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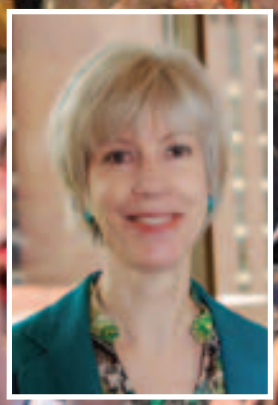

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Compliant DMEPOS telemarketing: Strategic approaches and practical tips

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This article is the second in a series on DMEPOS marketing compliance by Foley & Lardner LLP published in **Compliance Today**. *This month, the authors provide a practical summary of the Medicare DMEPOS telemarketing rules, offer strategic advice and opportunities regarding DMEPOS telemarketing, and apply the rules to real-world situations. Subsequent articles will discuss marketing arrangements under the Anti-kickback Statute and HIPAA; practical solutions for obtaining beneficiary consent to marketing; and strategies for allowable cross-promotion and co-promotion of DMEPOS items.*

Part 1 of this series (published in the May 2011 issue of **Compliance Today**) explained the statutory and regulatory requirements relating to durable medical equipment, prosthetics and orthotics supplies (DMEPOS) telemarketing and beneficiary solicitation under the Medicare regulations and guidance. This article covers how that guidance is transformed into a manageable set of rules and applied to a number of real-world DMEPOS marketing situations. Suppliers will learn: (1) what is allowed and prohibited under the telemarketing and beneficiary contact rules; (2) advice to ensure compliance with these rules; (3) strategic marketing opportunities for suppliers; and (4) practical solutions and real-world examples of permissible telemarketing and beneficiary contact activities.

Enforcement of telemarketing rules

Complaints about telemarketing practices filter into a number of different regulators and law enforcement agencies. We are aware of criminal investigations by the Department of Justice (DOJ) of some suppliers and their marketing vendors related to allegations of cold-calling Medicare beneficiaries. The Office of the Inspector General (OIG) settled a Civil Monetary Penalties case in 2009 with Matrix Diabetics, Inc., a Florida distributor of blood glucose testing supplies. The former owners and officers of the DMEPOS company agreed to pay $260,000 for allegedly paying telemarketing firms to make unsolicited telephone calls to beneficiaries to market DMEPOS items on behalf of the company. The company in turn submitted claims for these items for Medicare reimbursement.[1]

Medicare's Zone Program Integrity Contractors (ZPICs) have also made outreach through letters to suppliers alerting them to complaints of violations of the Telemarketing Statute. The volume of these enforcement activities and the number of different agencies involved highlight that the risk to suppliers who violate the Anti-kickback Statute is real, not hypothetical.

Rules for DMEPOS telemarketing and beneficiary solicitation

DMEPOS suppliers may not make unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of covered items, unless:

- the beneficiary first calls the supplier or initiates contact, and the supplier is responding to that contact;
- the beneficiary gave the supplier written permission to contact the beneficiary;
- the supplier has already furnished a covered item to the beneficiary and the supplier is contacting the beneficiary regarding the furnishing of that same 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.[2]

Although these summarized rules may seem simple enough, they can become complicated and nuanced when applied to real-world DMEPOS marketing situations. The table on page 56 applies the telemarketing rules to a number of DMEPOS situations.

Suppliers should keep in mind, however, there are a number of other federal and state laws that impose restrictions on telemarketing in general (e.g., the Federal Trade Commission's Telemarketing Sales Rule and state restrictions on telemarketing) and to Medicare beneficiaries in particular (e.g., HIPAA, the Anti-kickback Statute, and the Civil Monetary Penalties Law, including the provisions on beneficiary inducements). Those laws intersect with DMEPOS marketing and must also be considered, but the scope of this article is limited to the Medicare rules on telemarketing and beneficiary solicitation.

Contracting with third-party vendors and telemarkers

Third-party vendors and telemarketing companies are commonly used vehicles for marketing and customer outreach. DMEPOS suppliers may engage these vendors, but should understand that if the vendor violates the Telemarketing Statute, the supplier can be held responsible and face severe sanctions for the vendor's conduct. For this reason, suppliers who choose to contract with these vendors should include oversight provisions in their vendor contracts, under which the vendor agrees to adhere to the telemarketing rules applied to Medicare beneficiaries and patients in general. This is important because many vendors, particularly those who deal with a broad spectrum of customers beyond solely Medicare beneficiaries, are unaccustomed to these restrictions. In addition to the contractual language, suppliers should be diligent in ensuring the vendor is complying with those restrictions.

Written policies and procedures

Suppliers should have written policies and procedures in place to delineate the steps the supplier will take to promote compliance with the Medicare supplier standards and the Telemarketing Statute. The written policy should clearly state that the supplier's employees, as well as individuals and entities working on the supplier's behalf, are prohibited from making unsolicited contact with Medicare beneficiaries unless one of the statutory exceptions apply. The written procedure should include a step-by-step process for contacting current and prospective customers. It should be written in a manner employees can easily understand and follow, and should be tailored to the supplier's specific business practices. As with all compliance policies and procedures, it should be reviewed periodically and updated as needed to comply with changes in the law and the supplier's operational requirements.

Documentation advice and approaches

The original Centers for Medicare and Medicaid Services (CMS) Frequently Asked Questions (FAQs) took the position that a supplier need not collect and maintain documentation from the physician reflecting that the

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Table 1: DMEPOS Medicare Telemarketing and Beneficiary Solicitation	
Telemarketing Situation	**Allowed Under Telemarketing Rules?**
A physician sends the supplier a work order for a new patient. The patient is informed that a supplier will contact him, but does not sign a written permission form. The supplier then calls the patient.	No, because the current regulations require the beneficiary's written permission. Under the proposed rule, this would be allowed.
A physician sends the supplier a work order for a new patient and checks a box attesting that the patient has given written permission to contact. The supplier then calls the patient.	Yes, but only if the beneficiary actually gave written permission. Because the supplier does not know whether or not the beneficiary actually gave written permission, this situation presents a high level of risk and is not recommended. Under the proposed rule, this would be allowed, but the proposed rule does not require the patient to give written permission.
A physician sends the supplier a work order for a new patient, along with the patient's signed written permission to contact. The supplier then calls the patient.	Yes, because the beneficiary gave written permission. Under the proposed rule, this would be allowed, but the proposed rule does not require the patient to give written permission.
A physician sends the supplier a work order for a new patient, along with the patient's signed written permission to contact. The order is for home oxygen equipment. The supplier calls the customer and promotes/discusses other items (e.g., ventilator or respiratory assist devices).	No, because the scope of consent was limited only to those items in the physician order. If this is the first contact ever made by the supplier to the beneficiary, the supplier may not attempt to solicit the purchase of additional covered items. After the supplier provides the covered items to the beneficiary, the supplier may then promote additional products.
A potential customer sees the supplier's television commercial and places a call to a third-party vendor handling responses to the commercial. The vendor then transfers the patient to the supplier (i.e., a warm transfer).	Yes, because the beneficiary initiated contact.
A potential customer finds the supplier's Internet site and completes an online form asking the supplier to contact him. The supplier then calls the customer.	Yes, because the beneficiary initiated contact. The supplier should verify that the language of the online consent is adequate. Also a two-step process (e.g., two clicks to submit) is advised to guarantee the customer's willful consent and to serve as an online signature.
A potential customer finds the supplier's Internet site and completes an online form asking the supplier to contact him. Although there are a number of possible areas of interest, the customer only checks the "wound care" box as his interest. The supplier calls the customer and promotes/discusses other non-wound care items (e.g., crutches and ambulatory equipment).	No, because the beneficiary gave consent only to wound care supplies. If this is the first contact ever made by the supplier to the beneficiary, the supplier may not attempt to solicit the purchase of additional covered items because the supplier only had permission to contact the beneficiary regarding the particular covered items ordered. After the supplier provides the covered item to the beneficiary, the supplier may then promote additional products.
A potential customer sees the supplier's television commercial and places a call to the supplier, leaving a voicemail message. The supplier then calls the customer the next day.	Yes, because the beneficiary initiated contact.
A hospital care coordinator sends the supplier an enrollment form for the patient to coordinate the patient's discharge orders. The patient previously gave the hospital written permission or the patient signs the form to give permission for a supplier to contact him. The supplier then calls the patient.	Yes, because the beneficiary gave written permission. Under the proposed rule, this would be allowed, but the proposed rule does not require the patient to give written permission.

Table 1 continued

Telemarketing Situation	Allowed Under Telemarketing Rules?
A hospital care coordinator sends the supplier an enrollment form for the patient to coordinate the patient's discharge orders. The patient is informed that his care is being coordinated through the supplier, but has not given any written permission. The supplier then calls the patient.	No, because the current regulations require the beneficiary's written permission. The Preamble to the regulations explains that, if hospital staff obtain a patient's written consent, the hospital may order supplies on the patient's behalf. The patient's written permission need not be on the enrollment form itself, but could be on another document. Under the proposed rule, this would be allowed because the proposed rule does not require the patient to give written permission.
A DMEPOS manufacturer receives an order from a physician, with the proper patient written permission. After calling the patient, the manufacturer determines it does not provide the items directly to patients, so the manufacturer sends the order to the supplier. The supplier then calls the patient.	Yes, this is potentially allowed because the beneficiary gave written permission. However, it depends on the scope of that permission. If the permission form allows phone contact by "a supplier," it is probably acceptable. If the permission form allows a call only by the particular manufacturer, the supplier should not call the patient.
A DMEPOS manufacturer receives a call from a patient asking about how to get the manufacturer's DMEPOS supplies. The manufacturer then transfers the patient to the supplier (i.e., a warm transfer).	Yes, because the beneficiary initiated contact.
The supplier hosts a health fair or community event. A potential customer visits the event and gives his information on a written card, giving permission for the supplier to contact him. After the event, the supplier calls the customer.	Yes, because the beneficiary gave written permission. In addition, health fairs and community events are permissible methods of beneficiary contact.
The supplier hires a third-party vendor to use door-to-door salespeople to reach out to beneficiaries.	No, because under the current regulations, CMS expanded the telemarketing and beneficiary contact restrictions to include in-person contact. The proposed rule deletes this restriction.
The supplier mails a card to a large number of potential customers who are Medicare beneficiaries. After receiving the card, a potential customer places a call to the supplier.	Yes, this is probably allowed because the beneficiary initiated contact and the supplier's contact was sent by mail to a large number of customers. CMS' 2011 FAQs state that "targeted mailings to specific beneficiaries are prohibited," but that "general mass advertising through the post office" is allowed." However, neither the regulation nor the statute expressly encompass direct mail and CMS has not explained the basis for its authority to expand the Telemarketing Statute into direct mailings. There are arguments that the telemarketing rules should not apply to direct mailings. The proposed rule deletes this restriction.
The supplier mails cards to a group of potential customers who are Medicare beneficiaries. A potential customer fills in his phone number and mails back the card, indicating his interest in being contacted about the supplier's services. The supplier then calls the customer.	Yes, this is probably allowed because the beneficiary initiated contact and the supplier's contact was sent by mail. A customer signature field on the card, if not per se required, is a best practice and the recommended approach. The supplier should ensure the customer signed the card before telephoning the customer.

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physician contacted the supplier with the beneficiary's knowledge. CMS stated "it would be a business decision on the part of the supplier whether to collect and obtain such documentation for their records." Even if it is not per se required that a supplier collect and maintain a copy of that documentation, the compliance risks are too high for a supplier not to take steps to ensure the beneficiaries gave their written permission (under the current regulation) or were made aware that a supplier would be contacting them (under the proposed rule).[3]

However, deciding to collect the documents is a far easier task than actually doing so, and suppliers understandably face a challenge in operationalizing this documentation requirement. One approach might be to build it into the supplier's physician work order. The revised work order would include a check box where the physician affirms he or she has obtained the patient's written permission for the supplier to contact the patient. This alone is likely not adequate under the current regulations, but it can serve as a reminder to the physician that he or she must obtain the beneficiary's written permission (or inform the beneficiary, under the proposed rule). The check box represents an affirmative effort by the supplier to help ensure compliance with the Telemarketing Statute and supplier standard number 11. This is a beneficial tool designed to protect the supplier in the event a patient complains that the supplier violated the Telemarketing Statute. On the other hand, if the physician submits a work order without checking the box, it might suggest the patient did not give permission, and could require additional back-and-forth with the physician to obtain such.

Another approach would be to update the existing physician work order to include a signature portion where the patient authorizes the supplier to contact him/her. The patient would sign that portion in the physician's office. This approach allows the supplier to obtain the beneficiary's explicit written permission in accordance with the current regulations. But, having a patient sign a physician work order is very unusual, and the same risks apply if the physician forgets to have the patient sign the work order. Moreover, under the proposed rule, the patient is not required to give his or her written permission.

A third approach would be to create an authorization form/response card and mail it to the beneficiary immediately upon receipt of the written order for a new patient. Once the beneficiary signs and returns the authorization card, the supplier can telephone the patient. The response card could also ask the patient to call the supplier and discuss the order. This approach could be a potential fail-safe in the event a supplier receives a work order without the beneficiary's written permission (or physician attestation that the beneficiary knows a supplier will call him or her). But, from an operational perspective, mailing a card and waiting for the response would likely cause unacceptable delays in sending the patient his/her medically-necessary items.

A fourth approach would be to create a complete authorization form and provide it to the supplier's referring physicians. The physician would have the patient review and sign the form during the office visit. The physician would then send the signed authorization form along with the work order. Once the supplier receives the signed authorization form, the supplier could contact the patient.

This approach imposes the greatest operational burden on suppliers and physicians, because it requires a separate document in addition to the existing paperwork physicians must send to suppliers. However, it is probably the most comprehensive practice because it most clearly satisfies the current regulations (though this should not be necessary under the proposed rule).

DMEPOS advertisements in Internet, television, and new media

Although the current regulations and guidance purport to restrict communications through certain new technologies such as e-mail, instant messaging, and text messages, the Internet remains—at least to a certain degree—fair game. In 2008, CMS drafted a proposed prohibition on "coercive Internet advertising," but did not include it in the 2010 final regulations. The revised DMEPOS supplier standards do not prohibit television, radio, or Internet advertisements, or advertisements at health fairs, community events, or the supplier's own website.[4] Implementing and enforcing a restriction on Internet advertising might be (for the time being) too difficult and costly for CMS or the OIG to manage. In addition, media such as television and the Internet can be considered advertisements to the public or to Medicare beneficiaries generally.

The fact that the Telemarketing Statute does not apply to Internet advertisements may potentially open some opportunities for savvy suppliers who are interested in using social media tools to promote their products. For example, a supplier might consider using Google's sponsored searches so their website appears at the top when someone enters a search for "Medicare prosthetic arm." Sponsored searches are not new, and are permitted under the new regulation. But, for something more cutting-edge, suppliers might consider other Internet advertising methods, such as Facebook.

The Facebook advertisement tool allows someone to publish their advertisement to a certain segment of Facebook users, narrowed by the users' demographics and stated interests. For example, a diabetes supplier might want to place a Facebook advertisement, requesting that the advertisement only be displayed to Facebook users who are over 65 years old and who have an interest in diabetes or who "like" the American Diabetes Association. New Internet advertising approaches such as these can potentially pose a higher level of compliance risk, because the advertisements are targeted toward a specific group of people, rather than Medicare beneficiaries generally. The more specific and targeted the advertisement, the more likely CMS or OIG will find it objectionable. And yet, the Facebook advertising tool is still a "passive" advertisement in that it is placed on a webpage and not directly sent to a beneficiary by telephone, e-mail, instant messaging, or in-person contact (the four CMS-defined methods of direct solicitation). Unless and until CMS issues further guidelines on Internet advertising, the landscape of opportunities and risk remains largely uncharted.

Conclusion

The telemarketing and beneficiary contact rules have a significant impact on a DMEPOS supplier's operations because the restrictions go to the lifeline of a supplier's business: the customers. The April 4, 2011 proposed rule helps to make these restrictions more workable and better reflect industry practices. Yet, it remains essential for DMEPOS suppliers to understand the applicable restrictions and build operational and procedural safeguards to promote compliance, while also having a keen knowledge of the marketing opportunities that can be pursued. ■

1 See www.oig.hhs.gov/fraud/enforcement/cmp/false_claims.asp.
2 As explained in the previous article, John Spiegel, Director of CMS' Program Integrity Group, stated on January 19, 2011 that CMS "does not intend to instruct Medicare contractors to implement the expanded provision" of the telemarketing regulations. The telemarketing rules may change depending on CMS' subsequent actions.
3 The differences between the current regulation and the proposed rule were discussed in last month's issue, particularly the proposed change in the written permission requirement. See also 76 Fed. Reg. 18472 (Apr. 4, 2011).
4 75 Fed. Reg. 52629, 52638-9 (Aug. 27, 2010).