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Health Law Bulletin

Changes to the Stark Law Enacted as Part of Health Reform Legislation

After more than a year of intense debate, President Obama and the 111th Congress have succeeded in enacting comprehensive health care reform legislation. The legislation is composed of two separate laws—the Patient Protection and Affordable Care Act (the PPACA), which was signed into law by President Obama on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (the Reconciliation Act), amending certain provisions of the PPACA, which was signed into law on March 30, 2010. This Bulletin, the first in a series of Bulletins for health care providers and other Vedder Price clients in the health care industry, discusses the changes to the federal prohibition on physician self-referral, commonly known as the Stark Law.

The Stark Law Generally. The federal prohibition on physician self-referral, commonly known as the Stark Law, prohibits a physician from referring a patient to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship for designated health services (DHS) reimbursable by Medicare or Medicaid, unless an exception applies. The PPACA amends Stark Law in several material respects, by:

- adding a new requirement to the so-called In-Office Ancillary Services Exception (the IOAS Exception) for referrals of certain diagnostic imaging services,
- substantially limiting the scope of the so-called Whole-Hospital Exception permitting referrals to hospitals in which the referring physician has a financial relationship, and
- requiring the Department of Health and Human Services (HHS), together with the Office of the Inspector General of HHS (OIG), to establish a protocol for health care providers to self-disclose actual or potential violations of the Stark Law.

The In-Office Ancillary Services Exception. The IOAS Exception generally permits referrals for certain DHS furnished in the referring physician's office (or a centralized location utilized by the referring physician's group practice) if the referral meets certain conditions concerning the location where the DHS is furnished, the individual who performs the DHS, and the manner in which the DHS is billed.

The PPACA adds an additional criterion with respect to referrals for MRI, CT and PET services furnished on or after January 1, 2010, and such other diagnostic imaging services as the Secretary of HHS may later determine. To qualify for the IOAS Exception for such tests, the referring physician must first notify the patient in writing that the patient may obtain the test from another supplier, and provide a list of suppliers offering the service located in the area where the patient resides.

Restrictions on Physician-Owned Hospitals. The Whole-Hospital Exception permits referrals by a physician to a hospital in which the referring physician has an ownership interest, provided the ownership interest is in the whole hospital, as opposed to a subdivision of the hospital. The PPACA, as amended by the Reconciliation Act, limits the Whole-Hospital Exception to investments in hospitals existing (that is, which have a Medicare provider agreement in place) as of December 31, 2010.

Physician-owned hospitals are required to include a notice that the hospital is wholly or partially owned by physicians in any public advertising for the hospital and on any public website for the hospital. Further, a physician-owned hospital must ensure that any patient who is referred to or treated at the hospital by a physician owner is notified of such ownership or investment interest.

Except under limited circumstances discussed below, physician-owned hospitals may not expand the number of beds, procedure rooms, or operating rooms for which the hospital is licensed as of March 30, 2010 (or if the hospital is licensed after that date, the number of beds, procedure rooms and operating rooms as of the date of licensure). The PPACA contains an exception to the expansion limitation for "applicable hospitals," and the Reconciliation Act added an exception for "high-Medicaid facilities." Only a single hospital in given county will qualify as an applicable hospital or high-Medicaid facility, meaning that, at most, there will be no more than two physician-owned hospitals located in any county.

The PPACA requires the Secretary of HHS to promulgate regulations pursuant to which a hospital may apply for "applicable hospital" or "high-Medicaid facility" status. At a minimum, the hospital applying for "applicable hospital" status will be required to show that: (i) the hospital is located in a county in which, during the preceding 5-year period, the population has increased at a rate at least 50 percent higher than the population increase in the state; (ii) the hospital is located in a State in which the average bed capacity is lower than the national average; (vi) the hospital has an occupancy rate that is higher than the statewide average; (iii) the hospital has the highest rate of Medicaid inpatient admissions in the county in which it is located; and (iv) the hospital does not, and does not permit any physician practicing at the hospital to, discriminate against Medicare and Medicaid beneficiaries. A hospital applying for "high-Medicaid facility" status will be required to show, at a minimum, that: (i) it is not the only hospital in the county in which it is located; (ii) for the preceding three-year period, the hospital has had the highest rate of Medicaid inpatient admissions in the county in which it is located; and (iii) the hospital does not, and does not permit any physician practicing at the hospital to, discriminate against Medicare and Medicaid beneficiaries.

Annual Reporting Requirements for Physician-Owned Hospitals. Physician-owned hospitals will be required to annually submit to the Secretary of HHS a report detailing the identify of each physician owner and the nature and extent of each such owner's investment interest in the hospital. The information contained in these reports will be made publicly available on the CMS website.

Self-Disclosure Protocol. The OIG announced in March 2009 that, to enable it to focus its attention on potential violations of the anti-kickback statute, it would no longer accept self-disclosures of Stark Law violations which did not also involve a "colorable" violation of the anti-kickback statute. This left providers with no clear method of self-reporting potential violations of the Stark Law. The PPACA attempts to remedy this issue by requiring the Secretary of HHS, in cooperation with the OIG, to establish a protocol enabling health care providers to self-report any actual or suspected violations of the Stark Law on or before September 30, 2010.

This self-referral disclosure protocol (SRDP), which will be made publicly available on the CMS website, is to provide specific instructions concerning where such self-reports are to be submitted, and describe the implications of such reports on corporate integrity agreements and compliance agreements. The PPACA further provides that CMS may reduce any Medicare payments owing to the health care provider for self-reported violations of the Stark Law. In determining the amount of such reduction, the Secretary is required to take into account the severity of the reported violation, the timeliness of the report and the cooperation of the health care provider in providing additional information requested by CMS.

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