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Cold calls, hot lines: DMEPOS telemarketing and beneficiary contact

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This article is the first in a series on DMEPOS marketing compliance by Foley & Lardner published in **Compliance Today**. *Next month, the authors will develop this topic by providing a practical summary of the various telemarketing rules, strategic advice for DMEPOS telemarketing, and guidelines for applying the rules to real-world situations. Subsequent articles will discuss DMEPOS marketing arrangements under the Anti-kickback Statute, HIPAA, practical solutions for obtaining beneficiary consent to marketing, and strategies for allowable cross-promotion and co-promotion of DMEPOS items.*

Suppliers of durable medical equipment, prosthetics, and orthotic supplies (DMEPOS), whether home care companies, mail-order suppliers, or manufacturers, provide an important service to a medically-frail group of people. The Medicare population, in particular, constitutes an important customer base and a significant source of revenue for DMEPOS suppliers. Understandably, suppliers continue to seek new ways to reach out to Medicare beneficiaries and grow their customer base. However, agencies such as the Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General (OIG) have announced new restrictions on how DMEPOS suppliers can conduct telemarketing activities and solicit beneficiaries.

The Telemarketing Statute

The Telemarketing Statute[1] prohibits suppliers from making unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of covered DMEPOS items unless one of three exceptions apply. The statute does not apply if:

- the beneficiary has given the supplier written permission to contact him/her by telephone;
- the supplier has already furnished a covered item to the beneficiary and the supplier is contacting the beneficiary regarding the furnishing of that item; or
- the supplier has furnished at least one covered item to the beneficiary during the preceding 15 months, in which case the supplier may discuss or promote other covered items with the beneficiary.

A point of caution: a supplier cannot avoid application of the statute by contracting with a third-party vendor or telemarketing company. The statute also applies to vendors or agents working on the supplier's behalf. If the vendor violates the telemarketing statute, both the vendor and the supplier can be held responsible.

The penalties for violating the statute can be severe. If a supplier knowingly submits a claim for an item in violation of the statute, CMS must deny payment. Violations of the statute, particularly a pattern of violations, can expose suppliers to potential civil, criminal, and administrative penalties, including exclusion from participation in federal health care programs.

OIG Guidance and Updated Special Fraud Alert

OIG has long cautioned suppliers against improper telemarketing practices and noted, in its DMEPOS Compliance Program Guidance,[2] that suppliers are prohibited from making unsolicited telephone contact to Medicare beneficiaries. OIG also issued a 2003 Special Fraud Alert[3] reiterating the prohibition on unsolicited telemarketing. Both publications reference the Telemarketing Statute but do not expand on the scope of the statutory language.

In 2010, OIG issued an Updated Special Fraud Alert on DMEPOS telemarketing, drawing attention to the telemarketing activities of independent marketing firms that make unsolicited telephone calls on behalf of suppliers to Medicare beneficiaries to market the suppliers' products.[4] In the updated alert, OIG explained that the practice violates the Telemarketing Statute because "suppliers cannot do indirectly that which they are prohibited from doing directly." OIG has indicated that the need for the Special Fraud Alert grew directly out of ongoing enforcement activities

it was undertaking in conjunction with the Department of Justice (DOJ).

The updated alert took the position that, when a physician sends a supplier the written or verbal order for a beneficiary, and the supplier calls the beneficiary regarding that order, such telephone contact is a violation of the Telemarketing Statute. OIG reasoned that "a physician's preliminary written or verbal order is not a substitute for the requisite written consent of a Medicare beneficiary."

A number of industry representatives criticized the OIG's position, because it is common practice for physicians to send orders directly to the supplier. Requiring physicians to obtain a beneficiary's written consent for each new patient could be a challenging task, particularly because the already busy physicians have no incentive to add this step to their paperwork process. It would be similarly challenging to require the supplier to obtain the written consent. For example, it would be impractical, costly, and inefficient for a supplier, after receiving the physician order, to then mail a written authorization card to the new patient and wait for a signed response before contacting the patient by telephone to arrange for delivery of the ordered item.

From a legal perspective, it is unclear whether the OIG's expanded interpretation is adequately rooted in the language of the Telemarketing Statute and, at the time the updated alert was issued, no regulations were in place. From an operational perspective, the OIG's interpretation would likely result in significant delays before patients could receive their prescribed items, thereby limiting beneficiary access to essential Medicare-covered items.

CMS response to Updated Special Fraud Alert

A month after the OIG released its updated alert, CMS responded by issuing Frequently Asked Questions (FAQs) regarding telemarketing.[5] The CMS FAQs differed from the OIG alert, and many believed CMS took a more reasonable interpretation consistent with how the DMEPOS industry operates. The fact that CMS responded with differing guidance so quickly after the OIG's release of the Updated Special Fraud Alert suggests that OIG and CMS did not coordinate prior to the OIG release. The CMS FAQs included the following guidance:

- If a supplier returns a beneficiary's phone call, the supplier's contact is not unsolicited.
- If a physician contacts a supplier on behalf of a beneficiary and with the beneficiary's knowledge, and a supplier then calls the beneficiary to confirm or gather information needed to provide that particular covered item (including delivery and billing information), then that contact is *not* unsolicited. The beneficiary need only be aware that a supplier will be calling him/her regarding the covered item, recognizing that the appropriate supplier might not be identified at the time of the physician's consultation. This guidance provided flexibility, because the physician need not inform the patient that a specific supplier will call the patient. It also did not require a physician to obtain the beneficiary's written consent.
- If a supplier calls a beneficiary based solely on the physician order, but the beneficiary did not know a supplier would call him/her, that call would be unsolicited contact. The physician must let the beneficiary know the physician will send the order to a DMEPOS supplier and a supplier will call the beneficiary.
- A supplier is not required to collect and maintain documentation from the physician reflecting that the physician informed the beneficiary that a supplier will call. CMS stated "It would be a business decision on the part of the supplier whether to collect and obtain such documentation for their records."
- If a supplier makes solicited contact with a beneficiary for a particular covered item, the supplier cannot speak with the beneficiary about other covered items during that same contact. This generally applies to new customers because, after the supplier has provided a covered item to the beneficiary, the supplier may then subsequently contact the beneficiary to offer other covered items in accordance with the exceptions in the Telemarketing Statute.

The CMS FAQs elucidated a reasonable position consistent with existing business practices and the Telemarketing Statute, and provided useful and practical guidance to DMEPOS suppliers. OIG indicated both informally, and through a cover letter distributing the FAQs to suppliers that it would defer to these interpretations by CMS. However, the CMS FAQs differed from the OIG's published position and, moreover, CMS continued to change its position in the regulations and a second set of FAQs, as discussed in detail below.

New regulations and Preamble commentary

In August, 2010, CMS released final regulations updating the DMEPOS supplier enrollment standards.[6] The regulations introduced new telemarketing rules, imposed stricter program standards for suppliers, and implemented many of the standards in CMS' 2008 proposed regulations.[7] The regulations took effect on September 27, 2010 and all suppliers must meet these standards.

The Preamble to the regulations contains twelve comments regarding telemarketing and beneficiary contact. CMS's comments in the Preamble are consistent with its FAQs;

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namely, while a Medicare beneficiary must know that a supplier will be contacting him/her, nowhere did CMS state that the referring physician must obtain the beneficiary's written permission. For example, CMS stated:

> [A] supplier may contact a beneficiary if a physician contacts a DMEPOS supplier on behalf of a beneficiary with the beneficiary's knowledge, and then a supplier contacts the beneficiary to confirm or gather information needed to provide that particular covered item (including delivery and billing information). In that instance, the contact would not be considered a direct solicitation and therefore, would not implicate [the Telemarketing Statute].

However, CMS also stated it considers the Telemarketing Statute to apply not only to solicitation by telephone, but also by "e-mail, instant messaging, or in-person contact." That position represented a significant expansion on the statutory language. Although e-mail and instant messaging may arguably be sufficiently similar to telephone calls to be a reasonable extension of the statute, CMS offered no basis to support its position that the prohibition on *telephone contact* would also ban in-person contact. OIG has previously expressed concerns with in-person direct marketing, but that OIG position cannot serve as the basis for expanding the statute.

In addition, the regulation required that a referring physician obtain *written permission* before the supplier may contact the beneficiary. It required that "[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." (emphasis added)

Yet, the Telemarketing Statute has always held that if a beneficiary gives written permission to a supplier, the supplier may contact that beneficiary. It seemed to many that the language "or the ordering physician or non-physician practitioner" was misplaced and did not belong in the regulation because it meant a physician must obtain written permission (not simply inform the beneficiary) before the supplier could contact the beneficiary.

CMS could have expressed a more consistent position by deleting the language "or the ordering physician or non-physician practitioner." Suppliers could then refer to the Preamble to understand that the beneficiary must know that a supplier will contact him/her. This approach would have remedied the inconsistency between the regulations and the FAQs and Preamble, and provided clear instruction to suppliers who receive orders from referring physicians. This approach would also have been also consistent with current industry practices and standards. Instead, the regulation triggered the same concerns as the OIG's Updated Special Fraud Alert, and suppliers were concerned that a requirement for written permission would be burdensome, costly, and cause potential delays for Medicare beneficiaries.

CMS 2011 FAQs

CMS received a number of critical responses to the regulations and, in January 2011, issued updated FAQs addressing the industry queries.[8] For suppliers, these 2011 FAQs were even more problematic than the regulations. CMS seemed to take some inexplicable and highly unfavorable positions regarding telemarketing and beneficiary contacts, including:

- The 2011 FAQs expanded telephone contact to include mailings made through the US Post Office. The 2011 FAQs prohibit "targeted mailings to specific beneficiaries," although "general mass advertising" is allowed. CMS offered no explanation of what those terms mean or how the Telemarketing Statute could apply to direct mail.
- A supplier may not contact a beneficiary based solely on a physician order unless the physician obtains the beneficiary's written permission. This position is consistent with the language of the regulation, but differs from the guidance in CMS' previous FAQs.
- If a supplier makes solicited contact with a beneficiary for a particular covered item, the supplier cannot speak with the beneficiary about other covered items during that same contact. This position is largely consistent with CMS' previous FAQs.
- For companies with multiple subsidiaries, if one subsidiary is permitted to contact a beneficiary (e.g., by written permission or by previously providing covered items), a related company under the same parent corporation may not make contact without separately meeting one of the exceptions in the Telemarketing Statute. Even if all the subsidiaries are enrolled DMEPOS suppliers, CMS seems to view each as a separate entity and require each to meet an exception to the Telemarketing Statute in order to contact beneficiaries.

Rather than providing clarity, the 2011 FAQs served to increase confusion about CMS' restrictions on telemarketing and beneficiary solicitation.

Revised regulations

On April 4, 2011, CMS released a proposed rule revising supplier standards, particularly supplier standard 11.[9] CMS acknowledged that its expanded interpretation had been criticized as overly broad and prohibited marketing activities in a manner that would be unfeasible for DMEPOS suppliers to

implement. CMS indicated that it will further investigate how to address its concerns of abusive DMEPOS marketing practices. In the interim, CMS will instruct its contractors to apply the restrictions on telephone solicitation that were in effect prior to the August 2010 regulations (rather than all types of beneficiary solicitation and contact).

The current proposed rule deletes the reference to direct solicitation and instead focuses on telemarketing, tracking the exceptions under the Telemarketing Statute. It also deletes the language that requires a referring physician to obtain the beneficiary's written permission. CMS did not include any comments regarding its 2010 or 2011 FAQs, nor how suppliers should interpret the proposed regulations in light of those FAQs , nor which FAQs still remain in effect.

Conclusion

The changing landscape and conflicting guidance has led to much confusion among DMEPOS suppliers regarding telemarketing and beneficiary solicitation. Penalties for failing to comply with the telemarketing rules are severe. Because these rule changes have a significant impact on suppliers' business operations and marketing efforts, it is imperative for suppliers that serve Medicare beneficiaries to be aware of the restrictions. Despite the confusion, the various guidance can be boiled down into a manageable set of practical rules suppliers can use in their marketing activities, particularly as new communication technologies and marketing approaches change these activities. Next month's article will set forth those practical rules, apply them to a series of real-world DMEPOS marketing situations, and highlight key opportunities and approaches suppliers can take while still complying with the telemarketing and beneficiary solicitation rules. ■

1. Section 1843(a)(17)(A) of the Social Security Act; 42 U.S.C. § 1395m(a)(17)(A).
2. 64 FR 36368, 36380 (July 6, 1999).
3. 68 FR 10254 (Mar. 4, 2003).
4. 75 FR 2105 (Jan. 14, 2010).
5. Available at www.cms.gov/MedicareProviderSupEnroll/Downloads/DME%20Supplier%20Telemarketing%20FAQ.pdf.
6. 75 Fed. Reg. 52629 (Aug. 27, 2010).
7. 73 Fed. Reg. 4503 (January 25, 2008) (proposed rules); 42 C.F.R. § 424.57(c) (supplier standards).
8. Available at www.palmettogba.com/Palmetto/Providers.Nsf/files/FAQS6036FINAL.pdf/$File/FAQS6036FINAL.pdf.
9. 76 Fed. Reg. 18472 (April 4, 2011)