

Regulatory Review: CMS Issues Final Rule Regarding Stark's IOASE Disclosure Requirement

By Adrienne Dresevic, Esq. and Carey F. Kalmowitz, Esq.

We have been closely monitoring the fate of the Stark Law's (Stark) In-Office Ancillary Services Exception (IOASE) and have reported back to you in past issues of Link on its developments. By way of brief background, Stark generally prohibits Medicare referrals of designated health services (DHS) (including radiology testing services) to an entity if the referring physician (or his/her family member) has a financial relationship with that entity unless an exception applies. The IOASE permits referring physicians (eg, non-radiologists) to refer ancillary DHS within their offices to their Medicare patients.

As summarized in the Regulatory Review columns in the May and July 2010 issues of Link, Section 6003 of the Patient Protection and Affordable Care Act of 2010 (PPACA) imposed a new disclosure requirement under the IOASE, while the Centers for Medicare and Medicaid Services (CMS) issued its proposed rule on this requirement in the June 25, 2010 Federal Register (Proposed Rule). On November 29, 2010, CMS issued its final rule in the Federal Register regarding satisfying this new disclosure requirement (Final Rule).

Under the Final Rule, effective January 1, 2011, the IOASE will require referring physicians or referring group practices relying upon the IOASE for ancillary services to provide a disclosure to Medicare patients receiving advanced imaging services (eg, MRI, CT, or PET). The purpose of the disclosure requirement is to inform Medicare patients of their option (not their obligation) to obtain their ancillary DHS services from other suppliers. The disclosure must be in writing and "in a manner sufficient to be reasonably understood by all patients." Furthermore, the disclosure must be given at the time of the referral (not at the time of service) and must be given each time the services are needed and referred, not only for the initial referral of the service. According to CMS, for referrals made over the phone, so long as the disclosure has been made in the telephone conversation, a subsequent follow-up mailing or e-mail containing the disclosure is permissible.

The disclosure must contain a list of at least five suppliers of advanced imaging services who furnish the same service with-

in a 25 mile radius of the referring physician's office location, including the supplier's name, address, and phone number. The definition of supplier does not include hospitals; thus, inclusion of hospitals on the list of alternate suppliers is permissible, but does not qualify as one of the five required suppliers for purposes of the disclosure. For referring physician practices with multiple locations, each practice location may require a separate list, depending on the other practice's location. Referring physician practices should ensure, on an annual basis, that their lists are up to date and provide accurate information.

If there are fewer than five other suppliers located within a 25 mile radius of the physician's office location at the time of the referral, the physician must list all of the other suppliers of the imaging service that are present within that radius. Provision of the written list of alternate suppliers will not be required if no other suppliers of the necessary services are located within the 25 mile radius.

Even though the referring physician practice will be required to furnish its notice, it does not prevent a referring physician practice from identifying its own advanced imaging services on the disclosure. Furthermore, a referring physician practice may include language on the notice informing patients that the inclusion of the alternate suppliers is not intended to be an endorsement or a recommendation of those suppliers or their advanced imaging services.

The Final Rule is somewhat less onerous than the Proposed Rule. Specifically, the Proposed Rule required referring physician practices to obtain a patient's signature on the disclosure and to maintain the signed disclosure in the patient's file. The Final Rule does not require the patient's signature or maintaining the signed disclosure in the patient's file.

The IOASE continues to remain a viable and highly utilized vehicle for referring physicians to render ancillary advanced imaging services in their offices. Referring physicians (non-radiologists) must prepare to comply with these new disclo-

... continued on next page

Regulatory Review: CMS Issues Final Rule Regarding Stark's IOASE Disclosure Requirement

... from previous page

sure requirements beginning January 1, 2011. Failure to com-

ply with the new requirements will result in Stark law violations and submission of false claims.