

Proposed Rules Regarding Disclosure Requirements for In-Office Ancillary Services Issued by CMS

On June 25, 2010, the Centers for Medicare and Medicaid Services (“CMS”) released a proposed rule implementing the new disclosure requirements required by Section 6003 of the Patient Protection and Affordable Care Act (as amended by the Health Care and Education Reconciliation Act) (collectively referred to as the “Reform Act”).

Section 6003 of the Reform Act amends the in-office ancillary services (“IOAS”) exception to the Stark self-referral prohibition (“Stark”) by requiring a physician to notify a patient in writing at the time of a referral that the patient may obtain an MRI, CT, PET or any other DHS from a person other than the referring physician or someone in the physician's group practice and provide the patient with a list of suppliers who furnish the service in the area in which the patient resides.

In general, Stark prohibits a physician from making referrals for DHS to an entity with which he or she or an immediate family member has a financial relationship unless an exception exists. Stark also prohibits the entity from billing for DHS rendered pursuant to a prohibited referral. The IOAS exception to Stark permits a physician in a solo or group practice to order and provide most DHS in the office of the physician or group practice, provided that certain specific criteria are met.

Section 6003(a) of the Health Care Reform Act requires that the new disclosure requirement apply to MRI, CT, and PET services as well as such other radiology or imaging services included in the DHS category specified in section 1877(h)(6)(D) of the Act that the Secretary determines appropriate. CMS is considering whether to expand this disclosure requirement to other radiology and imaging services. Although CMS admits that it is “...not inclined to expand the disclosure requirement” it is soliciting comments regarding whether other radiology or imaging services should be included in the disclosure requirements.

According to the Proposed Rule, the disclosure must:

1. Be written so it can be reasonably understood by all patients;
2. Be given at the time of the referral;
3. Indicate that the services may be obtained from a person other than the referring physician or his or her group practice; and
4. Include a list of no less than ten (10) other suppliers who provide the service within a twenty-five mile radius of the practice.

A record of the patient's signature on the disclosure must be maintained in the patient's medical record.

The Proposed Rule specifies that only “suppliers” are required to be included in the disclosure, and therefore, the disclosure is not required to include “providers of services”, such as hospitals and critical access hospitals.

The Proposed Rule clarifies that the disclosure must include no less than ten (10) suppliers located within a 25-mile radius of the physician's office location regardless of whether the office is located in an urban and rural area. In locations where fewer than ten (10) other suppliers are located within 25-miles of the referring physician's office, the Proposed Rule requires the physician to include all suppliers within 25-mile radius. If no other suppliers exist within the 25-mile radius, the physician must disclose to his or her patients that the patients may receive the imaging services from another supplier, but the physician is not required to list other suppliers. The Proposed Rule requires that the list of suppliers include the name, address, phone number, and distance from the physician's office at the time of the referral.

Although physicians are permitted to choose which suppliers it includes in its list, CMS states that it is concerned that physicians located in large metropolitan areas will draft a list that includes suppliers located mostly at the edges of the 25-mile radius, thereby increasing the chances that the patient will choose to receive imaging services from the referring physician's practice. CMS is therefore seeking comment on whether it should require the list to include the ten (10) closest suppliers within the 25-mile radius.

Currently, no exception for emergencies is included in the Proposed Rule; however, CMS is seeking comments related to whether there are other procedures or circumstances in which it may be difficult or impractical to provide the written disclosure prior to provision of the imaging services.

When the Health Care Reform Act passed, there was some industry concern that the new disclosure requirement would apply retroactively to all services furnished on or after January 1, 2010; however, CMS believes that retroactive rulemaking is not required. Therefore, the Proposed Rule is set to take effect on January 1, 2011.