BROOKS PIERCE

A Check-Up for Practices that Provide MRI, CT, or PET Services: Are you complying with Stark?

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The Stark physician self-referral law is a strict liability law with many detailed technical requirements. The Affordable Care Act ("ACA") amended a key Stark exception for group practices —the in-office ancillary services exception ("IOAS"). IOAS is "key" because it allows physician-owners to refer to their group practices. The ACA added new technical requirements to the IOAS for practices that provide MRI, CT, or PET services at their practice. This advisory explores those requirements by reviewing CMS's guidance on the ACA amendment. CMS's guidance is important for any practice that relies on the IOAS for providing MRI, CT, or PET services.

Background

ACA added the following new requirements to the IOAS: A physician who refers a patient for MRI, CT, or PET services at the physician's practice must (A) inform the patient in writing at the time of the referral that the patient may obtain these services from someone besides the referring physician and his/her practice and (B) provide the patient with a written list of "suppliers" who furnish the services in the area in which the patient resides. ACA § 6003. These requirements were effective on January 1, 2010.

Subsequently, CMS adopted rules implementing the requirements. 42 C.F.R. § 411.355(b)(7). CMS's rules add additional requirements and fill in some of some gaps in the ACA amendment. The rules apply to services furnished on or after January 1, 2011. The rules' main provisions are summarized as follows:

- The rules apply only to MRI, CT, and PET services that are identified as "radiology and certain other imaging services" on CMS's List of CPT/HCPCS Codes—which List can be found on CMS website.
- If a physician refers a patient to his/her own practice for these MRI, CT, or PET services, the physician must provide a "written notice" to the patient "at the time of the referral."
- The notice must indicate that the patient may receive the "same services" from a person besides the physician and his/her group.
- The notice must list at least 5 other "suppliers" (as defined in 42 C.F.R. § 400.202) that (i) provide the services for which the patient is being referred and (ii) are located within a 25-mile radius of the referring physician's office at the time of the referral. "Supplier" has a technical definition, as discussed below. (Note: The ACA requires a list of suppliers in the area where the

patient resides. However, in its rules, CMS changed this requirement to a list of suppliers within a 25-mile radius of the referring physician.)

- If fewer than 5 such suppliers are located within the 25-mile radius, the notice must list all such suppliers within the radius.
- If no such suppliers are located within the 25-mile radius, the notice does not need to include a list of alternate suppliers. (However, apparently, notice still must be given that the patient may receive the services from another person.)
- For each alternate supplier listed, the notice should include at a minimum the supplier's name, address, and telephone number.
- The notice must be written in a manner that is reasonably understandable by all patients.

The rules answer some questions that were left unanswered by the ACA amendment. However, the rules themselves create questions. Fortunately, CMS clarified certain questions in its preamble to the rules. See 75 Fed. Reg. 73443 (Nov. 29, 2010). Below is a summary of CMS's clarifications and guidance. Now that CMS's rules have been in effect for just over one year, it may be wise for practices to review the clarifications and guidance to ensure that they are remaining in compliance.

To read the health care legal alert in its entirety, please click here.

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