

## ALERT

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For additional information on this or any health law related issue, please contact RMF's Health Law Department co-chairs: Alexander G. Bateman, who can be reached at 516-663-6589 or [abateman@rmfpc.com](mailto:abateman@rmfpc.com) or Jay B. Silverman, who can be reached at 516-663-6606 or [jsilverman@rmfpc.com](mailto:jsilverman@rmfpc.com)



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### Physicians Beware: New Disclosure Requirement Enacted For "Self-Referral" of MRI, CT and PET Scans

By Ellen F. Kessler, Esq.



Physicians who refer Medicare or Medicaid patients for MRI, CT or PET scans that are performed by their own medical practices will be directly affected by a new disclosure requirement imposed by the recently enacted health care reform legislation known as the Patient Protection and Affordable Care Act ("PPACA"). PPACA requires a physician who refers a patient for MRI, CT or PET scans within the physician's own medical practice to provide a specific written disclosure to the patient in order to satisfy a new requirement under the In-Office Ancillary Services Exception ("IOAS") to the Stark Law. The written disclosure must advise the patient that he/she may receive the imaging service from another supplier of the patient's choice and must include a list of ten (10) other suppliers of MRI, CT and PET services located within twenty-five (25) miles of the referring physician's office (the "Disclosure").

The Stark law prohibits a physician from referring a Medicare or Medicaid patient for certain designated health services ("DHS"), including MRI, CT and PET scans, to a provider with whom the physician has a financial relationship, unless an exception applies. The most common exception for a physician who "self-refers" a patient for DHS performed by the physician's own medical practice is the IOAS. There are already several requirements that must be met in order to satisfy the IOAS exception. PPACA has now added one more requirement – the disclosure.

To clarify the PPACA disclosure requirement, CMS has just issued a set of proposed regulations (the "Proposed Rule"). The proposed rule makes clear that the disclosure is not required to be given as of yet, contrary to the retroactive date stated in the PPACA law, but will apply to MRI, CT and PET services furnished on or after the effective date of a final regulation to be issued by CMS. CMS is proposing an effective date of January 1, 2011 for the disclosure requirement. When the final rule is issued, the effective date will be confirmed.

The proposed rule requires that the written notice must include no fewer than ten (10) other suppliers within the 25-mile radius, unless fewer than ten (10) other suppliers exist within such radius. If there are no other suppliers of the imaging services within such radius, the

referring physician need not provide a list of alternative suppliers at all, but must generally disclose to the patient that the patient may receive the imaging services from another supplier.

The list of suppliers in the disclosure notice must include the name, address, phone number, and distance from the referring physician's office location at the time of the referral. The physician must maintain the documentation of the written disclosure. The proposed rule requires that a record of the patient's signature on the disclosure notice must be maintained in the patient's medical record.

By way of example, if a neurologist wanted to refer a Medicare or Medicaid patient for an MRI to be performed by a radiologist within the neurologist's practice, the neurologist would have to provide the disclosure to the patient at the time the referral is made. If the disclosure is not given to the patient, the IOAS Exception cannot be satisfied and the referral is prohibited.

This new disclosure requirement, however, is not required for MRI, CT or PET referrals from physicians outside the performing physician's practice, or for "self-referrals" within a physician's practice of other radiology or imaging services. Physicians should be forewarned, however, that the PPACA law gives authority to extend the disclosure requirement to other radiology or imaging services that the Secretary of HHS determines is appropriate.

CMS has indicated in the proposed rule that it is also considering whether to expand the Disclosure requirement beyond MRI, CT and PET services, and is soliciting public comments on the issue of expanding to other radiology and imaging services, but seems disinclined to do so at this time.

Physicians who refer patients for MRI, CT or PET scans that are performed within their own practices should consult with legal counsel to develop an appropriate disclosure notice and methodology to ensure that the in-office ancillary services exception of the Stark law is properly satisfied and that the referrals are permissible.

## Changes to Stark Law IOAS Exception Under Consideration

Major reforms to the Stark Law's In-Office Ancillary Services ("IOAS") exception are now under consideration by the Medicare Payment Advisory Commission (MedPac), an agency that advises Congress on issues affecting the Medicare program.

Among the reforms being considered are: (1) excluding from the IOAS exception all radiation therapy and outpatient therapy services, including physical therapy, occupational therapy, and speech therapy services; (2) limiting the IOAS exception to only those medical practices that meet new and more demanding clinical integration requirements, such as requiring each physician in a group practice to provide a "substantial share" (e.g., 90%), of his services through the group; (3) excluding from the IOAS exception certain diagnostic tests that CMS determines are not typically provided on the same day as an office visit; (4) reducing Medicare payments for "self-referred" ancillary services performed under the IOAS exception; (5) re-evaluating and re-tooling payment rates for various ancillary services, which may include bundling or packaging multiple services into one payment and/or revising rates to better reflect time, equipment use rates, work effort and other factors; and (6) requiring prior authorization from a Medicare contractor for high volume "self-referring" physicians to perform certain advanced imaging tests like MRI, CT and PET scans.

MedPac is considering the foregoing strategies both individually or in combination as it attempts to craft a recommendation to Congress that is expected in the next few months. Physicians would be well advised to consider these potential reforms and consult with their legal advisers as they formulate future business plans.

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