HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

COMPLIANCE TODAY

Volume Thirteen
Number Eight
August 2011
Published Monthly

Meet

Catherine Wakefield
Vice President Corporate Compliance and Internal Audit, MultiCare Health System

PAGE 14

Earn CEU Credit

WWW.HCCA-INFO.ORG/QUIZ—SEE PAGE 66

Feature Focus:

Compliance officers beware! Feds targeting executives for prosecution and exclusion

PAGE 30

Managing conflict in the hospital: A Joint Commission requirement

PAGE 9

DMEPOS and the False Claims Act: Compliance and litigation strategies

By Nathaniel Lacktman, CCEP and Michael McCollum

Editor's note: Nathaniel (Nate) Lacktman is Senior Counsel in the Tampa office of Foley & Lardner LLP and is a member of the Health Care Industry Team. He advises DMEPOS suppliers and manufacturers on a range of business and regulatory issues, including False Claims Act litigation. Nate may be contacted by e-mail at nlacktman@foley.com.

Michael (Mike) McCollum is Senior Counsel in the Los Angeles office of Foley & Lardner LLP. He is a member of the firm's Government Enforcement, Compliance & White Collar Defense practice. He advises DMEPOS suppliers and manufacturers on a range of business and regulatory issues, including False Claims Act litigation. Mike may be contacted by e-mail at mmccollum@foley.com.

This article is the third in a series on DMEPOS compliance issues by Foley & Lardner LLP published in **Compliance Today**. *In the June issue of* **Compliance Today**, *the authors provided practical tips and compliance advice regarding DMEPOS telemarketing and beneficiary contact. This month, the authors discuss the Medicare DMEPOS supplier standards, liability under the False Claims Act, and strategic approaches to limiting damages in whistleblower lawsuits.*

Suppliers of durable medical equipment, prosthetics, and orthotic supplies (DMEPOS) face increasing scrutiny and oversight from federal agencies such as the Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General (OIG). In order to obtain and maintain Medicare billing privileges, DMEPOS suppliers need to meet the Medicare supplier standards. Late in 2010, CMS expanded the supplier standards and imposed significant new burdens on DMEPOS suppliers. The industry opposed many of these changes, but it remains likely that the government will continue to argue in the appropriate cases that failure to comply with the supplier standards not only exposes DMEPOS suppliers to administrative sanctions, but also creates False Claims Act liability. DMEPOS suppliers should understand the supplier standards and the enforcement implications, both to ensure compliance going forward, and, if necessary, to effectively defend past conduct in the event of an enforcement action, government investigation, or False Claims Act litigation.

Medicare has strict guidelines and standards that DMEPOS suppliers must meet to establish and maintain Medicare billing privileges. Among these rules is the set of federal regulations known as the Medicare DMEPOS supplier standards.[1] The supplier standards apply to all Medicare-participating DMEPOS suppliers and set forth the minimum operational requirements suppliers are asked to follow. First introduced in 1992, the supplier standards have expanded, and currently there are 30 standards.

New supplier standards and proposed revisions

In August 2010, CMS released a final rule that added four new DMEPOS supplier standards and made the existing standards more onerous. In response to significant backlash from the DMEPOS industry, CMS issued a proposed rule in April 2011, relaxing some of the standards introduced in the August 2010 final rule. When this article went to press, the April 2011 proposed rules had not been finalized.

DMEPOS supplier standards and Medicare enrollment

The National Supplier Clearinghouse (NSC) processes DMEPOS

supplier applications for Medicare, oversees the enrollment process, and with CMS is responsible for oversight of compliance with the supplier standards. Effective March 2011, new DMEPOS suppliers are now classified by the government as a "high risk" category for fraud, waste, and abuse and are subject to more stringent enrollment screening and oversight controls.

Generally, the Medicare DMEPOS supplier enrollment process is as follows. First, the applicant submits the CMS 855S enrollment application and supporting documentation to the NSC. In the application, the DMEPOS supplier certifies that it meets and will continue to meet the supplier standards. The NSC reviews the application and conducts a site visit to verify compliance with all DMEPOS supplier standards. After completing its review, the NSC notifies the applicant in writing of the enrollment decision. After enrollment, a DMEPOS supplier must maintain compliance with the supplier standards.

Implications of failure to comply

DMEPOS suppliers can face severe penalties for failing to comply, at least in material respects, with the supplier standards. From the government's perspective, all deviations from the black letter standards are material and require sanctions, including administrative penalties, billing revocation, Medicare recoupment, potential criminal liability, and potential liability under the False Claims Act. But, there are limits. Understanding the contours and limits of these potential penalties—and the issues and arguments that typically arise—is essential for a DMEPOS supplier to effectively position itself to avoid scrutiny by maintaining an effective compliance program and, if necessary, to respond to a regulatory or False Claims Act action.

Administrative penalties

If a DMEPOS supplier is found to not meet the supplier standards, CMS may revoke the supplier's billing privileges. The revocation is effective within 15 or 30 days of the notice of revocation, depending on the standard violated.

The new DMEPOS regulations also allow CMS to attempt recoupment of payments as of the date of certain final adverse actions:

- Revocation of Medicare billing privileges
- Suspension or revocation of a state license
- Conviction of a felony
- Exclusion from participation in a state or federal health care program
- Revocation for failure to meet DMEPOS quality standards

Under this rule, CMS is authorized to assess and collect Medicare overpayments back to the date of the final adverse action. This means that all funds received by a DMEPOS supplier subject to one of the adverse actions can potentially be deemed an overpayment. This rule strengthens CMS' view that when a DMEPOS supplier is not allowed to participate in Medicare, funds the supplier receives are deemed to be overpayments.

However, the new regulations do not contain a provision authorizing recoupment retroactive to the date of the DMEPOS supplier's non-compliance—only to the date of the final adverse action. The lack of a retroactive recoupment provision benefits DMEPOS suppliers significantly, because it limits the potential overpayment liability for non-compliance with certain supplier standards. Moreover, a DMEPOS supplier who is assessed an overpayment under this provision has administrative appeal rights. Given the current regulatory environment and the new 60-day overpayment rule, DMEPOS suppliers should develop a thoughtful approach for determining how overpayments are identified and potentially reported and refunded.[2]

Potential liability under the False Claims Act

Of potentially even greater concern than the possible administrative sanctions is the potential for False

Continued on page 44

 ...continued from page 43

Claims Act liability. Given the current enforcement environment, government scrutiny and *qui tam* whistleblowers are a reality for DMEPOS suppliers. The supplier standards have been considered a hybrid between the Medicare conditions of participation and the conditions for payment. Whereas a violation of Medicare conditions for payment is generally considered grounds for a False Claims Act violation, some courts have ruled that a violation of Medicare conditions of participation does not necessarily give rise to a False Claims Act violation. In some recent cases in the DMEPOS industry, the government has taken a more aggressive position that the supplier standards are conditions for payment. The good news for DMEPOS suppliers is that at least one recent court ruling held that a violation of the supplier standards does not necessarily trigger a false claim.[3]

Supplier standards as conditions of participation or conditions for payment

The vast majority of courts that have examined the issue have held that False Claims Act liability does not arise simply by virtue of a violation of an underlying Medicare rule or regulation.[4] Rather, one of two conditions must exist:

- The supplier expressly certified compliance with the standards when submitting a claim; or
- Compliance with the standards is written into the regulation as a condition for payment, rather than simply a condition of participation, in the Medicare program.

The issue of Medicare conditions of participation versus conditions for payment is more complicated for DMEPOS suppliers than for other providers, such as hospitals. This is largely due to the nature of the supplier standards. The government has pointed to some characteristics of the supplier standards to support its argument that the supplier standards are conditions for payment. For example, the supplier standards are contained under the regulatory section titled "Conditions for Medicare Payment." The payment regulations require that certain conditions be met "as a basis for Medicare payment," including, among other things, conditions regarding the source of services.[5] The "source of services" category includes the requirement that services must have been furnished by a provider, nonparticipating hospital, or supplier that was qualified to have payment made for the services at the time it furnished them. Under the government's argument, these payment regulations can and should be interpreted to mean that compliance with the supplier standards is a condition for payment.[6]

However, DMEPOS suppliers can identify other aspects of the supplier standards to refute the government's argument, and instead demonstrate that the supplier standards are simply conditions of eligibility that afford the DMEPOS supplier the privilege to prospectively bill the Medicare program. The regulatory subsection titled "Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges" sets forth several conditions that a DMEPOS supplier must meet "in order to be eligible to receive payment for a Medicare-covered item." One of those conditions is listed as "CMS has not revoked or excluded the DMEPOS supplier's privileges during the period which the item was furnished."[7] The 30 supplier standards are listed thereafter as standards "the supplier must meet and must certify in its application for billing privileges." As noted above, there is no provision for retroactive recoupment, only recoupment following actual revocation. These aspects make the supplier standards akin to conditions of participation.

No appellate court has opined on this issue. However, in examining the interplay between these regulatory provisions, at least one court clearly held that the supplier standards are conditions of participation and not payment,

concluding that "proper redress for violations of the standards established therein is not the denial of payment, but the revocation of the supplier's billing privileges."[8] Case law continues to evolve and DMEPOS suppliers—and their legal counsel—should stay attuned to new developments on this issue.

Falsity, knowledge, and limits on damages

If a DMEPOS supplier is facing a False Claims Act investigation or lawsuit that alleges liability based on noncompliance with the supplier standards, the supplier should articulate several reasons why key elements of False Claims Act liability cannot be met. This is because alleged violations of the supplier standards may bear little-to-no relation to the core elements of False Claims Act liability, namely the knowing submission of a false or fraudulent claim or statement that is material to the government's payment of a claim. A DMEPOS supplier will want to be familiar, in particular, with the legal elements of falsity and knowledge, and how damages are to be measured under the False Claims Act.

Regarding falsity, obviously, if no supplier standard has been violated, no false claim or statement can be predicated on noncompliance with the supplier standards. Yet, the government can, and sometimes does, interpret a standard in a manner unsupported by the regulatory language itself. Further, compliance with the supplier standards can sometimes be unclear, particularly where the regulations are vague or complicated. A recent court ruling lends support to the argument that lack of clarity alone may undermine the ability of the government or a private litigant to satisfy the "falsity" element of the False Claims Act.[9]

By that same token, courts have held that even if a claim is technically false, a sufficiently high level of uncertainty and vagueness in the regulations will undermine the knowledge element of False Claims Act liability. Under the same court's opinion noted above, it was noted that a defendant cannot have knowingly submitted a false claim if the regulations are thoroughly unclear (i.e., where there are legitimate grounds for disagreement over the scope of the regulatory provisions) or if CMS actually knows and approves of the facts surrounding the supplier's conduct before the challenged claims for payment are submitted, upon which conduct the supplier relies.

Beyond the issue of liability, DMEPOS suppliers should further seek to limit the amount of damages by arguing that damages are to be calculated not as the full amount of the Medicare payment, but instead according to a benefit-of-the-bargain analysis. Under that approach, damages are measured by the difference between the value of what Medicare paid for the item and the value of what the beneficiary actually received. This concept is increasingly being applied by courts in False Claims Act cases.[10]

This methodology does not apply to actions under the Civil Monetary Penalties Law because that statute fixes damages as the full value of the claims improperly made. There is also some authority holding that a Medicare regulatory violation demands full repayment of the Medicare payments, because Medicare would not have paid any funds without the false claims, and Medicare does not actually receive any direct benefit from the supply of covered items.[11] But, that ignores the fact that beneficiaries are the true recipients of the covered items, as well as the Medicare funds to pay for those items. Therefore, DMEPOS suppliers may find success with courts recognizing that the government receives a benefit from the provision of covered items to beneficiaries, and the courts may apply the benefit-of-the-bargain rule in the Medicare context to limit the damages in DMEPOS supplier False Claims Act lawsuits.[12]

Practical compliance advice for future conduct

DMEPOS suppliers should carefully review the existing supplier

Continued on page 47

 ...continued from page 45

standards to ensure they understand all the rules and requirements for Medicare participation. In addition to the regulations, DMEPOS suppliers should review the preambles to the 2010 final rule and the 2011 proposed rule. That will help DMEPOS suppliers understand CMS' purpose in issuing the rules, as well as give additional detail on how CMS interprets the regulatory language. CMS and NSC have also published FAQs on the new supplier standards and DMEPOS suppliers should read them to help answer any additional questions on how to interpret the regulations.[13] (Note: These FAQs have been revised, so be certain to obtain a copy of the most current version.) DMEPOS suppliers will also find a wealth of information in Chapter 15 of the ***Medicare Program Integrity Manual***, as well as the supplier manuals issued by each of the four regional DME Medicare Administrative Contractors.

Using these materials, as well as the regulations themselves, DMEPOS suppliers can create and tailor risk assessment tools specific to their company's compliance needs on a going forward basis. Certainly, DMEPOS suppliers should address key risk areas, such as accreditation compliance, billing and documentation, medical necessity of items ordered, state licensure and Medicaid requirements, referral relationships and contracting, and marketing to beneficiaries. DMEPOS suppliers should also ensure their compliance program policies and procedures are current with the recent changes to the supplier standards, keeping in mind the relaxed rules contained in the recent proposed rule. DMEPOS suppliers should then verify that their actual practices regarding the supplier standards match up with the expectations set forth in their written policies and procedures. Staff should be periodically trained and educated on relevant requirements under the supplier standards and related state law rules (e.g., licensure and contracting).

Responding to an investigation of past conduct

Once the foundation has been built for an effective compliance program, DMEPOS suppliers should also be aware of the various legal arguments and strategies to defend against a CMS administrative action or a False Claims Act lawsuit regarding past conduct. Suppliers should not assume the government's informal interpretation of a standard is the only interpretation or even the correct interpretation, nor should suppliers assume that any and every violation of the supplier standards is of equal materiality or significance. Suppliers should recognize that CMS may only try to recoup funds paid after a formal adverse action, not before. Suppliers should be able to articulate why a particular violation of a supplier standard may not give rise to a false claim (e.g., the standard may not be a condition for payment) and why the government or a litigant cannot prove the other elements of False Claims Act liability. Suppliers should be able to articulate how the regulations or previous government conduct might have been overly vague or confusing and how that uncertainty might have contributed to the suppliers' past conduct in reliance thereon. Finally, suppliers should understand how to argue for a proper measure of damages based on the benefit-of-the-bargain approach.

Conclusion

DMEPOS suppliers can look to the supplier standards as the cornerstone of their operational compliance concerns. The supplier standards can serve as the framework for risk assessments and proactive compliance reviews as part of an overall effective compliance program. In the unfortunate event of an administrative enforcement action or a whistleblower lawsuit under the False Claims Act, DMEPOS suppliers should be certain their legal counsel understands and takes full advantage of the various defenses they can raise in such litigation. ■

1 42 C.F.R. § 424.57(c).
2 J. Gresko, M. McCollum, H. Sorensen, L. Noller: "A Reasoned Approach to Identify-

Continued on page 66

 ...continued from page 47

ing Federal Health Care Program Overpayments." ***Compliance Today Magazine***, vol. 13, no. 2, February 2011, pp 8-11,19.

3 *United States ex rel. Cooper v. Gentiva Health Serv's, Inc.*, 2003 WL 22495607 * 9 (W.D. Pa., Nov. 4, 2003). See also *United States ex. rel. Jamison v. McKesson Corp.*, 2011 WL 1158945 * 1 (N.D. Miss., March 28, 2011)

4 See e.g., *United States of America ex rel. Williams v. Renal Care Group*, 2010 WL 1062634 *10 (M.D. Tenn., March 22, 2010) (listing similar holdings from courts in the 2nd, 5th, 6th, and 7th Circuits); *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 997-1001 (9th Cir. 2010); *United States ex rel. Conner v. Salina Reg'l Health Ctr.*, 543 F.3d 1211, 1217 (10th Cir. 2008); *United States ex rel. Freedman v. Suarez-Hoyos*, 2011 WL 972585 * 8 (M.D. Fla., March 18, 2011); *United States ex rel. Landers v. Baptist Memorial Health Care Corp.*, 25 F. Supp. 2d 972 (W.D.Tenn., 2007).

5 42 C.F.R. § 424.5.

6 See e.g., *United States ex. rel. Jamison v. McKesson Corp.*, 2011 WL 1158945 * 1 (N.D. Miss., March 28, 2011); *United States ex. rel. Jamison v. McKesson Corp.*, 2009 WL 3176168 (M. D. Miss., Sept. 29, 2009) (supplier standards are a condition for payment based on the three-year enrollment certification).

7 42 C.F.R. § 424.57(b)(3).

8 *United States ex rel. Cooper v. Gentiva Health Serv's, Inc.*, 2003 WL 22495607 * 9 (W.D. Pa., Nov. 4, 2003).

9 *United States ex rel. Jamison*, supra, at *11, 13.

10 See, e.g., *United States ex rel. Science Applications Int'l Corp.*, 626 F.3d 1257 (Dec. 3, 2010).

11 See, e.g., *United States v. Rogan*, 459 F.Supp.2d 692, 726 (N.D.Ill. 2006), affirmed at 517 F.3d 449 (7th Cir. 2008).

12 See, e.g., *United States of America ex rel. Williams v. Renal Care Group*, 2010 WL 1062634 *10 (M.D. Tenn. (March 22, 2010) (calculating government's recovery to be the difference between more expensive rate for home-provision of dialysis equipment and less expensive rate for equipment provided at facilities).

13 N. Lacktman, H. Sorensen: "Cold calls, hot lines: DMEPOS telemarketing and beneficiary contact. HCCA ***Compliance Today Magazine***, vol. 13, no. 5, May 2011, pp 42-45.

Be Sure to Get Your CHC® CEUs

Articles related to the quiz in this issue of **Compliance Today**:

- **Managing conflict in the hospital: A Joint Commission requirement**—By Stacey Mondschein Katz, page 9
- **Feature Focus: Compliance officers beware! Feds targeting executives for prosecution and exclusion**—By Francis J. Serbaroli, page 30
- **Power mobility devices: Is it really that easy?**—By Deborah Johnson, page 54

To obtain one CEU per quiz, go to **www.hcca-info.org/quiz** and select a quiz. Fill in your contact information and take the quiz online. Or, print and fax the completed form to CCB at 952/988-0146, or mail it to CCB at HCCA, 6500 Barrie Road, Suite 250, Minneapolis, MN 55435. Questions? Please call CCB at 888/580-8373.