these options must not be used exclusively as the primary business telephone during posted operating hours.

**Solicitation of Beneficiaries**

Under existing rule, the DMEPOS supplier agrees not to make a direct solicitation of a Medicare beneficiary unless one or more requirements are met.

- The individual has given written permission to the supplier or the ordering physician or non-physician practitioner to contact them concerning the furnishing of a Medicare-covered item that is to be rented or purchased.
- The supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item.
- 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.

The new regulations expand the prohibition on a DMEPOS supplier's telephone solicitation of a Medicare beneficiary to also include in-person contacts, emails, instant messaging, and Internet coercive advertising. The new definition for direct solicitation means direct contact, which includes, but is not limited to, telephone, computer, email, 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.50

One commenter questioned, under the new telephone standard, whether it is considered “cold calling” the beneficiary when the supplier has received a verbal order from a physician—if the supplier contacts a beneficiary via telephone after it has received a verbal order from the beneficiary’s treating physician. In response, CMS noted that it is “inappropriate for a DMEPOS supplier to contact a beneficiary based solely on a physician order.”51

CMS notes that in the described scenario, the contact is without the beneficiary’s knowledge that the physician would be contacting a supplier on the beneficiary’s behalf and would be prohibited unless an applicable provision applied.52 It is appropriate to contact the beneficiary, if a physician contacts the supplier on behalf of the beneficiary with the beneficiary’s knowledge; then that contact would not be considered a direct solicitation (even if the physician has not specified the precise DMEPOS supplier that will be contacting the beneficiary regarding the item referred by that physician).

Therefore, the new rules could have implications for existing DMEPOS suppliers whether small or large and whether managed independently or located within a hospital facility or larger complex. The final rule was published in the Federal Register (75 Fed. Reg. 52629) on August 27, 2010, and relevant information can be found at the following links:

- [www.cms.gov/Medicare/ProviderSupEnroll/09_ProviderEnrollmentRegulation.asp#TopOfPage](http://www.cms.gov/Medicare/ProviderSupEnroll/09_ProviderEnrollmentRegulation.asp#TopOfPage)

**Endnotes:**

1. CMS Press Release, Thursday August 26, 2010, Medicare Imposes Stronger Protections on Medical Equipment Suppliers, [www.cms.gov/apps/media/press/release.asp?Counter=3831&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1,+2,+3,+4,+5&srchPage=&showAll=&pYear=&year=&desc=&docOrder=desc](http://www.cms.gov/apps/media/press/release.asp?Counter=3831&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1,+2,+3,+4,+5&srchPage=&showAll=&pYear=&year=&desc=&docOrder=desc)

2. Department of Justice, Office of Public Affairs, Attorney General Holder and HHS Secretary Sebelius Host Second Regional Health Care Fraud Prevention...
5. 75 Fed. Reg. 52629, 52644. CMS notes that the previously proposed tax delinquency provision as outlined in 42 CFR §424.57(c)(31) will be deferred due to the enactment of Section 189 of the Medicare Improvements for Patients and Providers Act (MIPPA) (Pub.L. 110-275) on July 15, 2008.
6. 42 CFR §424.57(c)(27).
7. 42 CFR §424.57(c)(28).
8. Consistent with the provisions found in 42 CFR §424.516(f).
11. 42 CFR §424.57(c)(29).
12. For purposes of this standard, sharing a practice location refers to sharing of the physical location as described on the CMS-855S; generally the physical space where a DMEPOS supplier operates the business and meets with existing or potential customers. 75 Fed.Reg. 52629, 52641.
13. Where a physician whose services are defined in Section 1848(j)(3) of the Social Security Act (the Act) or a non-physician practitioner, as described in Section 1842(b)(18)(C) of the Act, furnishes items to his or her own patient as part of his or her professional service.
14. Whose services are defined in Sections 1861(p) and 1861(g) of the Act.
15. As described in 42 CFR §489.2(b).
17. 75 Fed. Reg. 52629, 52642.
18. 42 CFR §424.57(c)(30).
19. Whose services are defined in §848(j)(3) of the Act.
20. Whose services are defined in §1861(p) and 1861(g) of the Act.
21. 42 CFR §424.57(a), "Definitions."
23. Set forth at 42 CFR §405.350 et seq. The underlying basis to report "adverse legal actions" to the NSC are found in §424.530 and §424.535, which state the provisions for denial of enrollment and the revocation of billing privileges.
24. 75 Fed.Reg. 52629, 52644. This definition is narrower than the list of final adverse actions contained in Section 3 of the CMS-855S, which was published on March 23, 2009. In fact, we limited the definition of "final adverse action" in this rule to those actions that currently serve as a basis for CMS to revoke a supplier's Medicare billing privileges under 42 CFR §424.535(a). If a final adverse action has been imposed upon a supplier, then that supplier would not be eligible to maintain Medicare billing privileges from the date of a final adverse action. This provision provides CMS or its contractors with the discretion to establish an overpayment determination (as defined in §405.350) for all Medicare items and services furnished from the date of the final adverse action. CMS or our contractors may reopen all claims paid to the supplier on or after the date of the final adverse action that had been imposed upon that supplier. Moreover, suppliers who are assessed overpayments under this provision may appeal these determinations in accordance with the Medicare claims appeal procedures set forth in §405.900 through §405.1140.
26. 42 CFR §424.57(e).
27. It should be noted that proposed changes to various provisions are still under consideration by CMS including 42 CFR §424.57(c)(10) in relation to Comprehensive Liability Insurance; and 42 CFR §424.57(c)(12) in relation to Product Delivery and Beneficiary instructions.
28. 42 CFR §424.57(c)(1).
29. As described in 42 CFR §424.57(c)(1)(ii)(C).
32. 75 Fed.Reg. 52629, 52634.
34. 42 CFR §424.57(c)(7).
35. 42 CFR §424.57(c)(7)(i)(A).
36. 42 CFR §424.57(c)(7)(i)(B).
37. 42 CFR §424.57(c)(7)(i)(C).
38. 42 CFR §424.57(c)(7)(i)(D).
41. 42 CFR §424.57(c)(7)(i)(F).
42. 75 Fed.Reg. 52629, 52635.
43. 75 Fed.Reg. 52629, 52636.
44. 42 CFR §424.57(c)(8).
46. 75 Fed.Reg. 52629, 52631.
47. 75 Fed.Reg. 52629, 52637.
48. 42 CFR §424.57(c)(9).
49. 42 CFR §424.57(c)(11).
50. 42 CFR §424.57(a) Definitions.
52. See 42 CFR §424.57(c)(11)(i)-(iii).