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CHANGES TO THE FEDERAL PHYSICIAN SELF-REFERRAL LAW INCLUDED IN THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

April 9, 2010

IMPORTANT DATES

January 1, 2010
Date included in PPACA when physician offices relying upon in-office ancillary services exception for PET, CT and MRI services must begin to disclose ownership interest to patients and provide such patients with list of alternative vendors.

March 24, 2010
PPACA enacted; after this date, physician ownership in hospital cannot increase beyond the aggregate percentage held by physicians on March 24, 2010.

September 24, 2010
HHS required to have developed Self-Referral Self-Disclosure Protocol.

December 31, 2010
In order to qualify for physician ownership in hospital exception, the hospital must have obtained provider agreement by this date.

Narrowing the Ability of Physicians to Own an Interest in a Hospital

In 2003, Congress modified the federal physician self-referral law (commonly referred to as the "Stark Law") and adopted an 18-month moratorium on the ability of physicians to own an interest in a specialty hospital.[1] Although the moratorium officially lapsed in June 2005, over the last several years, Congress has continued to monitor and debate the issue of whether this exception to the Stark Law should be modified.

With the passage of the Patient Protection and Affordable Care Act, as modified by the Health Care and Education Reconciliation Act of 2010, ("PPACA"), Congress has again placed significant limitations on physicians' ownership interests in hospitals located both in urban and rural areas. Section 6001(a)(3) of PPACA limits the ability of a hospital to have physician owners unless the ownership interest was obtained by the physicians prior to December 31, 2010, and the hospital had a provider agreement in place as of that date.

However, there are some questions that arise concerning the applicability of the December 31, 2010 date. For example, Section 6001(a)(2) states that, in order to qualify for the exception for physician ownership in a hospital, the hospital must meet various requirements "not later than 18 months after the date of enactment … ." It is unclear what requirements can be satisfied after December 31, 2010, but before September 24, 2011 (which is 18 months after the enactment of PPACA). Also, in limiting the ability of the hospital to expand the amount of ownership interests held by physicians, the statute requires that "the percentage of the total value of the ownership or investment interests held in the hospital, … by physician owners or investors in the aggregate does not exceed such percentage as of [March 24, 2010]." However, if the amount of physician ownership has to be set as of the date of the enactment of the statute, it is unclear what effect the December 31, 2010 date has and whether a hospital that was under construction and is able to receive its provider agreement by December 31 could qualify if the physicians had not already purchased their ownership interests in the legal entity prior to March 24, 2010.

IMPORTANT DATES

September 24, 2011
HHS required to submit report to Congress on Self-Referral Self-Disclosure Protocol.

January 1, 2012
HHS must promulgate regulations setting forth the process for physician-owned hospital to apply for waiver of the expansion limitation.

May 1, 2012
HHS will begin conducting audits to determine if hospitals are in compliance with Stark Law requirements for physician ownership.

With limited exceptions, PPACA precludes a physician-owned hospital from expanding the number of licensed beds and operating or procedure rooms beyond the number that exists as of the date the hospital is licensed following the enactment of the law. PPACA establishes that a facility can seek a waiver from the expansion limitation in two separate sets of circumstances: (1) a hospital that, among other things, is in a county that has percentage increase in population over the last 5 years that is 150 percent of the population growth in the state; or (2) a hospital that constitutes a "High Medicaid Facility" that is not the sole hospital in a county and, for the three most recent years, has a larger percentage of Medicaid inpatient admissions than any other hospital in the county. PPACA establishes that the Secretary of Health and Human Services ("Secretary") is to promulgate regulations by January 2012 that set forth the process by which a hospital can apply for one of these exceptions. PPACA also limits the ability of a hospital to apply for an exception once every two years.

As part of these modifications, Congress imposed additional requirements in order to ensure that the physicians' ownership interests are "bona fide." For example, the terms upon which a physician is offered an ownership interest in the hospital can be no different than the terms upon which a non-physician would be offered the same interest. Congress also provided that, not only is the hospital prohibited from loaning money to a physician, but the hospital cannot guarantee a loan that a physician might obtain from a third party. This requirement may prove difficult with a number of lenders that, in addition to obtaining a guarantee from the physicians, want a guarantee from the hospital because the hospital is generally the entity with the "deeper pockets."

Congress also enacted a number of disclosure requirements that the hospital and physician owners must make to patients concerning the existence of the ownership interest. PPACA requires the hospital to disclose to patients if the hospital does not have a physician on-site 24/7. Congress adopted the specialty hospital moratorium in 2003 when a number of incidents occurred at specialty hospitals allegedly because there was not adequate physician coverage. Although the Centers for Medicare and Medicaid Services ("CMS") adopted regulations a few years ago that require certain of these items to be disclosed by hospitals to patients,[2] Congress apparently saw a need to codify these requirements into the Social Security Act.

PPACA also includes a provision requiring the Secretary to collect information regarding physician ownership in hospitals. We note that the Stark Law already includes a provision providing the Secretary with the authority to request information regarding physician ownership and compensation arrangements that health care entities may have with physicians. However, to date, CMS has not been able to finalize a process by which it intends to collect this information.

Creation of New Self-Referral Disclosure Protocol

In 2009, the Department of Health and Human Services' Office of the Inspector General ("OIG") issued an Open Letter to the health care community that stated the OIG would no longer accept self-

disclosures of matters that only involve liability under the Stark Law without any potential liability under other similar laws (*e.g.,* the federal health care program anti-kickback statute).[3]

As a result, Congress set forth in Section 6409 of PPACA that, within six months, the Department of Health and Human Services ("HHS") is to develop a self-disclosure protocol related to Stark Law violations (referred to as the "self-referral disclosure protocol" or "SRDP"). Eighteen months after the SRDP is established, the Secretary must issue a report regarding the number of entities disclosing under the SRDP, the amounts collected and the nature of the issues being disclosed under the SRDP.

In addition to establishing a process by which entities can self-disclose Stark Law violations, this PPACA provision authorizes the Secretary to negotiate settlements for an amount less than the amount set forth under the Stark Law. Under the SRDP, HHS can negotiate a settlement down based upon a variety of factors, such as the timeliness of the disclosure, the level of cooperation and the nature of the violation. Prior to the enactment of this language, the regulators responsible for enforcing the Stark Law were known for having stated that their ability to negotiate a settlement with a provider was significantly limited by the nature of the Stark Law's penalties.

While many view the official development of a self-referral disclosure protocol for Stark Law violations in a positive light, a number of issues remain that could affect the utility of this process. First, it is unclear what level of discretion CMS may use when negotiating Stark Law violations for, what some might consider, relatively innocuous violations (*e.g.,* a lease that extended beyond the six-month grace period but was otherwise not re-executed, or a hospital providing non-monetary compensation to a physician above the $355 threshold that was not identified until two years later, as a result of an internal audit). Second, as CMS is only able to provide an entity with a release from potential liability under the self-referral law, it will still be necessary for providers to decide whether a disclosure should be made to OIG, Department of Justice, etc.

New Disclosure Requirements Under the In-Office Ancillary Services Exception

The federal physician self-referral law includes a general exception that permits the provision of designated health services to patients when those services are provided through a physician's office (referred to as the "in-office ancillary services exception"). There has been much discussion over the last few years on whether Congress would further limit the in-office ancillary services exception.

Section 6003 of PPACA sets forth a requirement that, for MRI, CT, PET and any other designated health services identified by the Secretary, the provider must inform the individual in writing at the time of the referral that the individual may obtain the services from another health care provider and provide the patient with a written list of suppliers who furnish services in the area in which such patient resides.

Based upon PPACA, this notification requirement applies to services furnished on or after January 1, 2010, and it does not appear that the effective date of this new requirement was modified in either the Chairman's mark or the Budget Reconciliation bill.

As a result, PPACA requires a physician practice that offers MRI, CT and PET services to its patients to immediately adopt a disclosure document that informs patients of their rights and sets forth a list of others "who furnish such services in the area in which such individual resides." However, there are a number of details surrounding this notification requirement that remain unclear. For example, is a

physician's office required to list ***all*** potential suppliers in a particular service area (*i.e.,* must they include all other physician offices that have MRI, CT or PET capabilities, or can they simply list freestanding centers and/or hospital outpatient departments)? Is a physician's office required to maintain separate lists based upon where a particular patient resides, since some patients may not necessarily reside in the same service area where the physician's office is located?

Until additional clarification is promulgated, it is unclear exactly what the physicians' offices are required to disclose.

For more information about this issue of *IMPLEMENTING HEALTH AND INSURANCE REFORM*, please contact the author below or the member of the firm who normally handles your legal matters.

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[1] Medicare Prescription Drug, Improvement and Modernization Act of 2003, Publ. L. No. 108-173 § 507.
[2] 42 CFR 489.20(u) – (v).
[3] http://oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf

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