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HEALTHCARE BULLETIN

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CMS RELEASES PROPOSED CHANGES TO STARK LAW IN-OFFICE ANCILLARY SERVICES EXCEPTION

In the proposed 2011 Medicare Physician Fee Schedule Rule released for display on June 25, CMS included a proposed amendment to the Stark in-office ancillary services exception (IOAS) to implement Section 6003 of the Patient Protection and Affordable Care Act (PPACA). The rule, when finalized, will take effect on January 1, 2011, along with the rest of the MPFS.

PPACA. PPACA changed the IOAS to require that a referring physician inform patients in writing, at the time of a referral, that the patients may obtain specified imaging services (MRI, CT, and PET), or other designated health services (as designated by the Secretary) from a person other than the referring physician, a physician who is a member of the same group practice, or an individual directly supervised by the physician or by another physician in the group practice. The statutory provision requires the referring physician to provide the patient with a written list of suppliers who furnish such services in the area in which the patient resides.

The Proposed Rule. The proposed rule adds subsection 411.355(b)(7) to the existing IOAS regulatory exception. As proposed, physicians making in-office self-referrals for MRI, CT and PET services must:

- provide the patient with a written notice at the time of the referral that the patient may receive the same services from a "supplier" other than the self-referring physician;

- include in the notice at least ten other "suppliers" within a 25 mile radius of the physician's office that can provide the referred service;

- include the name, address, telephone number, and distance from the referring physician's office for each alternative supplier listed; and

- obtain and retain a record of the disclosure notification, signed by the patient, as part of the patient's medical record.

If the referring physician is located in an area in which fewer than ten alternative suppliers of the applicable service exist within a 25 mile radius, then the physician need not list ten alternatives, but rather all alternative suppliers in the 25 mile radius. If there are no alternative suppliers in the 25 mile radius, then the physician must only inform the patient that he or she may obtain services from another supplier, but need not provide a list of alternatives.

Although within its statutorily granted authority, CMS did not: (1) extend services for which disclosure is required beyond MRI, PET, and CT; or (2) require the alternative list to be focused on suppliers within a particular radius of the patient's residence (as opposed to the physician office). In addition, CMS emphasized that the alternative list must consist of “suppliers" (defined at 42 U.S.C. § 1395x(d), “a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services . . ."), and not “providers of services” (defined at 42 U.S.C. § 1395x(u), including hospitals, critical access hospitals, and other facilities).

The proposed rule sets several traps for possible technical Stark law violations. For example, the following would technically violate Stark under the rule in its proposed form: (1) failing to retain (e.g. losing) a signed patient disclosure form; (2) failing to obtain a patient signature; (3) providing a list of ten alternative suppliers that does not include an address, telephone number, distance, etc. for one or more of the suppliers; and (4) overlooking or omitting a supplier in a 25 mile radius that has fewer than ten suppliers.

Due to possible liability created by this rule for innocuous behavior (such as omitting a telephone number), we believe that affected physicians and providers should take advantage of the comment period to point out the burdens and potentially draconian results of the rule.

CMS will accept comments on the proposed rule until August 24, 2010, and will address them in the final rule, estimated for issuance on about November 1, 2010.

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