

**Summary of Transmittal 297 (Aug 7, 2009):  
Compliance Standards for Consignment Closets and Stock and Bill Arrangements**

By Jeffrey S. Baird, Esq. and Phuong D. Nguyen, Esq.  
Brown & Fortunato, P.C.

On August 7, 2009, the Centers for Medicare and Medicaid Services (CMS) issued Change Request 6528, Transmittal 297, which adds a section to the Medicare Program Integrity Manual (PIM) addressing consignment closets and stock and bill arrangements. The stated purpose of the Transmittal is to “define and prohibit certain arrangements where an enrolled supplier of ... (DMEPOS) maintains inventory at a practice location which is ... owned by a physician, non-physician practitioner or other health professional.” The Transmittal is also intended to define “specific compliance standards for NSC-MAC [National Supplier Clearinghouse-Medicare Administrative Contractor] validation” of consignment closets. The changes outline in the Transmittal will be effective September 8, 2009.

The new PIM provisions state that “most consignment closets or stock and bill arrangements do not satisfy the DMEPOS supplier standards” and allow a supplier to maintain inventory at a practice location owned by a physician or non-physician practitioner only when certain conditions are met. A non-physician practitioner includes physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, clinical psychologists, and registered dietitians or nutrition professionals. For this article, we use the term “practitioner” to collectively refer to physicians and non-physician practitioners. The conditions the foregoing consignment arrangement must meet are the following:

1. Title to the DMEPOS is transferred to the practitioner at the time the item is furnished to the patient;
2. The practitioner bills Medicare for furnishing the item under his, her, or its own DMEPOS billing number;
3. All services concerning fitting or use of the item are performed by individuals being paid by the practitioner (and not by any other DMEPOS supplier); and
4. The patient is advised to contact the practitioner concerning problems or questions regarding the DMEPOS item.

We note that under such an arrangement, the supplier is limited to the role of a vendor to the practitioner. In addition to the above, the NSC-MAC will also verify that two or more Medicare-enrolled DMEPOS suppliers are not enrolled or located at the same practice location. A practice location must have a separate entrance and United States Post Service post office address.

The consignment arrangement permitted under the new PIM provisions is of limited value, for the provision of DME, due to the requirements of the Stark law. Briefly, Stark prohibits a

physician from referring patients to entities for the furnishing of designated health services (which includes DME), if the physician (or an immediate family member of the physician) has a financial relationship with the entity, unless a Stark exception applies. There is an exception to Stark for “in-office ancillary services,” but that exception is only applicable to limited items of DME (i.e., canes, crutches, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps). Under Stark, a physician may furnish prosthetics and orthotics under the in-office ancillary exception, because prosthetics and orthotics are not DME.

The Transmittal references consignment arrangements with a physician, non-physician practitioner or other health care professional. The new PIM provisions reference arrangements only with physicians and non-physician practitioners, with no inclusion of “other health care professional,” which is not a defined term. Therefore, it appears that consignment closet and stock and bill arrangements with hospitals, sleep labs, or other Medicare non-practitioner providers are not subject to the new PIM provisions. We will seek clarification from CMS regarding consignment arrangements involving non-practitioner entities.

The new PIM provisions state that “most consignment closets or stock and bill arrangements do not satisfy the DMEPOS supplier standards,” but then fails to identify which standards are not being met or why. For this reason, even though the new PIM provisions appear not to apply to consignment arrangements with hospitals, sleep labs, or other Medicare non-practitioner providers, entities involved in consignment arrangements should not assume the Transmittal, or further CMS action, will not impact these arrangements.

The new PIM provisions state that the parties to a consignment arrangement will be held responsible for compliance with the new section of the manual. Also, the conditions that the consignment arrangement must meet are subject to verification by the NSC-MAC. This suggests that CMS may require DMEPOS suppliers to report any consignment arrangements entered into by the suppliers.