By **DEVON BERNARD**

Dissecting the Standards

Tips for complying with the 30 Supplier Standards

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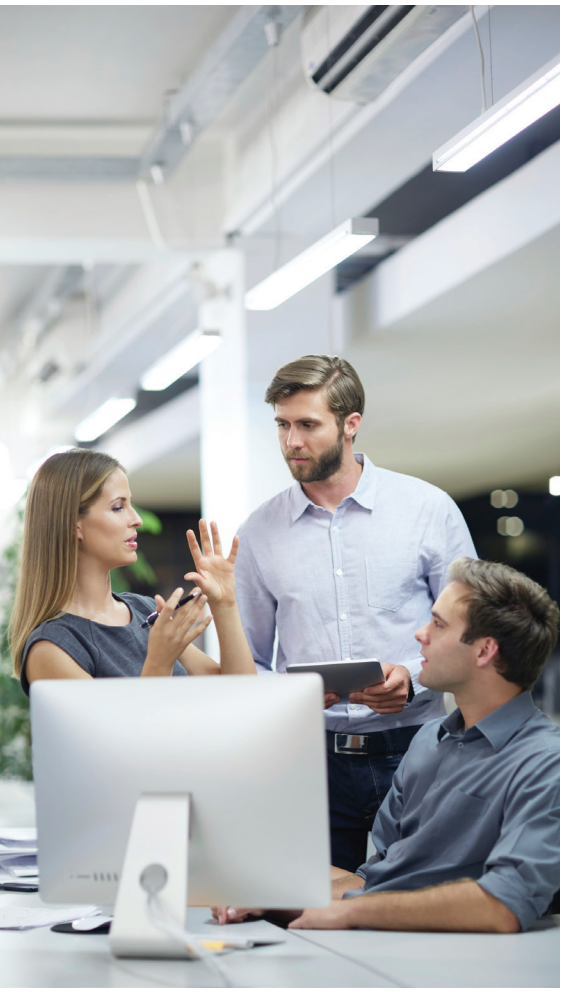


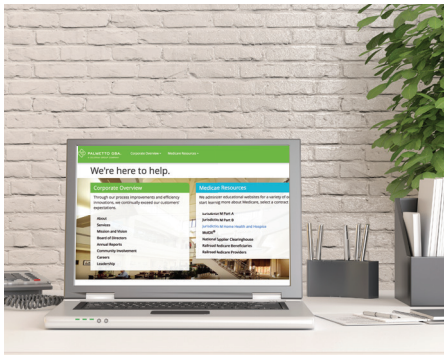
WITH MEDICARE'S REVALIDATION CYCLE 2 in full swing, and with its continued use of the strengthened enrollment screening process—including site visits—for all Medicare, Medicaid, and Children's Health Insurance Plan providers, the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) Supplier Standards are taking on greater significance. Your compliance with the standards is even more important.

This issue's *Compliance Corner* examines the 30 DMEPOS Supplier Standards in detail, and offers tips for understanding each standard and an explanation of how to comply with each one.

STANDARD 01

This standard ensures that you are operating your business in accordance with all applicable federal regulatory, state regulatory, and state licensure requirements. Therefore, you must obtain all of the proper local and state licenses, and make sure you are licensed if you are in a state that requires licensure. If you are unsure what type of licensure your state requires, visit the website of the National Supplier Clearinghouse (NSC), the contractor in charge of enforcing the Supplier Standards, at *www.palmettogba.com*. The database offers information on the licenses you may require as well as the agency in charge of providing the licenses and contact information for each agency. You may want to visit the licensure database and double-check the information to ensure it is accurate. If the database incorrectly lists that you require a specific license, you will want to get the site updated before your site visit, or determine if something has changed and you now require a license.

This standard was updated in 2010 to officially eliminate the use of contracted employees to provide licensed services;



however, the standard does have some wiggle room. CMS and NSC have stated that contracting is considered acceptable for DMEPOS suppliers, unless they are in a state that specifically prohibits contracting. If you use contracted employees, be sure you can demonstrate that your state does not prohibit the use of contracted employees.

STANDARD 02

This standard deals with the responsibility of providing NSC with the most accurate and up-to-date information about your facility. At any time when completing your enrollment application forms, be sure to provide the most up-to-date

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information. In addition, notify NSC of any changes in your business, such as a change in ownership, a new address, or dropping or adding a new product line, within 30 days.

STANDARD 03

This standard requires that an authorized individual must sign the enrollment application for billing privileges. Typically, this will be someone who has the legal authority to enroll a facility in Medicare—for example, a chief executive officer, chief financial officer, partner, chairman, or someone with a 5 percent or greater stake in the company.

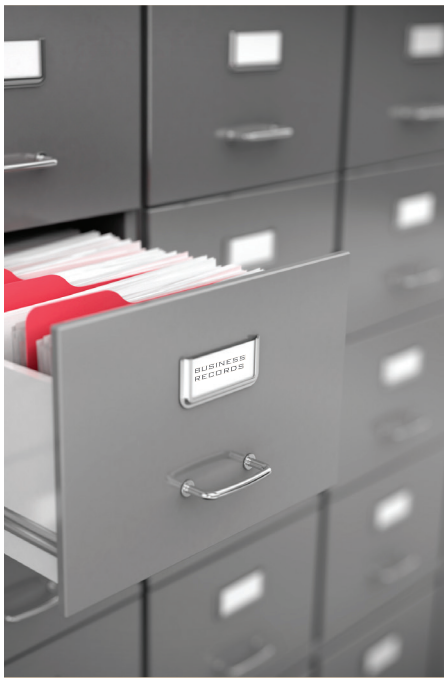
STANDARD 04

Under this standard, you must be able to demonstrate that you have an adequate inventory on hand or the ability to obtain an adequate inventory to fill and complete orders, based on what you indicated you are providing to beneficiaries. This does not mean that you must have formal contracts with all of your vendors; a purchasing agreement or a credit letter is acceptable. However, the document should contain, at minimum, these specific terms: an established credit limit, credit terms, both companies identified in the terms, and the length of the contract or agreement.

In addition, you may not contract with any entity that is currently excluded from the Medicare program. Double-check the Office of Inspector General (OIG) exclusion list at *www.oig.hhs.gov/fraud/exclusions.asp* to ensure any company you have a contract with is not excluded from Medicare or any other federally funded program—and continue to check the list on a routine basis to make sure that your contracted partners do not become excluded.

STANDARD 05

A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment and of the purchase option for capped rental equipment. This standard will typically not apply to an O&P supplier



because O&P items do not have a rental option. However, a site inspector may ask to see a form that you use to notify patients about the rental option. The NSC website has a notification form you may download and place in your operations manual to demonstrate that you have a form ready and available.

STANDARD 06

You must inform all of your Medicare patients about applicable warranties (state, manufacturer, company, etc.), and you must honor all applicable warranties, including free repair and replacement of any Medicare-covered items under warranty. Under this standard, you must be able to provide documentation that proves you provided warranty information to your patients; this can be accomplished with copies of letters, logs, or signed notices. The NSC has a notice template that you may use for your files if you don't already have one.

STANDARD 07

You must maintain and operate your business on an appropriate site, and the physical location of your business operations must have space for storing business records, unless you are a multisite business and you use a central record storage site. "Business records" include proof of delivery forms, beneficiary communication records, and complaint forms. Follow these guidelines to make sure you are operating out of a valid facility on an appropriate site:

The facility must be in a location that is accessible to the public and can easily be located and identified by patients as well as site inspectors. This means that it must have a valid U.S. Postal Service (USPS) address. Keep this in mind if you are located in a building or office complex utilizing suite numbers or some other designation; the suite must be a valid suite number recognized by USPS. In other words, you cannot have space in a building, then place a sticker on the door and call it "Suite A"—the USPS must recognize the suite number.

The location must have a permanent, visible, in-plain-sight sign outside of the facility that identifies the business and posts the hours of operation. All interested parties should be able to find your facility and your hours of operation through the use of these permanent signs without any assistance from you or other parties. If your office is located within a building or complex, your signage may be placed at the main entrance of the complex or the lobby of the building, as long as it is visible. However, it is advisable to post your hours and information outside your door with a separate sign. In addition, your posted hours must reflect your true hours of operation, and they must match what is found on your most recent Medicare enrollment application. If you close for an hour during the day for lunch, your posted hours should reflect this closure. If your hours change, you should notify the NSC (see Standard 2).

Your facility must be accessible and staffed during your posted hours of operation. This doesn't mean that you must have an orthotist or prosthetist or any other clinical staff in the office during the hours you are open to the public, but there must be someone there. It is acceptable to have your facility hours "by appointment only," as long as this information is posted and there is a way to set up an appointment, such as a contact number.

STANDARD 08

This standard gives permission to CMS, NSC, or any of their agents, such as Overland Solutions Inc. (OSI), to conduct site inspections to ensure your compliance with the Supplier Standards—and only the Supplier Standards. There is not much you need to do to be in compliance with this standard, except to allow CMS, NSC, or their agents to conduct a site inspection.

How can you tell if NSC is there to do a site inspection, and how do you know the person conducting the inspection is an authorized agent of NSC? An authorized site inspector will always have a photo ID and a signed letter on CMS letterhead. If the individual doesn't have the letter or the ID, or you have general reservations about the individual, you may contact NSC at 866/238-9652.

The inspector may take pictures of your facility and may request to see patient charts, but he or she is not allowed to make copies of the charts or remove the charts from your facility.

STANDARD 09

You must have a valid primary business telephone that is operating at the appropriate site, as defined by Standard 7. Cell phones, beepers, pagers, answering machines, and fax machines are not valid for a facility's primary business phone. In addition, a phone number that exclusively forwards calls to cell phones, beepers, pagers, or another office is not considered a valid primary business number. In addition, a call answering service during posted hours is not considered appropriate. To be valid, the phone number should be listed under the name of the business in a local directory (phone book, Google, etc.).

STANDARD 10

Maintain up-to-date insurance records that show you have a liability insurance policy, in the amount of at least $300,000, that covers your place of business, including the employees and your patients. If you fabricate any items in-house, the insurance must include product liability provisions. These insurance policies must be kept up to date; if they lapse for any reason, your Medicare billing privileges will be revoked and the revocation will be retroactive to the date the insurance coverage lapsed.

STANDARD 11

You are prohibited from calling beneficiaries to solicit new business, and you may only contact your patients if one of these three criteria have been met:

1. The beneficiary has given written permission to the supplier to make contact by telephone.
2. The phone call is related to a covered item that is to be delivered and you are contacting the patient to coordinate the delivery.
3. You have furnished at least one covered item to the beneficiary during the preceding 15 months.

Remember this standard only restricts telephone contact as means of direct solicitation; it does not prohibit marketing via other methods. Advertising to the general public, by methods such as online, yellow pages, direct mail, and other electronic means of communication, is still permitted and not considered direct solicitation under this standard.

In the past, OIG has taken an interest in this standard and released a special fraud alert regarding the prohibition of suppliers making unsolicited telephone contact with Medicare beneficiaries. The alert focused on the practice of DMEPOS suppliers contacting beneficiaries solely based on an order provided by the referring physician and no written permission from the beneficiary, and the possibility that this practice may lead to unsolicited contacts.

In the alert, it was clarified that suppliers may contact Medicare beneficiaries via telephone based on a physician's preliminary written or verbal order as long as the physician notifies those beneficiaries that a supplier will be contacting them to arrange the provision of their DMEPOS item or service. In other words, you cannot contact a new patient at the physician's request, unless the physician has informed the patient that he or she has asked a supplier to contact the patient about providing the service.

Remember that the beneficiary only needs to be made aware that someone will be contacting him or her regarding the item/service being ordered. This notification doesn't need to be in writing; the patient does not need to sign anything; and the physician does not have to specifically name your facility. The beneficiary just needs to be notified that he or she may be contacted by a separate entity. If you receive a physician request to see a new patient, you may want to make sure that the physician has informed that patient that someone will be contacting him or her regarding follow-up care and the item or service being provided.

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STANDARD 12

This standard is easy to comply with because it requires you to do things that you normally do and are required to do if you are accredited. You must instruct beneficiaries on the proper use and care of items delivered to them, and you must obtain and keep on file a proper and valid proof of delivery, and documentation that the beneficiary received proper care instructions.

STANDARD 13

You must be willing and able to answer questions, or refer the patient to the proper entity, and respond to any and all complaints regarding the Medicare-covered items and services you provided. You also must document all complaints, including any actions taken to resolve the complaints. Consider creating a protocol that all employees follow when receiving and handling complaints. The protocol doesn't need to be elaborate; it can be simple and straightforward as shown in the below sample text from the NSC website:

"The patient has the right to freely voice grievances and recommend changes in care or services without fear of reprisal or unreasonable interruption of services. Service, equipment, and billing complaints will be communicated to management and upper management. These complaints will be documented in the Medicare Beneficiaries Complaint Log. All complaints will be handled in a professional manner. All logged complaints will be investigated, acted upon, and responded to in writing or by telephone by a manager within a reasonable amount of time after the receipt of the complaint. If there is no satisfactory resolution of the complaint, the next level of management will be notified progressively and up to the president or owner of the company."

In addition, if you receive complaints that may not be directly related to your services but may be more general in nature about Medicare or Medicare's coverage policies, be sure you are able to point the patient in the right direction. Provide them with information regarding who they may talk to about their concerns, such as CMS, OIG, or the durable medical equipment Medicare administrative contractors.

Finally, to help you log, track, and document all of the pertinent information regarding complaints, see Standard 20.

STANDARD 14

This standard does not apply to O&P facilities because O&P facilities do not rent items to Medicare beneficiaries.

STANDARD 15

You must accept returns from beneficiaries for items delivered that are deemed to be of substandard quality or unsuitable. This standard can become complicated because the definitions for "substandard" and "unsuitable" are a little vague, and the timeframe during which a patient may return an item for a refund is not set in stone. The standard defines "substandard" as anything that is "less than full quality for the particular item," and "unsuitable" as anything that is "inappropriate for the beneficiary at the time it was fitted or sold."

This standard only refers to the act of accepting the returns of items, and it does not state that you must refund the patient, unless Medicare specifically requests, via an overpayment demand letter, that you refund the money. In the case that you must refund the money, you will want to be sure that you have documented or can otherwise show that you did not provide any substandard or unsuitable items, as this will help you in fighting the Medicare overpayment request.

To demonstrate that you did not provide any substandard items, document that the items you provided were from a reputable supplier/manufacturer by showing your compliance with Standard 4—that the supplier/manufacturer is not or has not been on the OIG exclusion list. If you fabricated the item in-house, you can explain that your fabrication methods follow industry standards and show that your raw materials are from reputable vendors.

To document that you did not provide any unsuitable items, focus on two key areas. First, show that you delivered and provided exactly what was requested on the physician's order, and that the item was appropriate for the patient. Second, document that the patient was satisfied and happy with the item at the time of delivery and fitting; and if there are any issues, document those issues and explain what you did to work with the patient and correct the issues. This documentation can ultimately demonstrate the patient's acceptance of a suitable item and his or her happiness with the service/item provided.

If the patient is returning an item stating that it is unsuitable or substandard and the item is under a warranty, explain to the patient that the item is under warranty and may be able to be replaced. This step will reinforce your compliance with Standard 6.

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STANDARD 16 You must disclose and make the patient aware of the Supplier Standards for each and every Medicare-covered item and service you provide. There are three established methods to show compliance with this standard:

- You may provide a copy of the standards to each patient and ask that he or she sign an acknowledgement of receipt; you should keep a copy of the acknowledgement in the patient's record. This acknowledgement form/statement could be included with your proof of delivery forms, and the Supplier Standards could be printed on the back of the patient's copy of the delivery slip, eliminating the number of pieces the paper the patient receives.
- You don't have to give the patient a copy of the standards if your acknowledgment statement includes directions on how the patient can locate and access the standards; in essence, you must make each patient aware of the standards. If you go this route, it is recommended that you use the following statement created by NSC: "The products and/or services provided to you by [supplier legal business name or DBA] are subject to the Supplier Standards contained in the federal regulations shown at 42 Code of Federal Regulations Section 424.57(c). These standards concern business professional and operational matters (e.g., honoring warranties and hours of operation). The full text of these standards can be obtained from the U.S. Government Printing Office website. Upon request, we will furnish you a written copy of the standards."
- It has been stated that simply posting a copy of the Supplier Standards in your office in plain sight for all patients to see would satisfy the requirements of Standard 16. However, the first two options provide you with a little bit more coverage in demonstrating compliance, and may prevent a patient or site inspector from saying, "I never saw the standards."

STANDARD 17 You must disclose information about any person, or entity, having ownership or financial or controlling interest in your facility—any person who has a 5 percent or greater stake in the company. This information should be disclosed in Section 8 and/or 9 of your Medicare enrollment application.

STANDARD 18 You may not convey, reassign, sell, rent, or allow another supplier to use your Medicare supplier number or billing privileges. Each supplier number must be attached to one physical location. In addition, each location needs its own Provider Transaction Access Number. The NSC has not interpreted any of the standards to come to this conclusion, but it is has officially stated that each location that is used to provide Medicare-covered items to beneficiaries must be enrolled separately. In essence, each location requires an individual supplier number. The only locations that do not require separate supplier numbers are locations that you use solely as warehouses or fabrication sites, places where you are not seeing patients, or places where you are delivering items.

STANDARD 19 You must have a written complaint resolution protocol in place to address beneficiary complaints that relate to the Supplier Standards. This is different and separate from the protocols created for Standard 13. The protocol does not need to be elaborate, and can be as simple and straightforward as the one you created for Standard 13. Remember that a log or record of these complaints and protocol must be kept at each physical location where you are providing a copy of the Supplier Standards or where you are treating patients.

STANDARD 20 In your complaint logs/records for Standards 13 and 19, you must include the name, address, telephone number, and health insurance claim number of the beneficiary who lodged the complaint. You also should include a summary of the complaint and any actions taken to remedy it, even if no action was required. If you do not wish to create your own log, the NSC has a template you may use.

STANDARD 21 You must agree to furnish CMS any information required by the Medicare statute and implementing regulations. Complying with this standard would involve providing proof of delivery slips or detailed written orders when requested since these are required by Medicare statute for payment.

STANDARD 22-25 These standards relate to accreditation. There is currently an exemption for O&P providers from having to be accredited. However, this exemption only extends to orthotists and prosthetists. Pedorthists, orthopedic fitters, and mastectomy fitters working independently of an O&P company must be accredited. What's more, this exemption only applies to items provided in the normal scope of the supplier's specialty; any items provided outside of the supplier's specialty will require accreditation. Thus, if you are providing any type of DME items (i.e., dynamic splinting, the WalkAide, the Bioness, canes, crutches, etc.), you would not be fully exempt, and would be required to be accredited for these items. In other words, you would not have to be accredited for the O&P items, but you would have to be accredited for the DME items. In such an instance, you should contact your accrediting body and determine how it handles partial accreditations.

STANDARD 26 Unless exempt, you must obtain a $50,000 surety bond for each of your enrolled facilities. To be exempt from obtaining the surety bond, you must meet the following criteria: The company must be solely owned and operated by O&P professionals (anyone listed as having any ownership stake in the company must be a certified orthotist and/or prosthetist); those O&P professionals must be the only ones seeing patients (if you employ other orthotists/prosthetists and they are not part owners, then you would not be exempt); and you must be providing custom orthotic, prosthetic, and supply items. In addition, if you are in a state that requires licensure, you must be licensed.

STANDARD 27 This standard pertains only to oxygen and does not apply to O&P.

Knowing which standards apply to your facility and how you can demonstrate compliance may be the difference between **a successful site visit** and an unsuccessful site visit.

STANDARD 28 A supplier must maintain ordering and referring documentation consistent with provisions found in 42 C.F.R. 424.516(f). You must retain your documentation for seven years, including the ordering/referring provider's National Provider Identifier information.

STANDARD 29 This standard prohibits a supplier—a person or entity that has a Medicare approved supplier number—from sharing the same space with another supplier. In short, if two suppliers are billing for DMEPOS services/items, they cannot share space. Each supplier would have to have a separate approved location (Standard 7). You may share space with a provider or supplier if that provider does not have a DMEPOS supplier number and is not providing or billing for DMEPOS items.

STANDARD 30 This standard requires offices to be open for a minimum of 30 hours per week. However, there is an exemption for O&P providers providing custom-fabricated prostheses and orthoses. To qualify for the exemption, you must have indicated on your enrollment application that you provide one or more of the following items/services to Medicare beneficiaries: breast prostheses and/or accessories, cochlear implants, diabetic shoes/inserts, eye prostheses, facial prostheses, limb prostheses, ocular prostheses, orthoses—custom fabricated, prosthetic cataract lenses, somatic prostheses, and/or voice prosthetics. If you are providing any other items/services to Medicare beneficiaries, not including prefabricated orthoses, such as dynamic splinting or TENS units, then the exemption no longer applies and you are required to be open at least 30 hours a week.

Knowing which standards apply to your facility and how you can demonstrate compliance may be the difference between a successful site visit and an unsuccessful site visit. Follow these tips to prevent a delay in receiving a Medicare supplier number or the revocation/suspension of a current Medicare supplier number. CP

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