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Final In-Office Ancillary Service Exception Disclosure Requirements to Take Effect January 1, 2011

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Final In-Office Ancillary Service Exception Disclosure Requirements to Take Effect January 1, 2011

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New disclosure requirements to the In-Office Ancillary Services (IOAS) exception, issued as part of the final 2011 Physician Fee Schedule (the "PFS," a Final Rule with a Comment Period [PDF]), call for physicians to meet minimal, but essential requirements. 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 CT, MRI or PET that the imaging services can be purchased from suppliers other than the physician. Although there was initially confusion regarding the provision's effective date, CMS clarified in its proposed version of the rule that the additional criteria added by PPACA was not self-implementing and that compliance by physicians would not be required until after the issuance of a final rule.

The Final Rule takes a much more measured approach than the rule as originally proposed. The Final Rule dispenses with the proposed requirement that the required disclosures be signed by the patient and retained by the physician. It also significantly decreases the amount of information physicians are required to provide to patients with regard to alternate suppliers. The net result is a Final Rule that reduces or eliminates many of the more burdensome provisions that had been proposed. Providers should remember, however, that a failure to comply with the Final Rule's requirements will prevent compliance with the In-Office Ancillary Services exception to the Stark law.

The Final Rule, as part of the 2011 PFS, takes effect January 1, 2011 (meaning that it will apply to all services provided on or after that date). Physicians should begin the preparations necessary to provide the required disclosures to ensure that their forms and internal processes are patient-ready on the first of the year.

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Changes to the Proposed Rule

When the proposed version of the Rule was issued, we wrote about it here. CMS received approximately 45 comments to the proposed rule, and the final version of the Rule reflects many of the concerns expressed by commenters. In short:

- The number of suppliers to be listed in the written disclosure has been reduced from 10 to 5.
- The written disclosure need not include a measure of the distance between the referring physician's office and the supplier's place of business.
- So long as the list includes 5 suppliers, as required, physicians are free to include other providers, such as hospitals.
- Physicians need not obtain a signed patient statement indicating that they received the disclosure. Physicians must, however, "be able to document or otherwise establish that they have complied with the requirement." CMS provides, as an example, that physicians can note in a patient's chart that they provided the necessary disclosure.

Additional Clarifications

While the remainder of the Proposed Rule's provisions was finalized as proposed, CMS's response to comments in the preamble of the Final Rule provides additional guidance as to how CMS will interpret certain provisions. The preamble to the Final Rule noted the following:

- CMS declined to add services other that CT, MRI or PET (those specifically enumerated by Congress) to the services for which disclosure would be required.
- A new disclosure must be presented to the patient each time they are referred for CT, MRI or PET services. A single or yearly disclosure will not satisfy the requirements and permit reliance on the In-Office Ancillary Services exception.
- CMS will not provide a form disclosure, but sees no statutory barrier to disclosure language that makes clear to patients that a supplier's presence on the list does not indicate that the referring physician endorses or recommends that supplier.
- In terms of measuring the 25 mile distance required by the Rule, CMS explained that "any reasonable method for measuring distance will be acceptable."

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- Referring physicians must ensure that the suppliers listed on the disclosure are able to perform the service the patient needs. For instance, if a patient has been referred to an imaging center for a CT scan, and the list of suppliers contains an imaging center that only provides x-rays and MRIs, the list would not meet the disclosure requirement.
- Physicians must review their list of suppliers and correct any errors (such as suppliers that have moved, changed numbers, or that have ceased providing a specific service) at least annually.
- Physicians need not confirm that each supplier is accepting new Medicare patients before including them on the list, but they must 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."

Ober|Kaler's Comments

Statutory requirements mandate disclosures for CT, MRI and PET referrals. Given the statutory requirements, the Final Rule has provided physicians a fairly flexible means of compliance with a minimum of "paperwork." Physicians who rely on the In-Office Ancillary Services exception to the Stark law, however, must be careful to maintain strict compliance with the new requirements beginning on the first of the year. Failing to properly document a disclosure or to make reasonable efforts to include viable suppliers within the Final Rule's 25 mile limit may subject otherwise compliant self-referrals to scrutiny and the substantial penalties that come with non-compliance.

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