

CMS Finalizes Written Disclosure Requirements For "Self-Referral" Of MRI, CT And PET Scans Under The Affordable Care Act

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Effective January 1, 2011, referring physicians (non-radiologists) who provide MRI, CT, and PET scans in their office practices will be required to make certain disclosures and provide information to their Medicare patients or risk violation of the Stark Law.^[2] The Stark Law prohibits a physician from making referrals for designated health services (DHS) payable by Medicare to an entity in which the physician (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies.^[3] In addition, the Stark Law prohibits any provider from submitting claims for payment to Medicare for services provided as the result of a prohibited self-referral.^[4]

The Stark Law's In-Office Ancillary Services Exception (IOASE) sets forth the exceptions that permit a physician in a solo or group practice to order and provide DHS in the office of the physician or practice group, provided that certain criteria are met.

PPACA Changes To Stark IOASE

Section 6003 of the Patient Protection and Affordable Care Act ("PPACA") makes a change to the IOASE exception that impacts physician practices providing certain radiology services in their offices. Specifically, Section 6003 provides that, with respect to referrals for magnetic resonance imaging (MRI), computed tomography (CT), positron emission tomography (PET), and other advanced imaging services as determined, the referring physician must inform a patient **in writing** at the time of the referral that the patient may obtain the service from a person other than the referring physician or someone in the physician's group practice, and the referring physician must provide the patient with a **list of suppliers** who furnish the service in the area in which the patient resides.^[5]

Proposed CMS Rule On Changes To Stark IOASE

On June 13, 2010, CMS published a proposed rule on how the new disclosure requirements under Section 6003 of the PPACA would be implemented. See 75 Fed. Reg. 40140-2 ("Proposed Rule"). The Proposed Rule required that written notice must include no fewer than 10 other suppliers within a 25-mile radius, unless fewer than 10 suppliers exist within such radius. The list of suppliers in the disclosure notice must include the name, address, phone number, and distance from the referring physician's office location. The proposal also required the physician to obtain the patient's signature on the disclosure notice and retain a copy of the signed disclosure in the patient's medical record.

Final CMS Rule On Stark IOASE

CMS has now finalized the Proposed Rule with an effective date of January 1, 2011. There are a number of key changes between the Proposed Rule and the Final Rule. Specifically, CMS reduced the number of suppliers that must be listed from 10 to 5. CMS removed the requirement that the supplier's distance from the physician's office be listed on the disclosure. CMS also removed the requirement that the physician must obtain the patient's signature on the disclosure notice and retain a copy of the disclosure in the patient's medical record. Effective January 1, 2011, the Final Rule:

- Applies to MRI, CT, and PET services identified by the List of CPT/HCPCS Codes as "radiology and certain other imaging services."
- Requires the referring physician to provide a written disclosure notice to the patient at the time of the referral. The disclosure notice must include a list of 5 other suppliers that provide the same services and are located within a 25-mile radius of the referring physician's office. The disclosure notice must include, at minimum, the supplier's name, address and telephone number. If there are fewer than 5 suppliers within the 25-mile radius, the referring physician must list all of the suppliers. If there are no alternative suppliers within a 25-mile radius, a written list is not required.
- Requires the disclosure notice to be written in a manner "sufficient to be reasonably understood" by all patients.

Additional CMS Guidance On Final Rule

The Final Rule addresses other disclosure issues in the Comments and Response section:

- The disclosure requirement applies only to the advanced imaging services specified in Section 6003 of the PPACA, which are MRI, CT, and PET services. CMS declined to expand the disclosure requirements to any of the other radiology or imaging services, including X-rays and ultrasound services.
- The disclosure requirement does not apply to any request that is not a "referral" as defined in § 411.351. Requests by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy does not constitute a "referral," as defined in § 411.351. Therefore, the use of a CT scanner for the performance of radiation therapy treatments does not require a

disclosure notice.

- The disclosure notice must be presented to the patient each time one of the listed advanced imaging services is referred. Patients should receive the disclosure each time these services are needed, not just for the initial service. The patient should be made aware that he or she may obtain the services from another supplier any time advanced imaging is ordered.
- For subsequent referrals made via a phone call, the written disclosure must still be provided to the patient and adequately documented. Mailing or e-mailing the disclosure to the patient would be acceptable if verbal notification also has occurred.
- CMS does not plan on posting standard disclosure language for the notice. Instead, each physician office will be responsible for drafting the notice.
- Nothing in Section 6003 of the PPACA prohibits a physician from including language informing the patients that inclusion of other suppliers is not intended as an endorsement or recommendation of those suppliers.
- The referring physician is not required to include hospitals in the written list of alternative suppliers which provide imaging services since hospitals are “providers of services” not “suppliers.” However, physicians are not precluded from listing hospitals in the disclosure notice as long as the required number of suppliers also is included. CMS encourages physicians to list a hospital on the disclosure notice as an alternative location where no other suppliers exist in the 25-mile radius.
- CMS will not grant an exception to providing the disclosure notice to patients at the time of referral in cases of an emergency or time-sensitive nature. In those situations, physicians should make reasonable attempts to provide the notice to the patient and document that the attempt was made.
- In compiling the list of alternative suppliers the physician may use any reasonable means that he or she chooses in order to list the five alternative suppliers. CMS notes that some physicians may choose to compile the list of suppliers from an Internet search; others may know suppliers in the 25-mile radius who provide quality imaging and list these.
- Credentialed facilities are not given special designation on the disclosure notice. However, nothing in the statute or the Final Rule prevents a referring physician from furnishing a list that designates a supplier’s credentialing status.
- The referring physician should list suppliers that are able to perform the services for which the patient is being referred. Listing suppliers that are unable to perform the needed test does not provide the patient with meaningful choices about his or her care, as required by the statute and Final Rule.

- CMS suggests that the list of suppliers should be reviewed annually for accuracy and updated at that time, if necessary.
- Physicians are not obligated to list only suppliers that are accepting new Medicare patients; however, as the disclosure notice is intended to allow patients to make informed choices, referring physicians should make a reasonable effort to ensure that the suppliers listed in the disclosure are viable options for all of their patients for the services being referred.
- Physicians are not required to obtain the patient's signature or maintain a copy of such in the medical record. However, CMS notes, as a matter of prudent business practices, physicians should be able to document or otherwise establish that they have complied with the disclosure requirement.

If you have any questions about the Final Rule, please contact a member of Proskauer's Health Care Reform Task Force.

[1] The "Affordable Care Act" means The Patient Protection and Affordable Care Act ("PPACA") and the Health Care And Education Reconciliation Act of 2010 ("HCERA"). For more information about the Acts, please visit our Health Care Reform Task Force Web site at <http://www.proskauer.com/practices/health-reform-task-force>.

[2] The "Stark Law" is a common industry name for the Federal prohibition against physician self-referrals of Medicare patients. See 42 U.S.C. § 1395nn. The Stark Law requirements discussed in this Client Alert are in addition to any state law disclosure that might currently exist, and will continue to apply.

[3] See 42 U.S.C. § 1395(h)(6); see also § 1395nn.

[4] See 42 U.S.C. § 1395nn.

[5] The PPACA provided that the disclosure requirement would be effective on or after January 1, 2010. However, CMS delayed the effective date as reported in Proskauer's April 2, 2010 client alert, dated April 2, 2010: <http://www.proskauer.com/en-US/publications/client-alert/real-time-health-care-reform/>

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