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For more information contact

Neil B. Caesar, 864-676-9075

Health Law Center Finds "Back-Door" Solution for Supplier Standard 11 Prohibition on Patient Contact after Physician Referrals

(Greenville, SC – March 21, 2012) – Centers for Medicare and Medicaid Services (CMS) issued a final rule on March 14 which modified yet again the DMEPOS Supplier Standards. According to the Health Law Center (HLC), a national law firm headquartered in Greenville, South Carolina, the final rule clarifies and retracts a number of recent changes to the Supplier Standards which caused confusion and controversy. However, Neil B. Caesar, Esq., President of the Health Law Center, argues that some significant confusion remains regarding a supplier's ability to contact a patient following a physician referral. "In some ways, CMS' attempt to fix this confusion has made it worse," notes Caesar. "But I think we have figured out what CMS is trying to say here. I hope so."

"Anti-Solicitation" Standard 11 Shrinks to Original Scope, Prohibiting Unsolicited Telephone Contact Only.

Prior to August 27, 2010, the Supplier Standard 11 prohibited the direct telephonic solicitation of Medicare beneficiaries by DMEPOS suppliers unless one of three exceptions applied: 1) The beneficiary gave written consent to the solicitation; 2) the contact involved an item already ordered for the beneficiary; or 3) the beneficiary received a covered product from the supplier during the prior 15 months, and the solicitation involved a different covered product. CMS expanded the scope of this provision in its August 27, 2010 rulemaking, to

include in-person contact, email and instant messaging. Subsequently, according to CMS, it "discovered that implementation of the expanded portions of this provision as written was unfeasible," primarily because it was "overly broad" and prohibited some forms of marketing activity beyond CMS' intended scope. "CMS declined to state what sort of overly broad activities were captured by the too broad language" observes Caesar.

To fix this problem, in the March 14, 2012 final rule CMS removed its definition of "direct solicitation" from the Standard, as well as all language that broadened the scope of the prohibition. "Once again, the Standard only prohibits uninvited solicitation by telephone," states Caesar.

Physician Referral Confusion Remains

According to Mr. Caesar, the 2010 changes to Standard 11 went beyond the issue of direct solicitation and also added new language prohibiting unsolicited patient contact after physician referrals. "Unfortunately, the March 14, 2012 final rule did not change the physician referral patient solicitation language," states Caesar. "But careful reading of CMS' commentary on this point indicates that CMS will not enforce this prohibition, as long as certain safeguards are present."

Specifically, Standard 11 still states that a DMEPOS supplier may not contact a beneficiary based on a physician's oral order, unless one of the three exceptions listed above applies (written consent, already-ordered item, 15 month window). According to Caesar, this requirement for written consent created a cumbersome and frequently impractical burden. Suppliers have repeatedly asked CMS to modify Standard 11 so as to allow suppliers to contact

Medicare beneficiaries upon receipt of a written or oral prescription or prescriber order, as long as beneficiary has been made aware that a supplier will contact the beneficiary.

In its comments to the March 14 final rule, CMS stated that it was not presently allowed to change this portion of Standard 11, because CMS "did not specifically solicit comments on [the physician referral] proposed change ... ." Nonetheless, according to the Health Law Center, analysis of the CMS commentary to the March 14 final rule indicates that CMS does not intend to enforce the "written consent" requirement as regards the physician referrals. In the March 14 comments, CMS repeated what it stated in the 2010 final rule on this topic:

> "... If a physician contacts the supplier on behalf of the beneficiary's [sic] 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 the delivery and billing information), then that contact would not be considered a direct solicitation for the purpose of this standard. This is the case even if the physician has not specified the precise DMEPOS supplier that will be contacting the beneficiary regarding the item referred by that physician."

CMS then followed this 2010 quote with the following: "The quoted verbiage still reflects our policy with regard to this provision."

The March 14 commentary also includes CMS' response to a commenter who stated that CMS also allowed solicitation of physician referred patients in CMS' 2010 Frequently Asked Questions (FAQ) #3, regarding what constitutes "unsolicited contact" with a beneficiary. CMS,

after paraphrasing that commenter in the March 14 final rule, stated that its 2010 response to that question was:

> "If a physician contacts a 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), then that contact would not be considered "unsolicited." Please note that the beneficiary need only be aware that a supplier will be contacting him/her regarding the prescribed covered item, recognizing that the appropriate supplier may not have been identified at the time of consultation."

Caesar points out that CMS did not clearly affirm this 2010 FAQ in its March 12, 2012 response, nor did it repudiate it. Instead, CMS rather obliquely stated that it addressed these concerns in its Frequently Asked Questions section on the website, found by clicking on "DME Supplier Telemarketing Frequently Asked Questions." Unfortunately, CMS' citation to its website is wrong; not only does CMS' link not take you to the correct document, but the current DME telemarketing FAQs no longer includes a FAQ regarding beneficiary contact after physician referrals. The language quoted by CMS in the March 14, 2012 comments, supposedly from Frequently Asked Question #3, is not currently found at the location cited by CMS. "I do not know whether CMS removed that language at some point," Caesar speculates, "but CMS' inattention to detail here has created unnecessary confusion for DMEPOS suppliers."

Nonetheless, Caesar believes that the correct interpretation of the commentary in the March 14 final rule is that written patient consent is not necessary for a supplier to follow up a physician referral. The supplier may contact the beneficiary to confirm or gather information, as

long as the physician has contacted the supplier on behalf of the beneficiary with the beneficiary's knowledge. "CMS created ambiguity with its comments, and confusion with its inaccurate citations, but none of that actually contradicted CMS' position on this point," suggest Caesar. "It seems to be more a problem of inattention and imprecision, rather than contradictory policy."

The Health Law Center recommends that DMEPOS suppliers who contact a beneficiary after a physician referral begin the conversation by confirming that the patient knew that a supplier would be in contact and consented to such contact. In the event of any ambivalence or confusion by the patient, the supplier should terminate the conversation and have the physician's office reconnect with its patient to confirm the consent to supplier contact. "It is also smart for the supplier routinely to document this portion of the patient's conversation," suggests Caesar, "as evidence that the patient has confirmed his or her consent."

Along these lines, CMS also stated in the March 14 commentary regarding Standard 11 that, "we believe it is important that there be a documented record of the beneficiary's approval of the contact." "A 'documented record' is not the same thing as 'written consent,'" observes Caesar. He believes that this language may open the door to CMS approval of internet consent, such as by clicking on an "I Consent To Contact" box on a website, as long as certain other safeguards are present. "Indeed," suggests Caesar, "the Electronic Signatures in Global and National Commerce Act (E-Sign Act) may itself allow internet consent, contrary to CMS' ostensible position on this point. This means that a supplier's preferred course of action must be carefully considered."

The March 14 final rule also made clarifying corrections to the prior Supplier Standards 1 (regarding employment of licensed personnel; also, compliance with local zoning requirements); Standard 7 (exception to 200 square feet size requirement for orthotic and prosthetic locations); and Standard 30 (exception to 30 office hours weekly for certain outpatient physical therapy and occupational therapy services).

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*The **Health Law Center** is a national health law practice in Greenville, SC. It focuses on business opportunities and regulatory issues for homecare providers.*

Neil Caesar is an attorney with the Health Law Center (Neil B. Caesar Law Associates, PA), a national health law practice in Greenville, SC. The firm may be contacted at1200 Woodruff Road, Building A-3, Greenville, SC 29607, 864-676-9075, Fax: 864-297-8725, Email: info@healthlawcenter.com; Website: www.healthlawcenter.com.