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DMEPOS Updates: Proposed Rule for Direct Solicitation of Medicare Beneficiaries and Highlights from the April 2011 PAOC Meeting

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In this Client Alert, which is part of our ongoing series on developments in the durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS") industry, we examine proposed changes to the DMEPOS supplier standards and highlight recently announced updates to the DMEPOS Competitive Bidding Program ("Program").

CMS Proposes Changes to Rule for Direct Solicitation of Medicare Beneficiaries

On April 4, 2011, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule that would remove the definition of, and modify requirements regarding, the "direct solicitation" of Medicare beneficiaries by DMEPOS providers. CMS is accepting comments on the proposed rule through **June 3, 2011**.

DMEPOS suppliers and other providers need to be aware of this proposed rule because, when finalized, it may require suppliers to modify their business practices with respect to the solicitation of Medicare beneficiaries for DMEPOS items and services.

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 by DMEPOS suppliers.[1] In that guidance, the OIG confirmed that suppliers are prohibited from making unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of covered items, except in three specific situations:

[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/fraud.asp ("2003 OIG Special Fraud Alert").

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 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 such third parties was not obtained or derived from such prohibited activity.

The OIG's guidance was reissued in January 2010. The 2010 guidance did not articulate a new interpretation of the prohibition but, rather, served to again highlight what OIG considers a fraudulent and abusive practice within the health care industry. Also in 2010, CMS issued its own guidance in the form of Frequently Asked Questions ("FAQs") regarding telemarketing practices by DMEPOS suppliers.[4]

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[2] These prohibitions on telemarketing by DME suppliers are formally outlined in Section 1834(a)(17)(A) of the Social Security Act ("Act"). Further, Section 1834(a)(17)(B) of the Act specifically prohibits payment to DME suppliers that knowingly submit claims generated pursuant to prohibited solicitations.

[3] 2003 OIG Special Fraud Alert, *supra* note 1.

[4] In these FAQs, CMS clarified several points:

- A scenario where a DME supplier is returning a beneficiary's telephone call is not considered "unsolicited contact" because the beneficiary is the one who is initiating the contact and is inviting a response from the DME supplier;
- If a physician contacts a DME supplier on behalf of a beneficiary, with the beneficiary's knowledge, and then the DME supplier contacts the beneficiary to confirm or gather information needed to provide the specific covered item—including delivery and/or billing information—such contact is not considered "unsolicited" and the beneficiary need only be aware that a DME supplier will be contacting him or her regarding the covered item prescribed by his or her physician (recognizing that the appropriate DME supplier may not have been identified at the time of consultation between the beneficiary and the physician);
- By contrast, if a DME supplier contacts a beneficiary based solely upon the physician order and, therefore, the contact is without the beneficiary's knowledge that the physician would be contacting a DME supplier on the beneficiary's behalf, such contact would be considered "unsolicited" and, depending on the facts and circumstances, may be prohibited;
- A DME supplier does not need to collect and maintain documentation from physicians reflecting that they have contacted the DME supplier with the beneficiaries' knowledge (CMS characterized it as a "business decision" to collect and obtain such documentation, but there is no affirmative duty to collect and obtain it); and
- If a DME supplier makes "solicited" contact with a beneficiary for a particular covered item, the DME supplier may not speak with the beneficiary about additional covered items during that same contact, since the DME supplier only had permission to contact the beneficiary regarding the particular covered item prescribed by the beneficiary's physician. However, once the DME supplier has provided the covered item to the beneficiary, the 15-month exception would be applicable.

Thereafter, in August 2010, CMS issued a final rule modifying the DMEPOS supplier standards at 42 C.F.R. § 424.57(c) ("Final Rule").[5] Specifically, the standard in § 424.57(c)(11) was revised to require a supplier to:

> Agree not to make a direct solicitation (as defined in § 424.57(a))[6] of a Medicare beneficiary unless one or more of the following applies: (i) [t]he 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; (ii) [t]he supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item; (iii) [i]f 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.[7]

In the preamble to the Final Rule, CMS confronted many of the same issues addressed by the OIG in its guidance. Overall, CMS's position in the Final Rule appeared consistent with the OIG's 2010 (and 2003) guidance.

What Has CMS Proposed to Change?

The proposed rule would, in part, revise the supplier standard at 42 C.F.R. § 424.57(c)(11) to modify the prohibition against DMEPOS suppliers' "direct solicitation" of Medicare beneficiaries, reverting instead to the restrictions on suppliers with regard to solicitation that were in place prior to publication of the Final Rule. The revised standard would read as follows:

> Must agree not to contact a beneficiary by telephone when supplying a Medicare-covered item unless one of the following applies: (i) [t]he individual has given written permission to the supplier to contact them by telephone concerning the furnishing of a Medicare-covered item that is to be rented or purchased; (ii) [t]he supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item; (iii) [i]f 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.[8]

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[5] 75 Fed. Reg. 52629 (Aug. 27, 2010).
[6] As defined in 42 C.F.R. § 424.57(a), the term "direct solicitation" means "direct contact, which includes, but is not limited to, telephone, computer, e-mail, 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."
[7] 42 C.F.R. § 424.57(c)(11).
[8] 76 Fed. Reg. 18472, 18474 (Apr. 4, 2011).

Significantly, the revised standard modifies the prohibition on DMEPOS suppliers soliciting Medicare beneficiaries by telephone, e-mail, instant message, or in-person, without permission. The prohibition would remain in place with respect to telephone solicitation but would be removed with respect to the other forms of communication. Although 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, this revised standard seemingly relaxes the burden currently on suppliers as a result of the Final Rule, as they attempt to provide quality care and maintain access to DMEPOS items and services for Medicare beneficiaries.

The proposed rule also would make several other modifications. First, it would allow DMEPOS suppliers, including those participating in the Program as contract suppliers, to contract with licensed agents to provide supplies, unless prohibited by state law. Additionally, the proposed rule would remove the requirement for suppliers' compliance with local zoning laws, and also would modify certain state licensing requirement exceptions for orthotics and prosthetics suppliers.

What Suppliers and Providers Need to Know

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 will fax an order to a DMEPOS company. The company then contacts the patient by phone to arrange delivery of the ordered DMEPOS item. This practice does not fit within one of the three telemarketing exceptions previously noted and, as such, remains improper according to the recent proposed rule. Thus, even in light of the proposed rule, the onus of compliance is on the DMEPOS supplier, not the physician, because it is the supplier that bills Medicare. As a result, DMEPOS suppliers need to revisit this business practice to ensure that, for any new customers, suppliers are reaching out in writing (not by telephone) to arrange delivery or work with physicians' offices to supply the necessary consent forms to new customers to streamline the delivery process.

April 2011 PAOC Meeting on the DMEPOS Competitive Bidding Program

On April 5, 2011, CMS convened a meeting of the DMEPOS Competitive Bidding Program Advisory and Oversight Committee ("PAOC") to provide an update on the impact of the Round 1 Rebid and to discuss the timeline of, and other details regarding, Round 2 of the Program.

Round 1 Rebid Update

The meeting served to emphasize that there are stark differences in perception between CMS and the industry about the progress of the Program, which began on January 1, 2011, in nine competitive bidding areas ("CBAs"). During the meeting, CMS officials stated that, during the initial three months of the Program, implementation has been smooth and there have not been major problems. According to CMS, there have been a total of only 43 complaints regarding the Program, most dealing with issues regarding mail-order diabetes supplies. CMS officials also shared that, of the 356 suppliers

participating in the Program, enforcement actions have been taken against only nine suppliers, and just three supplier terminations have resulted.

CMS also described its surveillance efforts for the Program, for which the agency has paired each of the nine CBAs with a "comparator area" to identify and examine any negative clinical changes.[9] According to CMS, the agency has seen few, if any, outcome differences using this surveillance method.

Non-CMS members of the PAOC seemed genuinely surprised by these updates, citing problems ranging from insufficient beneficiary education to an unwieldy pathway for beneficiary complaints, to a continuing resistance from CMS to release the financial standards used to determine the Round 1 Rebid bid winners. In response to these comments, CMS officials stated that, from the perspective of whether Medicare beneficiaries have had access to DMEPOS items and services, reports about the Program, to date, have indicated that the Program is running smoothly. CMS officials acknowledged, however, that they have heard concerns that the Program has been disruptive to the DMEPOS industry, and stated that one of the goals of this meeting was to hear from the industry regarding these concerns.

Round 2 Update

CMS announced at the meeting revisions to the Round 2 timeline, which is mandated by the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA") to begin in 2011.

CMS plans to announce the Round 2 product categories and begin pre-registration education for potential bidders during the summer of 2011. In the fall of 2011, CMS anticipates announcing the Round 2 bidding schedule as well as beginning bidder registration and education. Round 2 registration is expected to end in the winter of 2012, at which time the bidding window for Round 2 would open. CMS anticipates that the Round 2 bidding window would close in the spring of 2012 and, at that time, CMS would begin the bid evaluation process. Currently, CMS plans for the bid evaluation process to end in the fall of 2012, at which time CMS would announce the Round 2 single payment amounts and begin the contracting process. In the spring of 2013, CMS anticipates making announcements about the contract suppliers, and the Round 2 rates are currently targeted to take effect on July 1, 2013. CMS emphasized during the PAOC meeting that this timeline is tentative and potentially subject to further revision.

Although CMS has not yet confirmed the product categories for Round 2 of the Program, CMS announced the metropolitan statistical areas ("MSAs") for Round 2 in January 2008. The Round 2 MSAs include some of the largest beneficiary markets, including Chicago, New York City, and Los Angeles. A complete list of the Round 2

[9] The CBA-Comparator pairings are as follows: (1) Charlotte, NC-SC (CBA), and Virginia Beach, VA-NC (Comparator); (2) Cincinnati, OH (CBA), and Indianapolis, IN (Comparator); (3) Cleveland, OH (CBA), and Columbus, OH (Comparator); (4) Dallas, TX (CBA), and Houston, TX (Comparator); (5) Kansas City, KS-MO (CBA), and Oklahoma City, OK (Comparator); (6) Miami, FL (CBA), and Tampa, FL (Comparator); (7) Orlando, FL (CBA), and Jacksonville, FL (Comparator); (8) Pittsburgh, PA (CBA), and Detroit, MI (Comparator); and (9) Riverside, CA (CBA), and San Diego, CA (Comparator).

MSAs is available at http://www.cms.gov/DMEPOSCompetitiveBid. According to CMS, CBA-specific zip codes by MSA will be available sometime in the future.

What Suppliers and Providers Need to Know

Industry stakeholders already have spoken out in support of the revised timeline for Round 2 of the Program. Notably, sponsors of a bill to repeal the Program, H.R. 1041, support the planned delay of Round 2, stating that "[a]uction and bidding experts have resoundingly agreed that the program does not work. Delaying round two only kicks the can to a future date. While this is an indication that the Fairness in Medicare Bidding Act (H.R. 1041) is gaining momentum, we must continue efforts to educate policy makers here in Washington about the disastrous affects this program will have on our communities and Medicare beneficiaries."[10] The Fairness in Medicare Bidding Act calls for the immediate repeal of the Program and termination of all Round 1 Rebid contracts. As of May 2, 2011, the bill reflects Congressional support from 83 co-sponsors. To have the best chance of being successful, a companion Senate bill will need to be introduced. To date, however, a Senate champion has not stepped forward on this issue.

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*This Client Alert was authored by **Amy F. Lerman**. For additional information about the issues discussed in this Client Alert, please contact the author or the EpsteinBeckerGreen attorney who regularly handles your legal matters. Additionally, please see previous EpsteinBeckerGreen Client Alerts on the DMEPOS supplier standards and the Program. These Client Alerts are available under "News and Publications" at http://www.ebglaw.com/clientalerts.aspx.*

[10] Remarks by Congressman Glenn Thompson (R-Pa.), captured on the American Association for Homecare website, available at http://www.aahomecare.org (last viewed on Apr. 16, 2011). H.R. 1041, the Fairness in Medicare Bidding Act ("FIMBA"), was introduced by Congressman Thompson and Congressman Jason Altmire (D-Pa.) on March 11, 2011. FIMBA currently has 83 sponsors (as of May 2, 2011, per Thomas.gov), as well as support from a number of patient advocacy groups, including the ALS Association, the International Ventilator Users Network, the Muscular Dystrophy Association, the Brain Injury Association of America, the National Emphysema and COPD Association, the Christopher and Dana Reeve Foundation, the National Council on Independent Living, and the American Association for Homecare.

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