

Regulatory Review: CMS Issues Proposed Rules Relating to Physician Self-Referral

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Consistent with our previous predictions regarding the Stark Law's In-Office Ancillary Services Exception (IOASE) (see <http://www.ahraonline.org/link/linkonline/default/index.cfm/member-talk/regulatory-review-physician-selfreferral-updates/> for more information), on June 25, 2010, the Centers for Medicare and Medicaid Services (CMS) released the 2011 Proposed Physician Fee Schedule (the "Proposed Rule"). The Proposed Rule, which includes proposals related to new required disclosures under the IOASE, sets forth certain requirements that must be met in order for a referring physician (eg, a non-radiologist) to refer certain designated health services (DHS), including certain advanced imaging testing services, within his or her practice. While the new proposals do not fundamentally alter a referring physician's ability to rely on the IOASE, it nonetheless does present some procedural obstacles that a referring physician must handle in order to comply with the IOASE.

The Stark Law prohibits a physician from making referrals for DHS (including radiology testing services) payable by Medicare to an entity with which the physician has a financial relationship (unless an exception applies). Referring physicians, however, can lawfully furnish radiology testing services in-office, provided that they comply with the IOASE.

As summarized in the May 2010 Link Regulatory Review (<http://www.ahraonline.org/link/linkonline/default/index.cfm/member-talk/regulatory-review-physician-selfreferral-updates/>), Section 6003 of the Patient Protection and Affordable Care Act (PPACA) recently amended the Stark Law by creating a new disclosure requirement under the IOASE, in regards to referrals for MRI, CT and PET. The Proposed Rule puts CMS's contemplated regulatory framework to govern this new IOASE disclosure requirement into motion. Though this rulemaking currently represents only a proposal, it provides insight into the agency's intentions in handling the disclosure obligation and, thus, can serve as meaningful guidance for industry insiders. A final rule is expected to be published later this year.

Specifically, in addition to MRI, CT, and PET, CMS is considering the expansion of the new disclosure requirement to other radiology and imaging services. Although CMS is currently soliciting comments regarding the composition of such other radiology and imaging services that potentially may be subject to the disclosure requirement, CMS specifically states that, at this

time, it is not inclined to expand the disclosure requirement.

Additionally, CMS has proposed the disclosure notice be written in such a way that it can be reasonably understood by all patients. It proposes to require that the notice explains to the patient that the services may be obtained from a person or entity other than the referring physician or his or her group practice, and should include a list of other suppliers who provide the service. In order for the disclosure requirement to be satisfied, CMS proposes that a record of the patient's signature on the disclosure notification be kept in the patient's medical record.

In addition to written notification, PPACA specifies that the referring physician must also provide the patient with a written list of alternate suppliers at the time of the referral. Under the Proposed Rule, CMS states that it will not require or permit the list to include "providers of services," which includes hospitals and critical access hospitals, among other facilities. Additionally, PPACA requires that the alternative suppliers must provide the relevant services "in the area in which [the patient] resides." In order to mitigate the administrative burden of having multiple lists, CMS is proposing that the listed suppliers be located within a 25 mile radius of the physician's office location at the time of the referral.

In order to assist the patient to make an informed decision regarding the physician referral, CMS proposes that the written list include no fewer than 10 suppliers. CMS recognizes that there may be fewer than 10 other suppliers within the 25 mile radius, and under these circumstances, the physician must list all of the other suppliers that are present within the 25 mile radius, including up to 10 suppliers. If there are no other suppliers of the imaging services in the 25 mile radius, the physician need not provide the list of alternative suppliers, but is still required to disclose to patients that the patients may receive the imaging services from another supplier.

CMS proposes that the physician provide certain information about the listed suppliers, including the name, address, phone number, and distance from the physician's office location at the time of the referral. It is noteworthy that, although PPACA provided that this new disclosure requirement would be effective for referrals on or after January 1, 2010 (and most insiders have

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taken the position that it would be effective March 23, 2010, the date President Obama signed the bill into law), CMS is now proposing that the new disclosure requirement apply only to services furnished on or after the effective date of the final regulation, which CMS anticipates will be January 1, 2011.

As we have proposed throughout the past year, at the present

time, physician self-referral of advanced imaging services continues to be permitted under the IOASE. Nonetheless, effective January 1, 2011, referring physicians (non-radiologists) that furnish these services in-office will be required to make certain disclosures and provide information to their Medicare patients. Industry stakeholders should remain attentive to the final rule which is expected to be published later this year.