ALERT
MAY 12, 2010

HEALTH LAW
News Concerning
Recent Health Law Issues

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STARK REALITIES OF HEALTH CARE REFORM

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Our Health Law Alert of April 26, 2010 summarized recent amendments to the Anti-Kickback Statute ("AKS") concerning "reverse" federal false claims act ("FCA") and the implications of the requirement of Section 6402 of the Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148 (the "PPACA") to report and refund "overpayments" by Medicare and Medicaid within sixty (60) days of "identification." An "overpayment" is defined to take into account the amount due "after applicable reconciliation." There are as yet unanswered questions concerning when an overpayment has been "identified" and reconciled for purposes of Section 6402 of the PPACA, which directly implicate certain PPACA amendments to the physician self-referral, or "Stark," law.

SELF-DISCLOSURE REFERRAL PROTOCOL

In one key amendment to the Stark law, Section 6409 of the PPACA requires the Secretary of HHS, in cooperation with the Inspector General, to create and publish on the CMS Website a "protocol" for self-reporting "actual or potential" Stark violations within six (6) months of enactment—i.e., on or before September 23, 2010. The self-referral disclosure protocol ("SRDP") must instruct providers how and to whom to self-disclose, and take into account corporate compliance and corporate integrity agreements. This process is separate from the Stark "advisory opinion" process that implements Section 1877(g) of the Social Security Act. The new SRDP will fill a gap created by a March 24, 2009 "Open Letter" from the HHS Inspector General, announcing that the OIG would no longer accept self-disclosures concerning "pure" Stark violations (*i.e.*, those not also involving a "colorable" AKS violation).

Under § 1877(g) of the Social Security Act, no payment may be made under Medicare for a designated health service ("DHS") provided on a referral prohibited by the Stark law. It is unclear whether the obligation to timely report and repay (within 60 days of "identification") "overpayments" resulting from Stark violations is tolled pending the Secretary's publication of the SRDP. That is, until publication of the SRDP, it is not clear to whom a Stark violation properly must be "reported."

COMPROMISE OF STARK OVERPAYMENT LIABILITY

The reporting and repayment obligations under Section 6402 of the PPACA are further complicated by another provision of the PPACA. In Section 6409, Congress vested the Secretary with discretion to "reduce" liability for Stark violations, which can be grossly disproportionate to the underlying violation. Under a strict pre-PPACA application of Stark, a hospital would be deemed to have been "overpaid" for every inpatient or outpatient service or any other DHS provided to Medicare patients on referrals from a physician providing teaching or medical director services under an "expired" or "unsigned" personal services agreement. Section 6409(b) of the PPACA, "authorizes" the Secretary to develop rules for compromising (i.e., "reducing" the amounts due) for Stark violations, taking into account the following factors: (1) the nature and extent of violations; (2) the timeliness of self-disclosure; (3) the level of cooperation in providing additional information related to the disclosure; and (4) such "other factors as the Secretary considers appropriate."

The American College of Cardiology ("ACC") wrote to CMS on April 27, 2010, imploring the agency to take immediate action to adopt the protocol and promulgate implementing regulations, and to consider imposing no penalties, or nominal penalties for "inadvertent" or "technical violations" (such as agreements that are missing signatures) of this highly complex regulatory scheme. An obvious question is whether the ability to obtain an "applicable reconciliation" of a Stark overpayment would be deemed to be suspended pending the Secretary's development of a formal process for reducing overpayments. Although further guidance should be forthcoming from HHS, in the absence of prompt clarification, failing to take "timely" corrective action under Section 6402

in response to a clearly discernible Stark violation creates obvious risks, and should be discussed with competent counsel.

NOTICE OF ALTERNATIVE DHS SUPPLIERS

In a different vein, Section 6003 of the PPACA amends Stark by requiring physicians providing ancillary services (including DHS) under the "group practice" exception to inform patients in writing at the time of a referral that they may obtain MRI, CT, PET scan, "and any other [DHS]" that the Secretary determines appropriate, from another "supplier." Referring physicians are obligated under this provision to provide patients with a written list of alternative "suppliers . . . which furnish such services in the area in which such individual resides." The definition of suppliers is not limited to independent diagnostic testing facilities, but also includes other physician groups. The relevant geographic "area," and the details of what must be contained with the listing are undefined. For example, if the provider is located in a state other than that in which the patient "resides," must (and how will) the referring provider identify alternative suppliers in the other state?

Although the wording of this section suggests that it cannot be effectuated without detailed implementing rules, the PPACA makes these Stark amendments applicable "to services furnished on or after January 1, 2010." This deadline predates not only the issuance of regulations or guidance, but—by nearly three months—the effective date of the PPACA. Barring further clarification from CMS, the most conservative approach would be to develop an immediate form of notice concerning alternate suppliers of MRI, PET and CAT scan services.

WHOLE HOSPITAL EXCEPTION

Another Stark-related amendment contained in Section 6001 of the PPACA (as amended by the Affordable Care Act and the Health Care Reconciliation Act of 2010) limits the scope of the so-called "whole hospital" exception to the ban on referrals to hospitals in which referring physicians or their immediate family members have an ownership or investment interest. Under this PPACA amendment, physicians with such interests in the "whole hospital" are exempt from the self-referral ban *only if* the hospital has a provider agreement in place, and the physician ownership or investment is in effect, by December 31, 2010, and certain other requirements are met. However, the aggregate percentage of the physician ownership may not exceed that in effect as of the date of enactment (*i.e.* March 23, 2010).

These requirements include limits on expanding the number of operating rooms, procedure rooms and beds above the PPACA enactment date base-line, and obligations to submit annual reports to the Secretary detailing physician ownership. They also include the adoption of procedures by referring physicians for advance disclosures of ownership or investment interests to enable patients to "make a meaningful decision" about where to receive their care, and advertising and website postings must disclose that the hospital is owned or partially owned by physicians. Exceptions to the capacity limits—which enable providers to exceed the base-line numbers—are available only to "high Medicaid" facilities once in two years. Increases permitted through the exception process may not increase the baseline by over 100% and are limited to the hospital's main campus.

Other requirements bar hospitals from conditioning ownership on making or influencing referrals or generating business for the hospital; offering physicians preferred investment terms; or lending money for or financing the physician investments. An anti-"cherry picking" requirement obligates physician-owned hospitals to have the capacity to provide an assessment and initial treatment for medical emergencies, to refer and transfer patients to other hospital having the capacity to provide necessary care, and to notify patients if a physician is not on-site 24/7.

CONCLUSION

An already complex Stark law has been made ever more so by the PPACA. All of these amendments should be carefully factored into compliance plans (which will soon become mandatory under another PPACA provision).

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