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March 26, 2012

CMS Issues Final Rule Modifying Restrictions on "Direct Solicitation" of Beneficiaries by DMEPOS Suppliers; Changes to Other DMEPOS Supplier Safeguards

RESOURCE LINKS

OIG Guidance Regarding Telemarketing Activities:
http://oig.hhs.gov/compliance/alerts/index.asp

CMS's DME Supplier Telemarketing FAQs:
http://www.cms.gov/MedicareProviderSupEnroll/downloads/DME_Telemarketing_FAQs.pdf

IMPORTANT DATES

Final Rule becomes effective:
April 13, 2012

On March 9, 2012, the Centers for Medicare & Medicaid Services ("**CMS**") released a final rule ("**Final Rule**") that makes various modifications to the durable medical equipment, prosthetics, orthotics, and supplies ("**DMEPOS**") supplier standards (codified at 42 C.F.R. § 424.57(c)). The Final Rule was published in the *Federal Register* on March 14, 2012, with an effective date 30 days later (i.e., April 13, 2012).

Among the various changes the Final Rule makes to the supplier standards is one modification that focuses on the marketing of DMEPOS and, specifically, removes a definition of "direct solicitation" of Medicare beneficiaries. CMS indicates that its definition of the phrase "direct solicitation" was not feasible and had been "criticized as being overly broad as it covered some types of marketing activity outside the bounds of what we intended to prohibit under our regulations." As a result, the prohibition on the "direct solicitation" of Medicare beneficiaries has returned to its original limitation on telephonic contact.

DMEPOS suppliers and other providers need to be aware of the Final Rule and its collective effect on the DMEPOS supplier standards, because it may require modifications to suppliers' business practices.

Background

The direct solicitation of Medicare beneficiaries has been a topic of interest since the Office of Inspector General ("**OIG**") released guidance in March 2003 regarding telemarketing practices by DMEPOS suppliers.[1] In that guidance, the OIG confirmed that suppliers are prohibited from making

[1] U.S. Dep't of Health & Human Servs., Office of Inspector General, Special Fraud Alert, *Telemarketing by Durable Medical Equipment Suppliers* (Mar. 2003), *available at* http://oig.hhs.gov/compliance/alerts/index.asp ("2003 OIG Special Fraud Alert").

unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of covered items, except in three specific situations: (1) when the beneficiary has given written permission to the supplier to make contact by telephone; (2) when the contact with the beneficiary is regarding a covered item that the supplier already has furnished to the beneficiary; or (3) when the supplier has furnished at least one covered item to the beneficiary during the preceding 15 months.[2] This prohibition applies to situations where contact with a beneficiary is made by the DMEPOS supplier directly, as well as to situations where contact with a beneficiary is made by another party on the supplier's behalf.[3] Under this prohibition, DMEPOS suppliers are responsible for verifying that any marketing activities performed by third parties on the supplier's behalf do not involve this prohibited activity, and that any information purchased from those third parties was not obtained or derived from such prohibited activity. The OIG reissued its guidance in January 2010, but it did not articulate a new interpretation of the prohibition. Rather, the January 2010 reissued guidance served to highlight what the OIG considers a fraudulent and abusive practice within the health care industry.

CMS's actions in the Final Rule modify another final rule that the agency published in August 2010 ("**August 2010 Rule**"), in which the agency addressed several issues related to the DMEPOS supplier standards (codified at 42 C.F.R. § 424.57(c)). In particular, CMS revised one of the standards to clarify that the prohibition on "direct solicitation" of patients extended to include contact by telephone, e-mail, instant messaging, coercive response to Internet advertising, or in-person contact.[4] Prior to implementing the requirements in the August 2010 Rule, the definition of "direct solicitation" was generally limited to telephonic contact.

In practice, however, CMS discovered that the implementation of this expanded definition of "direct solicitation" was unfeasible. Therefore, in April 2011, CMS issued a proposed rule ("**Proposed Rule**") that removed the definition of, and modified the requirements regarding, "direct solicitation" and clarified that the prohibition is limited to telephonic contact.[5] CMS received a small, but noteworthy, group of comments regarding the Proposed Rule. The comments were generally supportive of CMS's proposal to remove the definition of "direct solicitation."[6] As a result of these efforts, the Final Rule adopted these modifications, so the prohibition against "direct solicitation" of Medicare beneficiaries will now be reverted to its original prohibition against only telephonic contact.

Significantly, the revised standard seemingly relaxes the burden currently on DMEPOS suppliers as they attempt to provide quality care and maintain access to DMEPOS items and services for Medicare beneficiaries. However, CMS indicates in the preamble that the agency continues to be concerned about the potential for abuse caused by the direct solicitation of Medicare beneficiaries by DMEPOS suppliers.

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[2] These prohibitions on telemarketing by DMEPOS suppliers are formally outlined in Section 1834(a)(17)(A) of the Social Security Act. Further, Section 1834(a)(17)(B) of the Social Security Act specifically prohibits payment to DMEPOS suppliers that knowingly submit claims generated pursuant to prohibited solicitations.
[3] 2003 OIG Special Fraud Alert, *supra* note 1.
[4] 75 Fed. Reg. 52629, 52631 (Aug. 27, 2010).
[5] 76 Fed. Reg. 18472 (Apr. 4, 2011). Refer to Epstein Becker Green's *Implementing Health and Insurance Reform* alert entitled "DMEPOS Updates: Proposed Rule for Direct Solicitation of Medicare Beneficiaries and Highlights from the April 2011 PAOC Meeting," *available at* http://www.ebglaw.com/showclientalert.aspx?Show=14277 (May 4, 2011).
[6] *See*, *e.g.*, 77 Fed. Reg. 14989, 14990-14991 (Mar. 14, 2012).

Other Changes

The Final Rule also modifies other DMEPOS supplier standards. Specifically, the Final Rule allows DMEPOS suppliers, including those that are competitive bidding program contract suppliers, to contract with licensed agents to provide such supplies, unless prohibited by state law. CMS stated in the Final Rule that, after the implementation of requirements in the August 2010 Rule that would provide an additional layer of oversight of DMEPOS suppliers via state laws, the agency determined that "the absence of specific State laws regarding certain areas of DMEPOS supplier oversight caused confusion among suppliers regarding who they could contract with."[7] CMS subsequently revised the standard in the Proposed Rule to clarify the agency's expectations with regard to state licensure and contracts.[8] CMS stated in the Final Rule that it intends to conduct outreach to DMEPOS suppliers, before and after implementation of the Final Rule, to help suppliers understand when certain types of scenarios would constitute violations of the DMEPOS supplier standards.

The Final Rule also removes the requirement for compliance with local zoning laws and modifies certain state licensure requirement exceptions. In the August 2010 Rule, CMS required that DMEPOS suppliers operate their businesses and furnish Medicare-covered supplies in compliance with local zoning requirements.[9] CMS explained in the Proposed Rule that this standard was enacted to ensure that DMEPOS suppliers were providing goods and services to beneficiaries in a physical location, rather than out of a residence, which is often prohibited by municipal code zoning requirements.[10] However, as CMS stated in the Proposed Rule, wide variances in state and municipal laws and, in particular, the potential difficulty that CMS contractors could have in verifying compliance with municipal codes have led the agency to decide to eliminate the requirement that suppliers comply with local zoning laws.[11] CMS stated in the Final Rule that the agency has reached the conclusion that, "[i]n hindsight . . . the task of ensuring that DMEPOS suppliers comply with local zoning requirements is best left to the States."[12]

Finally, CMS established an exception in the Final Rule to the proposed physical facility requirement for certain orthotic and prosthetic suppliers (42 C.F.R. § 424.57(c)(7)(i)(A)), to allow orthotic and prosthetic providers to qualify for the minimum square footage exception if the state does not offer licensure. According to CMS, "due to variations in State licensing procedures, comparable practitioners should not be excluded from this exception. Of course, if a State does offer licensure for orthotic and prosthetic professionals, the supplier must obtain licensure in order to qualify for the minimum square footage exception."[13] CMS also modified the open hours requirement as it pertains to "licensed non-physician practitioners" (42 C.F.R. § 424.57(c)(30)(ii)(B)), to clarify which providers are affected by this provision, by removing the phrase "licensed non-physician practitioners" and instead referring specifically to physical and occupational therapists.[14]

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[7] 77 Fed. Reg. 14989, 14991-14992 (Mar. 14, 2012).
[8] 76 Fed. Reg. 18472, 18474 (Apr. 4, 2011).
[9] 42 C.F.R. § 424.57(c)(1)(iii).
[10] 76 Fed. Reg. 18472, 18474 (Apr. 4, 2011).
[11] *Id*.
[12] 77 Fed. Reg. 14989, 14992 (Mar. 14, 2012).
[13] 77 Fed. Reg. 14989, 14993 (Mar. 14, 2012).
[14] *Id*.

What Should DMEPOS Suppliers Do?

Amidst the implementation of various restrictions on the actions of DMEPOS suppliers, the Final Rule is likely a welcome break from the constant scrutiny and increased oversight that DMEPOS suppliers face on a daily basis. However, as the issue of soliciting beneficiaries remains a concern for suppliers, and is one that carries significant operational burdens and implications, suppliers, in turn, must continue taking steps to ensure that day-to-day policies and practices are in line with these modified standards.

Generally, the limitation on solicitation raises compliance concerns for DMEPOS suppliers with regard to the common physician practice of asking patients if they have a preference for a supplier. If no preference is stated, the physician generally will fax an order to a DMEPOS supplier, which ideally would then contact the patient by phone to arrange delivery of the ordered DMEPOS item. However, this practice does not fit within one of the three telemarketing exceptions and, as such, remains improper according to the Final Rule. Thus, even in light of the Final Rule, the onus of compliance continues to be on the DMEPOS supplier, not the physician, because the supplier bills Medicare.

As a result, DMEPOS suppliers need to revisit their business practices to ensure that, for any new customers, suppliers are reaching out in writing, rather than by telephone, to arrange for delivery of DMEPOS items. DMEPOS suppliers also should consider working with physicians' offices to supply the necessary consent forms to new customers, which, in turn, will streamline the delivery process for DMEPOS items.

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For more information about this issue of *IMPLEMENTING HEALTH AND INSURANCE REFORM*, please contact one of the authors below or the member of the firm who normally handles your legal matters.

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