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Some Time to Adjust: CMS Proposes Disclosure Requirements for the In-Office Ancillary Services Exception

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Under the recently released 2011 Physician Fee Schedule Proposed Rule, CMS clarified that disclosure requirements under the in-office ancillary services (IOAS) exception will not be effective until January 1, 2011. CMS released a display copy of the calendar year (CY) 2011 Physician Fee Schedule (PFS) Proposed Rule [PDF] on June 25, 2010. As discussed in our article "[You Can Go Elsewhere . . . But Where? Imaging Services and the In-Office Ancillary Services Exception](#)," Section 6003 of the Patient Protection and Affordable Care Act of 2010 (PPACA) amended the IOAS exception to require referring physicians to provide written notice to patients being referred for specified imaging services, that states the patient can obtain such services from suppliers other than the physician. Some confusion existed as to whether the provision would apply retroactively, because the law stated that the disclosure provision applies to services provided on or after January 1, 2010 — a date more than 2 months prior to the enactment of PPACA. Relying on the statutory language authorizing the Secretary to impose additional requirements under the IOAS exception "by regulation as needed to protect against program or patient abuse," CMS believes that the disclosure requirements are not self-effectuating and will not be effective until CMS promulgates final regulations. CMS proposes that such final regulations will have an effective date of January 1, 2011.

In addition to clarification regarding the effective date, CMS makes the following substantive proposals regarding the disclosure requirement:

- **Imaging Services Included:** Despite having statutory discretion to expand the disclosure requirements to additional designated health services, CMS states that it is inclined to limit application to only those services specifically

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enumerated in the statute -- MRI, CT and PET. CMS is soliciting comments as to whether other radiology and imaging services should be included.

- **General Disclosure Requirement:** CMS proposes that disclosure must be provided by a written notice given to the patient at the time of the referral. The disclosure must indicate that the patient may obtain the services from a person other than the referring physician or his or her group practice and must not suggest that the patient must choose either the referring physician or another supplier included on the list of alternative suppliers.
- List of Alternative Suppliers:
 - CMS proposes that the written notice must include a list of at least 10 other suppliers that provide the services within a 25-mile radius of the referring physician's office location. If there are fewer than 10 suppliers within a 25-mile radius, CMS proposes that the list must include all other suppliers within the 25-mile radius and, if there are no other suppliers within 25 miles of the referring physician's practice, the provision of an alternative list of suppliers will not be required. CMS is soliciting comments regarding whether providing a list of 10 suppliers is sufficient or too burdensome, and whether the 25-mile radius requirement is appropriate. CMS has some specific concerns that providers in metropolitan areas will include only suppliers on the outer most edges of the 25-mile radius to increase chances that patients will choose to have their services completed in the referring physician's office.
 - Recognizing that some confusion exists as to whether the alternative list of suppliers may include "providers of services," which is defined under the Medicare Act to include, among other facilities, hospitals and critical access hospitals, CMS proposes that the list be limited to Medicare "suppliers." CMS is, however, soliciting comments as to whether the inclusion of providers of services on the written notice would benefit the patients by providing them additional alternatives.
 - CMS proposes that the list include the name, address, phone number, and distance from the physician's office location. The latter requirement is intended to "emphasize to the patient the relative convenience of the listed suppliers."

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- **No Exceptions:** CMS states that it is not proposing an exception to the disclosure requirement for emergency or time-sensitive circumstances at this time; however, CMS is soliciting comments as to whether there are circumstances where providing this written disclosure would be difficult or impractical.
- **Documentation of Disclosure:** CMS proposes to require that a record of the patient's signature on the disclosure notification be maintained in the patient's medical record. CMS solicits comments regarding the burden this requirement would create and proposed alternatives for record-keeping.

Ober|Kaler's Comments

The deadline for submission of comments is August 24, 2010. Physicians should consider the effect that these requirements will have on their practice of providing MRI, CT and PET services pursuant to the IOAS exception and their ability to continuously comply with the Stark Law exception. CMS states that the intent of the proposed rule is to provide clear guidance regarding the expectations under the disclosure requirements. Accordingly, in addition to seeking comments regarding the specific proposals discussed above, CMS is also soliciting comments regarding any other alternative methods of compliance that would satisfy the statutory requirements.