

## **CMS Changes Rules Regarding Use of “Consignment Closets”**

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CMS recently issued a change request which will amend the Medicare Program Integrity Manual to prohibit the use of certain “consignment closet” and “stock and bill” arrangements commonly utilized by durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers. Specifically, DMEPOS suppliers will no longer be able to maintain an inventory at a health professional’s office and bill Medicare beneficiaries for the supplies distributed by health professionals from the inventory.

DMEPOS suppliers will still be permitted to maintain an inventory at a health care professional’s office, but only under the following limited circumstances:

- The title to the DMEPOS is transferred to the health care professional at the time the DMEPOS is furnished to the beneficiary;
- The health care professional bills the patient for the DMEPOS supplies using the health care professional’s own enrolled DMEPOS number;
- Services related to the fitting or use of the DMEPOS are performed by individuals being paid by the health care professional and not by any other DMEPOS supplier; and
- The beneficiary should be directed back to the health care professional for any questions or problems regarding the DMEPOS.

The National Supplier Clearinghouse Medicare Administrative Contractor (NSC-MAC) has been charged with verifying that two or more DMEPOS suppliers are not located at the same practice location. A separate practice location is defined as a location with a separate entrance and a separate post office address.

According to the change request, the reason for this change was that most “consignment closets” or “stock and bill arrangements” were not in compliance with the DMEPOS supplier standards set forth in 42 CFR §424.57. Although CMS did not indicate which standards were problematic, it is likely that DMEPOS suppliers utilizing consignment closets were determined in some instances not to meet requirements to “enroll separate locations it uses to furnish Medicare covered DMEPOS” or the requirement that it “fills orders, fabricates, or fits items from its own inventory . . . .”

The Office of the Inspector General (OIG) for the Department of Health and Human Services (HHS) has also long been concerned about the use of “consignment closets”. Specifically, the OIG has expressed concern that DMEPOS suppliers were using payments for “consignment closets” and associated services as a vehicle to compensate physicians for access to the supplier’s patient base. For example, rent that is less than fair market value or payment for “management services” to physician offices that does not serve a legitimate business purpose have been cited by the OIG as potential anti-kickback violations in Advisory Opinions, Special Fraud Alerts and the DMEPOS Supplier Compliance Guidance.

Even if arrangements meet the current requirements, there may still be fraud and abuse concerns associated with the use of consignment closets. For example, to the extent that DME companies offer “discounts” on supplies to physicians, such discounts should be appropriately reported to Medicare. Arrangements between DMEPOS suppliers and health care providers should also be carefully analyzed to determine whether they could be construed as being a prohibited “contractual joint venture” that would violate the anti-kickback statute.

The OIG has identified certain characteristics that it considers to be “suspect” and potentially indicating an arrangement that would violate the anti-kickback statute. Some of these “suspect” characteristics that might be applicable to an arrangement between a DMEPOS Supplier and a health professional include:

- The health professional expands into a new health care service, i.e., DMEPOS, which is intended to predominately serve the health care professional’s existing patients with no effort to expand the business to a new customer base.
- The health professional enters into the venture with a DMEPOS supplier who would otherwise be its direct competitor.
- The health professional makes little or no financial investment, with its sole contribution to the venture being access to its patient base.
- The DMEPOS Supplier operates the venture and contributes the financial investment.
- The health professional’s remuneration is tied to the volume or value of patient referrals from the health professional’s patient base.

While all of these factors are illustrative of a suspect contractual arrangement, no one factor is considered determinative.

While the change request does not impact the use of consignment closets in hospitals, the anti-kickback concerns remain the same. Providers who currently utilize “consignment closets” or “stock and bill arrangements” in any setting should have these arrangements

reviewed by healthcare counsel for compliance with the new requirements, as well as the DMEPOS certification standards, the anti-kickback statute and the Stark regulations.



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