

Health Care Reform Legislation Makes Significant Changes to Fraud & Abuse Laws

by Douglas A. Grimm

The recently enacted health care reform law, the Patient Protection and Affordable Healthcare Act (the “Act”) (Pub. L. No. 111-148), includes substantial modifications to federal fraud and abuse laws. One such change is to the physician self-referral law, commonly referred to as the “Stark Law,” which regulates the financial relationships between physicians and the health care entities to which the physicians refer. A brief summary of the more significant changes follows.

Overview of the Stark Law

The Stark Law prohibits the referral of a patient by a physician to an “entity”¹ for the provision of designated health services (“DHS”) if the physician (or an immediate family member) has a financial relationship with the entity, absent application of an ownership, compensation, or investment interest exception to the law. 42 U.S.C. § 1395nn. Entities may not submit a claim or bill to a federal health care program for DHS furnished pursuant to a prohibited referral.

Modifications to the Stark Law

Medicare Self-Referral Disclosure Protocol

The Act requires that the Department of Health and Human Services (“HHS”), in conjunction with the Office of the Inspector General, implement a disclosure protocol for use by providers that discover actual or potential Stark law violations. See § 6409 of the Act. The Self-Referral Disclosure Protocol (“SRDP”) must be developed and effective by September 30, 2010. Instructions for use will be posted on the Centers for Medicare and Medicaid Services’ website, and will identify the specific person or office to whom disclo-



¹ “Entities” are generally defined as physician practices, hospitals, health plans, or any other health care provider that furnishes DHS.

asures should be made, as well as the effect of the SRDP on existing corporate integrity or corporate compliance agreements.

Significantly, HHS is authorized to consider the facts and circumstances related to the actual or potential violation, and to exercise its discretion in reducing the amounts due for any violations. HHS may consider the following factors in its analysis:

1. The nature and extent of the improper or illegal practice;
2. The timeliness of self-disclosure by the provider;
3. The provider's level of cooperation in providing additional information; and
4. Such other factors as HHS deems appropriate.

HHS is required to monitor the effectiveness of the SDRP, and make a report to Congress by September 30, 2011, regarding its implementation and usage. The report will include the volume of providers making disclosures, amounts of penalties collected, and the types of violations reported.

Limitation on Stark Exception for Physician Ownership of Hospitals

The Act curtails the Stark Law exception allowing physicians to hold ownership interests in hospitals. See § 6001 of the Act. The Act limits physical expansion of current facilities, expansion of physician aggregate ownership percentages, and requires facilities currently under construction to obtain Medicare provider numbers by December 31, 2010 or face permanent exclusion from Medicare.

Specifically, unless a facility meets a narrowly defined set of criteria involving geographic location and Medicaid payor mix percentages, existing facilities are prohibited from adding operating rooms, procedure rooms, and beds after March 23, 2010. "Procedure rooms" is defined broadly by the Act to "include rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed." Existing facilities should pay close attention to the implementing regulations of this broad statutory provision to determine whether the forthcoming regulatory language broadens or narrows the statute's breadth.

Disclosure Requirements for Use of the In-Office Ancillary Services Exception for Imaging Services

The Act also increased the requirements for use of the in-office ancillary services exception by requiring a physician making a referral for MRI, CT or PET services (or other services to be designated by HHS in the implementing regulations) to inform the patient in writing, at the time of the referral, that the patient may obtain these services from a physician other than the referring physician. See § 6003 of the Act. In addition, the physician must provide the patient with a list of providers that furnish these services in the area in which the patient resides. The amendment applies to services furnished on or after January 1, 2010. However, the statute makes no comment on the method of retroactive application of this requirement.

Conclusion

In keeping with the federal government's increased focus on health care fraud and abuse, the Act makes substantial changes to the Stark law. These changes have the potential to significantly affect providers' business and compliance strategies. Close attention should be paid to the issuance of HHS's regulations, as they will provide further guidance on implementation of the statutory provisions above.

If you have any questions about the content of this advisory, please contact the Pillsbury attorney with whom you regularly work or the attorneys below.

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