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PRACTICALHEALTH

Health Reform Limits Expansion of Physician-Owned Hospitals

While the expressed intent of these changes was to limit the expansion of physician-owned specialty hospitals, they may also impose restrictions on hospitals that are not typically considered "physician-owned."

OVERVIEW. As part of the Patient Protection and Affordable Health Care Act (the "Act"), the Centers for Medicare and Medicaid Services recently released final regulations implementing changes to the federal Stark Law "whole hospital" and "rural provider" exceptions, most notably prohibiting expansion of physician-owned hospitals that rely on these exceptions in order to comply with this law.

Generally, the Stark Law prohibits a physician from making a referral to an entity for the furnishing of certain "designated health services" (DHS) for which payment may be made under Medicare if such physician (or the immediate family member of such physician) has a "financial relationship" with the entity (the "DHS Entity"), unless an exception applies. Notably, DHS include, but are not limited to, laboratory, radiology, physical therapy, occupational therapy, nuclear medicine, and inpatient and outpatient hospital services. Further, the DHS Entity may not bill Medicare for DHS furnished pursuant to a prohibited referral, unless one of the Stark exceptions applies.

A "financial relationship" can consist of an ownership or investment interest in, or a compensation arrangement with, a DHS Entity. Financial relationships may be either direct or indirect. "Direct" financial relationships exist if remuneration passes between a referring physician and the entity furnishing designated health services without any intervening persons or entities. "Indirect" financial relationships, on the other hand, consist of an unbroken chain of either ownership/investment interests or compensation arrangements between the referring physician and the DHS Entity.

Under the Stark regulations, an ownership or investment interest may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in another entity that furnishes DHS. In other words, even indirect ownership interests implicate the Stark Law. CONTINUED ON PAGE 2

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(Continued)

Such ownership interests include stock, stock options, partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of such property or revenue.

Where a "financial relationship" exists, the ownership interest must meet an exception under the Stark Law in order for the physician-owner to refer to the DHS Entity. The Stark Law provides certain statutory and regulatory exceptions to the prohibitions set forth in the law, including as applicable here, the "whole hospital" and "rural provider" exceptions.

CHANGES TO CERTAIN STARK LAW OWNERSHIP EXCEPTIONS.

Prior to the Act, most physician-owned hospitals relied on "whole hospital" or "rural provider" exceptions. While the Act did not eliminate these exceptions, they have been significantly amended to include the following additional restrictions and requirements:

- **Restriction on Expansion.** In the event a hospital had physician ownership as of December 31, 2010, the hospital may not increase the number of operating rooms, "procedure rooms" (i.e., a room in which catheterizations, angiographies, angiograms, and endoscopies are performed, except such term shall not include an emergency room or department) beyond that for which the hospital was licensed on March 23, 2010 unless an exception is granted by the Secretary of Health and Human Services.
- **Conflict of Interest/Required Disclosures.** Effective September 23, 2011, the hospital must comply with significant con ict of interest disclosure requirements, including but not limited to (i) annual reports detailing physician ownership, (ii) disclosure of physician ownership in any public advertising, and (iii) requiring as a condition of medical staff membership that physicians who have an ownership interest in the hospital provide written disclosure of ownership to all patients referred to the hospital.
- **Ensuring Bona Fide Investment.** Effective September 23, 2011, the hospital must satisfy detailed criteria to ensure bona fide investment by physicians, including but not limited to, a requirement that the percentage of the total value of the ownership or investment interests held by physicians in the aggregate does not exceed such percentage as of March 23, 2010.
- **Patient Safety.** Effective September 23, 2011, the hospital must make certain disclosures prior to providing care to a patient if the hospital does not have a physician available on the premises to provide services during all hours in which the hospital is providing services to the patient.
- **Prohibition on Conversion from an Ambulatory Surgery Center.** The hospital must not have been converted from an ambulatory surgical center to a hospital on or after March 23, 2010.

APPLICATION/NEXT STEPS.

While the expressed intent of these changes was to limit the expansion of physician-owned specialty hospitals, they may also impose restrictions on hospitals that are not typically considered "physician-owned," most notably prohibiting expansion of hospitals that have outstanding debt held by referring physicians. Hospitals with physician ownership, whether by equity or debt, that have relied upon either the rural or whole hospital exceptions now find themselves subject to restrictions on expansion and other new restrictions and disclosure requirements. In order to avoid these requirements and restrictions, there are a few options that a physician-owned hospital might consider:

- **"Publicly-Traded Securities."** The parties could restructure the arrangement to comply with the Stark "publicly-traded securities" exception, which remains unchanged under the Act. This exception permits physician ownership of investment securities that can be purchased on the open market and are either (i) listed for trading on the New York Stock exchange, the American Stock exchange, or certain other specified types of exchanges, or (ii) traded under an automated interdealer quotation system operated by the National Association of Securities Dealers. However, it may be onerous from a legal and accounting standpoint to convert physician ownership to investment in publicly traded securities and would likely require consent of all of the physician owners and potentially third parties. Further, this option may result in a change of ownership for purposes of Medicare and other payor participation, requiring updated filings, notices, etc.
- **Unsecured Loan.** The parties could restructure the physician ownership as an unsecured loan to the hospital. CONTINUED ON PAGE 3

Under Stark, an unsecured loan subordinated to a credit facility is excluded from the definition of an "ownership and investment interest." While this sort of arrangement may not afford many of the advantages of physician ownership, such loan arrangement could be structured to permit the participating physicians to have a role in the governance and management of the hospital. Note, however, that the loan would likely create a compensation arrangement and therefore would be required to be structured in compliance with a compensation exception. Importantly, the Stark compensation exceptions were not affected by the Act and therefore do not include the restrictions and requirements at issue here. The relevant compensation exceptions generally require, among other elements, that the arrangement be for fair market value and commercially reasonable. This option may also result in a change of ownership for purposes of Medicare and other payor participation, requiring updated filings, notices, etc.

- **Management Agreement.** A physician-owned hospital could also redeem its physician owners and such physicians could form a management company. The management company could enter into a management services arrangement with the hospital to provide day-to-day management of the hospital in exchange for fair market value compensation. Again, this structure may not afford many of the advantages of equity ownership, but it could potentially provide an avenue for physician participation in the governance and management of the hospital. Further, the arrangement may create a compensation arrangement which must be structured in compliance with a relevant compensation exception. The parties must also be mindful of the Stark prohibition on "under arrangements" deals and restrictions on per unit of service rental payments for space and equipment. This option may also result in a change of ownership for purposes of Medicare and other payor participation, requiring updated filings, notices, etc. ■

CMS Finalizes Additional DMEPOS Enrollment Requirements

The Centers for Medicare & Medicaid Services ("CMS") recently clarified, expanded, and added additional enrollment requirements for suppliers of Durable Medical Equipment and Prosthetics, Orthotics, and Supplies ("DMEPOS") to receive and maintain billing privileges in the Medicare program. These new requirements are designed to target fraud and were effective September 27, 2010.

I. CMS CLARIFIED THE FOLLOWING EXISTING DMEPOS STANDARDS:

1. **DMEPOS suppliers must be licensed to provide licensed services.** Suppliers cannot contract with another individual or entity to provide such services unless permitted by State law. The supplier is ultimately responsible for determining what licenses are required.
2. **CMS requires suppliers to maintain a physical facility on an appropriate site.** The term "appropriate site" has been expanded to include "closed door" businesses such as pharmacies and suppliers providing services in nursing homes. The supplier must maintain a minimum of 200 square feet of space for inventory, storage, and patient records. A supplier with less than the required space in a long-term lease will have a three-year transition period to relocate to a space that meets the minimum square footage requirements. The supplier must have a permanent, durable sign that is visible to the public at the main entrance or the main lobby entrance if in a medical building. If signage con icts with a local zoning ordinance, the supplier must (i) obtain a waiver before submitting their application to the National Supplier Clearinghouse ("NSC"), or (ii) will need to select a different practice location.
3. **On-site Inspections.** Suppliers must permit CMS, the NSC, or their agents to conduct on-site inspections to ascertain supplier compliance.
4. **Suppliers must maintain a primary business telephone.** Suppliers are prohibited from using cell phones, beepers, or pagers as their primary telephone and calls may not be forwarded from the primary business telephone to a cell phone, beeper, or pager. Answering machines, answering services, or fax machines cannot be used as the primary business telephone during posted operating hours.
5. **Suppliers are not permitted to directly solicit patients.** Direct solicitation includes, but is not limited to, telephone, computer e-mail, instant messaging, or in-person contact.

   "Direct solicitation" occurs when a supplier or agent contacts a beneficiary without the beneficiary's consent for the purpose of marketing.

   CMS indicated the supplier cannot contact a beneficiary based solely on a physician order; however, if the physician contacts the supplier on behalf of the beneficiary, then the supplier may contact the beneficiary to gather additional information.

II. CMS CREATED THE FOLLOWING NEW STANDARDS:

1. **Obtaining Oxygen.** There is a new standard that requires DMEPOS suppliers to obtain oxygen from a State-licensed oxygen supplier if the State licenses oxygen suppliers. CONTINUED ON PAGE 4

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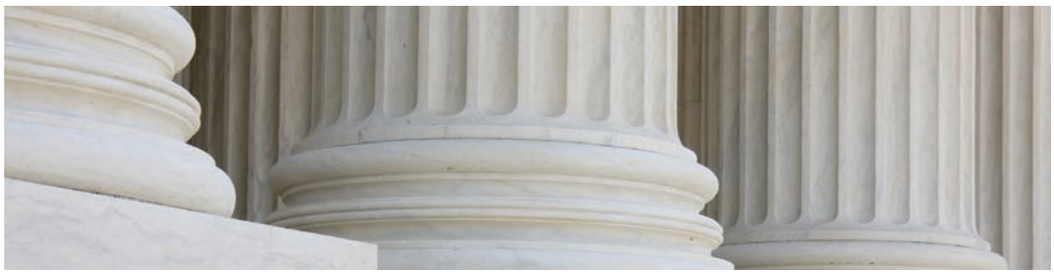

CMS Finalizes Additional DMEPOS Enrollment Requirements (Continued)

If the DMEPOS supplier is located in a State that requires a license but the oxygen supplier's physical location is in a State that does not license oxygen suppliers, then the DMEPOS supplier may still obtain oxygen and oxygen-related equipment from the out-of-State oxygen supplier.

2. **Documentation Maintenance.** Suppliers are required to maintain ordering and referring documentation, including National Provider Identifier ("NPI"), for seven (7) years from the date of service. If the information in the patient's medical record does not adequately support the medical necessity for the item, the supplier may be liable for the dollar amount involved unless the supplier obtained a properly executed Advance Beneficiary Notice of potential claim denial.

3. **Sharing of a Practice Location.** Suppliers are prohibited from sharing a practice location with another Medicare supplier or provider with limited exceptions. Commingling practice locations effectively limits the ability of CMS and the NSC to ensure that each supplier is complying with the standards specified within the regulations. Exceptions are established for physicians and non-physician practitioners who furnish items to their patients and for physical and occupational therapists who furnish items to their patients, or if DMEPOS suppliers are co-located with and owned by an enrolled Medicare provider such as a hospital, home health agency, or skilled nursing facility.

4. **Hours of Operation.** DMEPOS suppliers must be open to the public for a minimum of thirty (30) hours per week except for physicians and licensed non-physician practitioners who furnish items to their patients or to suppliers working with custom-made or fitted orthotics and prosthetics.

5. **Overpayments.** CMS defined "final adverse action" and added a provision which enables CMS or its contractors to reopen all Medicare claims paid on or after the date of a final adverse action in order to establish an overpayment determination. A final adverse action is: 1) a Medicare-imposed revocation of any Medicare billing privileges; 2) suspension or revocation of a license to provide health care by any State licensing authority; 3) revocation for failure to meet DMEPOS quality standards; 4) a conviction of a Federal or State felony offense within the last ten (10) years preceding enrollment; and/or, 5) an exclusion or debarment from participation in a Federal or State health care program.

DMEPOS Suppliers should be aware of the impact of these changes to the enrollment requirements and determine whether revisions to current business practices are necessary. ■

CONTRIBUTING AUTHORS

ERIN DRUMMY counsels clients regarding hospital and physician issues, medical record issues, joint venture and other collaborative efforts; preparation and review of hospital, physician and other provider contracts; physician recruitment; Stark Law/Fraud and Abuse opinions; board of director/trustee organization; corporate compliance issues; medical staff and peer review; accreditation matters; and Medicare reimbursement issues. Erin graduated cum laude from Indiana University School of Law-Indianapolis in 2005.

GREGG WALLANDER has made national and regional presentations on Stark Law/Fraud and Abuse for the American Health Lawyers Association, Indiana Hospital Association, Kentucky Hospital Association, Health Care Financial Management Association, and Indiana State Medical Association. Gregg graduated magna cum laude from Indiana University School of Law-Indianapolis in 1993.

BRIAN JENT counsels clients on a variety of regulatory issues including Clinical Services & Patient Care Issues, administrative law, appeals, compliance issues, Medicare and Medicaid reimbursement and certification, and long term care certification and compliance. Brian graduated from Indiana University School of Law - Indianapolis in 2005.