AHLA **PG Briefing**

Navigating the Regulatory Maze in Hospital-Supplier "Stock and Bill" Arrangements

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–From a declaration of the American Bar Association.

A “stock and bill” or “consignment closet” arrangement refers to an arrangement between a durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) supplier and a hospital or physician practice where certain of the DMEPOS supplier’s inventory is stored at the hospital or physician practice, dispensed[1] to patients as needed, and billed by the DMEPOS supplier. These arrangements are convenient for both the patients and the hospital or physician practice. They also present regulatory issues that must be considered. This article focuses on structuring hospital stock and bill arrangements in light of the Medicare requirements that apply to hospitals and DMEPOS suppliers.[2]

In order to satisfy the Medicare enrollment requirements and space-sharing prohibitions applicable to both hospitals and DMEPOS suppliers described below, it is important that the stock and bill arrangement not be deemed to constitute a new DMEPOS supplier location in the hospital. This requires the space remain as hospital space under the control of the hospital at all times. The arrangement should also be structured consistent with the favorable Department of Health and Human Services Officer of Inspector General (OIG) guidance discussed below. Specifically, the stock and bill arrangement should not contemplate rent for the space and no remuneration should flow from the DMEPOS supplier to the hospital. In addition, patients should be given the choice of alternative DMEPOS suppliers and the details of the arrangement should be memorialized in a written agreement signed by both parties that clearly specifies the role of each party, including responsibility for patient interaction and education, collection of paperwork, and billing.

Hospital Setting and Services Subject to Stock and Bill Arrangements

Stock and bill arrangements contemplate that the DMEPOS supplier bills Medicare Part B for the DMEPOS. Accordingly, stock and bill arrangements cannot be used for

[1] In addition to dispensing the product, the hospital (or physician practice) may also provide training, fitting, adjustment, documentation management, and other services related to the product.
[2] Commercial payers may be more flexible, but often follow Medicare rules.

hospital inpatients. The hospital is expected to provide all medically necessary services, including DMEPOS, during a beneficiary's covered Part A (inpatient) stay.[3] Payment for DMEPOS furnished to inpatients cannot be unbundled from payment to the hospital under the inpatient prospective payment system.

Although DMEPOS used by a patient while an inpatient is the hospital's responsibility, DMEPOS suppliers may deliver durable medical equipment, prosthetics or orthotics (but not supplies) to a hospital inpatient up to two days before the patient's discharge from the hospital if, among other conditions, the item is medically necessary for use in the beneficiary's home, and the DMEPOS supplier "delivers the item to the beneficiary in the facility solely for the purpose of fitting the beneficiary for the item, or training the beneficiary in the use of the item, and the item is for subsequent use in the beneficiary's home."[4] Interestingly, the rules relating to pre-discharge delivery of DMEPOS are silent as to hospital outpatients. However, for certain hospital outpatients, the policy underpinnings supporting this manual provision seem to support similar care pathways.

In the hospital outpatient setting, a hospital may choose to furnish and bill for DMEPOS, such as orthotics and prosthetics. While this may be common in a hospital rehabilitation department, in other outpatient settings, including an emergency department, a hospital may have the specialized personnel to provide fitting and other services that are paid for as part of the device itself but may not want to enroll as a DMEPOS supplier. In this situation, a hospital may consider a stock and bill arrangement with a DMEPOS supplier, where the DMEPOS supplier furnishes the DMEPOS, and the hospital furnishes the services for the convenience of patients who require the DMEPOS

[3] Centers for Medicare and Medicaid Services (CMS), Medicare Claims Processing Manual, CMS Pub. 100-04 Chapter 20, Sections 110 (Rev. 330, Issued Oct.22, 2004), 210 (Rev. 2993) *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf. Note that in the inpatient setting, a DMEPOS supplier could sell DMEPOS to the hospital, but in such case, the DMEPOS supplier would be a vendor to the hospital, and would not bill Medicare Part B. Such an arrangement could implicate the Anti-Kickback Statute (*see infra*) if the DMEPOS supplier's prices to the hospital are not consistent with fair market value. If, for example, the price to the hospital was below fair market value, the low pricing for the items purchased by the hospital could be viewed as inducement for the referral of patients for services directly billed by the DMEPOS supplier (i.e., "swapping").

[4] CMS, Medicare Claims Processing Manual, CMS Pub. 100-04 Chapter 20, Section 110.3.1 (Rev. 1, 10-01-03) *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf. We note that this manual provision explicitly applies to hospital "inpatients."

immediately on discharge, rather than directing patients to obtain DMEPOS after leaving the hospital.[5]

DMEPOS Considerations: Supplier Standards and Location-Sharing Prohibition

A key question raised by stock and bill arrangements is whether the activities performed by or on behalf of a DMEPOS supplier at a hospital (*e.g.*, product storage, fitting, paperwork) trigger Medicare DMEPOS supplier enrollment requirements for that location.

In order to enroll in Medicare and maintain billing privileges, DMEPOS suppliers must comply with various Medicare regulations, including the DMEPOS supplier standards. The supplier standards are 30 requirements ranging from physical facility specifications to solicitation prohibitions.[6] A DMEPOS supplier must assume responsibility for the delivery of DMEPOS to patients, document that the supplier or another qualified party provided beneficiaries with necessary information and instructions on how to use the DMEPOS, provide beneficiaries with a copy of the supplier standards, and answer questions and respond to beneficiary complaints. The Form CMS-855S Medicare enrollment application requires DMEPOS suppliers to attest that the supplier complies with the supplier standards, in addition to all applicable laws and requirements.

[5] CMS, Medicare Claims Processing Manual, CMS Pub. 100-04 Chapter 20, Section 150 (Rev. 2993) *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf. CMS MLN Matters Number: MM6416 (effective Apr. 1, 2009), *available at* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6416.pdf, "When hospital outpatient staff provide a prosthetic or orthotic device, and the HCPCS code that describes that device includes the fitting, adjustment, or other services necessary for the patient's use of the item, the hospital should not bill a visit or procedure HCPCS code to report the charges associated with the fitting, adjustment, or other related services. Instead, the HCPCS code for the device already includes the fitting, adjustment, or other similar services. For example, if the hospital outpatient staff provides the orthotic device described by HCPCS code L1830 (KO, immobilizer, canvas longitudinal, prefabricated, includes fitting and adjustment), the hospital should only bill HCPCS code L1830 and should not bill a visit or procedure HCPCS code to describe the fitting and adjustment."

[6] 42 C.F.R. § 424.57(c).

As a general rule, a DMEPOS supplier must separately enroll and meet the supplier standards at each location[7] where it furnishes Medicare-covered DMEPOS products.[8] A DMEPOS location is the physical space where a DMEPOS supplier operates its business and meets with patients and sells or rents products to them.[9] (Warehouses and repair facilities do not have to be enrolled.) Suppliers are also generally prohibited from sharing practice locations with other Medicare-enrolled suppliers or providers.[10] While beyond the scope of this article, consideration should also be given to state licensure laws that may, for example, limit or prohibit DMEPOS supplier space sharing or require that a DMEPOS supplier obtain licensure at each site where supplies are stored. Because of the supplier standards including the space-sharing prohibition, it is important to be able to establish that the DMEPOS supplier's activities at a hospital do not trigger DMEPOS supplier enrollment requirements.[11]

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[7] With limited exceptions, the location must be at least 200 square feet in size, have unrestricted access to the public (including Medicare beneficiaries, CMS, and its agents) for a minimum of 30 hours per week, maintain a visible sign in plain view listing hours of operation, be insured, and be accredited by an independent accreditation organization approved by CMS.

[8] 42 C.F.R. § 424.57(b)(1).

[9] 75 Fed. Reg. 52629, 52641 (Aug. 27, 2010).

[10] 42 C.F.R. § 424.57(c)(29)(i). A DMEPOS supplier is prohibited from sharing a practice location with any other Medicare supplier or provider unless the DMEPOS supplier is a physician or nonphysician practitioner furnishing items to his or her own patient as part of his or her professional service or a physical or occupational therapist furnishing items to his or her own patient as part of his or her professional service, or the DMEPOS supplier is co-located with and owned by an enrolled Medicare provider and operates as a separate unit and meets all other DMEPOS supplier standards. *See* 42 C.F.R. § 424.57(c)(29)(ii).[11] If CMS were to take the position that the space is a practice location of the DMEPOS supplier and, therefore, must be separately enrolled and comply with the supplier standards, the parties would need to determine whether there is space reasonably close to the outpatient department that could be leased to the DMEPOS supplier. The space would have to be sufficiently separated from hospital space, e.g., separate entrance, suite number, etc., so as to not violate the DMEPOS and hospital space-sharing prohibitions. The supplier would also have to take all additional steps (e.g., accreditation at the new location) to confirm that the location satisfies the supplier standards. Given that this latter scenario could adversely impact continuity of care for hospital patients, to date, we understand that CMS has not exercised its enforcement discretion. If CMS were to change its position, we would encourage the agency to do so in a way that allows for a smooth transition to alternative arrangements and does not impact continuity of care.

[11] If CMS were to take the position that the space is a practice location of the DMEPOS supplier and, therefore, must be separately enrolled and comply with the supplier standards, the parties would need to determine whether there is space reasonably close to the outpatient department that could be leased to the DMEPOS supplier. The space would have to be sufficiently separated from hospital space, e.g., separate entrance, suite number, etc., so as to not violate the DMEPOS and hospital space-sharing prohibitions. The supplier would also have to take all additional steps (e.g., accreditation at the new location) to confirm that the location satisfies the supplier standards. Given that this latter scenario could adversely impact continuity of care for hospital patients, to date, we understand that CMS has not exercised its enforcement discretion. If CMS were to change its position, we would encourage the agency

Hospital Considerations: Prohibition on Sharing Hospital Space

In order to enroll in Medicare and maintain billing privileges, hospitals must comply with the hospital conditions of participation.[12] The Form CMS-855A Medicare enrollment application requires hospitals to attest that the hospital complies with all applicable laws and requirements. Failure to satisfy the conditions of participation could result in revocation of the hospital's Medicare billing privileges. The conditions of participation for hospitals do not include a specific prohibition on space sharing similar to the prohibition applicable to DMEPOS suppliers. However, while not contained in statutes or regulations, CMS has taken the position that hospital space must be used as "hospital space" at all times. Co-mingling of space between hospitals and other providers and suppliers (whether concurrently or in blocks of time) could put the hospital's enrollment and billing privileges in jeopardy. In a 2015 presentation for the American Health Lawyers Association, David Eddinger, CMS, stated that hospital space, departments, services, and/or locations must be under the hospital's control 24/7, and are required to be "the hospital" 24/7. According to this presentation, hospitals cannot share clinical space with another Medicare-enrolled provider, or patient registration and waiting area space, but could share certain non-clinical areas, such as an atrium or elevator lobby.[13] Consideration should also be given to state licensure laws that may limit or prohibit hospital space sharing.

CMS Stock and Bill Guidance

In 2009, CMS issued Transmittal 297, which would have added a section to the Medicare Program Integrity Manual addressing physician (but not hospital) stock and bill arrangements and requiring physicians to bill for the DMEPOS and follow up with the

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to do so in a way that allows for a smooth transition to alternative arrangements and does not impact continuity of care.

[12] 42 C.F.R. § 482 *et seq*.

[13] American Health Lawyers Association, David W. Eddinger, *Hospital Co-Location* (May 5, 2015).

patient.[14] CMS rescinded Transmittal 297 before it went into effect[15] and has not issued any formal guidance on stock and bill arrangements involving hospitals or physicians since the rescinded Transmittal. The policy underpinnings, e.g., continuity of care, that caused CMS to rescind the physician office stock and bill prohibition arguably apply to hospital stock and bill arrangements as well.

Office of Inspector General Stock and Bill Guidance

In addition to navigating the supplier enrollment and space-sharing issues, DMEPOS suppliers must ensure that stock and bill arrangements are not used to induce hospitals to refer federal health care program patients to the supplier in violation of the Anti-Kickback Statute.[16] The OIG has promulgated "safe harbor" regulations specifying those arrangements that will not be subject to prosecution under the Anti-Kickback Statute. The failure to fit an arrangement within a safe harbor does not necessarily mean that the Anti-Kickback Statute has been violated or that the arrangement will be prosecuted. If an arrangement does not satisfy a safe harbor, the government will evaluate the

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[14] CMS Manual System, Transmittal 297, *Compliance Standards for Consignment Closets and Stock and Bill Arrangements*, (Aug. 7, 2009) *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R297PI.pdf. *See also* http://www.homecaremag.com/news/cms-changes-consignment-closet-rules-20090817.

[15] CMS Manual System, Transmittal 300, *Compliance Standards for Consignment Closets and Stock and Bill Arrangements,* (Sept. 1, 2009), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R300PI.pdf. [16] The Anti-Kickback Statute makes it a crime for any person to knowingly and willfully offer or pay any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce a person to make referrals for services or items that may be covered by Medicare or another federal health care program or to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any services or items that may be covered by Medicare or another federal health care program. The Anti-Kickback Statute also prohibits any person from soliciting or receiving any remuneration in return for making referrals for federal health care program-covered services and items or purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any service or item covered by a federal health care program. *See* 42 U.S.C. § 1320a-7b(b). State anti-kickback laws may also apply.

[16] The Anti-Kickback Statute makes it a crime for any person to knowingly and willfully offer or pay any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce a person to make referrals for services or items that may be covered by Medicare or another federal health care program or to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any services or items that may be covered by Medicare or another federal health care program. The Anti-Kickback Statute also prohibits any person from soliciting or receiving any remuneration in return for making referrals for federal health care program-covered services and items or purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any service or item covered by a federal health care program. *See* 42 U.S.C. § 1320a-7b(b). State anti-kickback laws may also apply.

totality of the facts and circumstances surrounding the arrangement to determine if any one purpose of the arrangement is to pay for or induce federal health care program business.

A safe harbor that could apply to stock and bill arrangements is the space rental safe harbor.[17] However, the space-sharing prohibitions described above would prevent a carve-out of hospital space and the lease of defined space within or adjacent to a hospital could raise the question of whether the DMEPOS supplier had created a new location requiring separate enrollment. Two OIG advisory opinions, summarized below, indicate that the preferred approach from an Anti-Kickback Statute perspective is to avoid any payment from the DMEPOS supplier to the hospital.[18]

OIG Advisory Opinion No. 02-4

In 2002, the OIG concluded[19] that a proposed arrangement whereby a DMEPOS supplier intended to place an inventory of portable oxygen equipment on-site at certain hospitals, clinics, and physicians' offices would not generate prohibited remuneration under the Anti-Kickback Statute. Under the proposed arrangement, the equipment would be distributed to homebound patients whose physicians order portable oxygen equipment for home use, and who chose to obtain the equipment from the supplier. The facilities would provide the supplier with the patient's name and insurance information,

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[17] The elements of the safe harbor include the following: (1) the agreement is set out in writing and signed by the parties; (2) the lease covers all of the premises leased between the parties for the term of the lease and specifies the premises covered by the lease; (3) if the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals; (4) the term of the lease is for not less than one year; (5) the aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, or other federal health care programs; and (6) the aggregate space rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental. *See* 42 C.F.R. § 1001.952(b).

[18] The OIG publishes advisory opinions addressing the Anti-Kickback Statute's applicability to existing or proposed business arrangements of the party requesting the opinion. While OIG advisory opinions are binding and may be relied upon only by the party requesting the opinion, the OIG's analysis of the arrangement provides guidance on how the OIG might assess regulatory risk generally.

[19] *Available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2002/02-4.pdf.

and the supplier would bill the patient and/or the patient's insurance company. The supplier would not pay the facilities for use of the storage space, and the facilities would not receive any remuneration from the supplier in connection with the arrangement. Furthermore, the supplier would provide a list of local DMEPOS suppliers to each facility and encourage the facility to provide the list to its patients in order to protect patient freedom of choice. The OIG cited the lack of remuneration flowing from the DMEPOS supplier to its potential referral sources (the facilities) as key to its decision.

OIG Advisory Opinion No. 08-20

In 2008, the OIG concluded[20] that a proposed arrangement whereby two DMEPOS suppliers would (1) place an inventory of DMEPOS in consignment closets on-site at certain hospitals and (2) have licensed personnel on-call or on-site at the hospitals to train and educate patients who have been prescribed respiratory equipment and have selected one of the companies as their supplier upon discharge to their homes would not generate prohibited remuneration under the Anti-Kickback Statute. Under the proposed arrangement, the parties proposed to enter into signed, written agreements and the suppliers would not pay any remuneration to the hospitals (or anyone affiliated with the hospitals) for the use of the consignment closets. Hospital discharge planners would provide each patient who is in need of DMEPOS with a list of local DMEPOS suppliers. While the suppliers would be identified as the suppliers utilized by the hospitals, the patients would be free to select the DMEPOS supplier of their choice. If the patient chooses one of the suppliers as the patient's DMEPOS supplier, that suppliers would bill the patient and/or the patient's insurance company.

The hospitals would provide the DMEPOS licensed personnel with a desk and phone connected to the hospital's internal telephone system to facilitate the coordination of services with the patient's treating physician, other clinicians, and the hospital's discharge planning staff. The hospitals would not charge for the use of the desk or telephone. The licensed personnel would not provide any other services to the patients

[20] *Available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2008/advopn08-20.pdf.

of the hospital (e.g., discharge planning or case management services), nor would they have any type of contact with the patients prior to the patients' selection of a supplier for respiratory equipment. Only if the patient selects the supplier, would the licensed personnel provide the required education, training, and coordination of care services to that patient. The licensed personnel would not provide training, education, or coordination of care services to patients who elect to obtain respiratory equipment from other suppliers.

The OIG cited the lack of remuneration flowing from the DMEPOS suppliers to the hospitals and their staff and physicians as key to its decision. The remuneration (the free telephones, desks, and consignment closets) and the referrals run the same way. Further, the licensed personnel would not provide any services that the hospitals are otherwise obligated to provide (e.g., discharge planning or case management services), nor would the services that the licensed personnel provide serve as any kind of substitute for services currently provided by the hospitals at their expense. Accordingly, the OIG found that there would be no financial benefit to the hospitals with respect to the licensed personnel.

While providing a positive opinion on the Anti-Kickback Statute issues, the OIG explicitly states: "We express no opinion as to whether the Suppliers are satisfying applicable CMS supplier standards with respect to the Proposed Arrangement."

Structuring Stock and Bill Arrangements

In order to satisfy the Medicare enrollment requirements and space-sharing prohibitions applicable to both hospitals and DMEPOS suppliers described above, the space utilized by the hospital for the DMEPOS supplier's inventory should remain hospital space, under the control of the hospital at all times, with the hospital simply providing the DMEPOS supplier a right of access for the convenience of hospital patients. This is important to reasonably argue that a stock and bill arrangement does not constitute a new DMEPOS supplier location in the hospital.

In addition, hospitals and DMEPOS suppliers should also attempt to structure such arrangements with those favorable factors identified in the OIG advisory opinions. Specifically, unless the DMEPOS supplier leases space outside the hospital certified space and establishes a separate location, the arrangement should not contemplate rent for the space and no remuneration should flow from the DMEPOS supplier to the hospital. Patients should be given the choice of potential DMEPOS suppliers, and hospital staff should not steer patients to the DMEPOS supplier that maintains a stock and bill arrangement with the hospital.[21] The details of the arrangement should be memorialized in a written agreement signed by both parties that clearly specifies the role of each party, including responsibility for patient interaction and education, collection of paperwork, and billing. Lastly, if the hospital and DMEPOS supplier desire to enter into an arrangement that includes rent for the space use, the parties should seek to structure the arrangement in a manner that satisfies the Anti-Kickback Statute space rental safe harbor.

Ultimately, each party should consult counsel when contemplating entering into such an arrangement and monitor future regulatory changes that impact stock and bill arrangements.

[21] The OIG has identified hospital steering of patients to a particular DMEPOS supplier as tampering with patient freedom of choice. *See* Compliance Program Guidance for Hospitals, 63 Fed. Reg. 35, 8987, 8990 (Feb. 23, 1998).