

CMS Issues Proposed Regulations Concerning Disclosure Requirements for Certain Imaging Services Under the Stark Law's In-Office Ancillary Services Exception

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On June 25, 2010, the Centers for Medicare & Medicaid Services ("CMS") issued the *Proposed Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011* (the "Proposed Rule").¹ Significantly, among its revisions are the proposed regulations implementing Section 6003 of the Patient Protection and Affordable Care Act ("PPACA")² concerning the physician self-referral provisions of Section 1877 of the Social Security Act, commonly known as the "Stark Law."³ Specifically, the Proposed Rule outlines a proposed disclosure requirement for certain imaging services (the "Disclosure Requirement") provided under the umbrella of the In-Office Ancillary Services Exception to the Stark Law.⁴ Suppliers and providers of imaging services should consider submitting comments on the Proposed Rule to CMS in either the specified areas requested by CMS or the other areas of concern related to this topic. The deadline to submit such comments is August 24, 2010. Also, as indicated in the Proposed Rule, the Disclosure Requirement will take effect on January 1, 2011—one year later than the potentially retroactive effective date of January 1, 2010, specified in PPACA.

The Stark Law

The Stark Law prohibits payment of Medicare claims submitted by a physician (or on that physician's behalf) if (1) the physician has made a patient "referral," as defined by the Stark Law and CMS's regulations; (2) the patient referral was made to an entity for the purpose of furnishing a "Designated Health Service";⁵ (3) the physician or a member of the physician's

¹ The Proposed Rule is available at: http://www.federalregister.gov/OFRUpload/OFRDData/2010-15900_PI.pdf.

² Pub. L. No. 111-148, 124 Stat. 119 (2010).

³ See the Proposed Rule at 743 (regulations concerning Section 6003 of PPACA are to be codified at 42 C.F.R. § 411.355).

⁴ See the Proposed Rule at 369-76.

⁵ See 42 C.F.R. § 411.351 ("Designated Health Services" include the following: clinical laboratory services; physical therapy, occupational therapy, and outpatient speech-language pathology services; radiology and certain other

immediate family has a financial interest in the entity to which the patient has been referred; and (4) the financial relationship does not fall into one of the exceptions set out in the Stark Law (e.g., the In-Office Ancillary Services Exception). Penalties under the Stark Law include the following: (1) the denial of payment and an obligation to refund payments made as a result of a tainted patient referral; (2) civil monetary penalties of up to \$15,000 for each service that a person knows or should know violates the Stark Law; (3) civil monetary penalties of up to \$100,000 for schemes to circumvent the Stark Law; (4) possible exclusion from the Medicare and Medicaid programs; (5) the imposition of up to three times the amount for each item wrongfully claimed; and/or (6) potential liability under the Federal False Claims Act.

The In-Office Ancillary Services Exception

The In-Office Ancillary Services Exception to the Stark Law permits a physician in a solo or group practice to *internally* order and provide certain Designated Health Services that are ancillary—or integral—to the medical services customarily provided by the physician or practice, provided that certain specific criteria are met. To fit within the In-Office Ancillary Services Exception, Designated Health Services must be (1) furnished by the referring physician, a member of his group, or an individual who is supervised by a physician in the group; (2) furnished to patients in a central building that functions to house the medical group's ancillary services (*centralized building test*) or in the same building where referring physicians provide their services (*same building test*); and (3) billed by one of the following: (i) the physician providing or supervising Designated Health Services, (ii) the group practice in which the physician providing Designated Health Services is a member (or the group practice if the supervising physician is a physician in the group practice), (iii) an entity that is wholly owned by the performing or supervising physician or group practice, or (iv) a billing company functioning solely as an agent of the performing or supervising physician or by the physician's group practice.

PPACA added the Disclosure Requirement to the In-Office Ancillary Services Exception to the Stark law. The Disclosure Requirement compels a physician referring a patient for certain in-office imaging services to (1) inform the patient in writing that the patient may obtain certain imaging services from a person other than the referring physician or his or her group practice, and (2) include a list of suppliers who provide the service being referred. PPACA requires this disclosure for magnetic resonance imaging (“MRI”), computed tomography (“CT”), and position emission tomography (“PET”), and also gives the Secretary the discretion to extend the disclosure obligation to any other Designated Health Services determined appropriate.

The Proposed Rule

CMS provided guidance regarding the Disclosure Requirement in the Proposed Rule. Despite the Secretary's broad statutory authority, the Proposed Rule's disclosure obligation is thus far limited to those Designated Health Services specified by PPACA: MRI, CT, and PET. Specifically, according to CMS, the disclosure must (1) be written in a manner

imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services).

sufficient to be reasonably understood by all patients; (2) be given at the time of the referral; and (3) include the name, address, telephone number, and distance from the referring physician's office of at least 10 other suppliers within a 25-mile radius of the referring physician (unless less than 10 suppliers are within the 25-mile radius, in which case all suppliers in the radius should be listed). Moreover, documentation of the disclosure must be signed by the patient and maintained in the patient's record.

CMS acknowledges that the proposed 25-mile radius is potentially prone to abuse in urban areas. For example, providers located in cities with large concentrations of competing suppliers could list only the competing suppliers located on the very outskirts of that radius. This would distort the patient's perception of the proximity of alternate suppliers and, accordingly, discourage usage of the referring physician's competitors. Accordingly, CMS is soliciting comments regarding this and other portions of the Proposed Rule, including:

- whether other radiology and imaging services should trigger the disclosure requirement;
- whether providing a list of 10 suppliers is sufficient or too burdensome on the referring physician;
- whether the 25-mile radius should be expanded or contracted;
- whether the list should include "providers of services" (which includes hospitals and critical access hospitals, among other facilities) as well as "suppliers";
- whether there are alternate criteria CMS should use that would result in an adequate list of convenient suppliers, such as a less specific requirement for a "reasonable" list;
- whether the proposed method of documenting the disclosure (i.e., patient signature) is too burdensome on the physician; and
- whether an exception to the disclosure requirement should exist in emergency or time-sensitive situations.

As previously noted, suppliers and providers of imaging services should consider submitting comments on the Proposed Rule to CMS in either the specified areas requested by CMS or the other areas of concern. The deadline to submit such comments is August 24, 2010.

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*This Client Alert was authored by **Jason Caron** and **Jason Christ**. The authors thank **Jonah Retzinger**, a Summer Associate (not admitted to the practice of law) in EpsteinBeckerGreen's Washington, DC office, for his significant contributions. For additional information about the issues discussed in this Client Alert, please contact one of the authors or the EpsteinBeckerGreen attorney who regularly handles your legal matters.*

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