

# Health Care Reform: Everyday Impact on Compliance with the Stark Law and its In-Office Ancillary Services Exception

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The healthcare reform act, known as the Patient Protection and Affordable Care Act (PPACA), has now been passed into law and will affect the lives of Americans in numerous ways. One change impacts the way in which some healthcare entities operate their businesses to comply with the ever changing landscape of the Stark law.

The Stark law prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which the physician has a financial relationship that does not meet an exception under the law. Stark also prohibits the DHS entity from filing claims with Medicare for those designated health services rendered as a result of a prohibited physician referral. The penalties for violations of Stark, no matter how innocent a violation may be, are aggressive and potentially devastating. Compliance with Stark is more important now than ever, as the Department of Justice has announced three billion dollars worth of settlements in the first half of 2010 alone.

Stark sets forth numerous exceptions for circumstances under which it is acceptable for a physician to refer DHS to an entity in which the physician has a financial relationship. One of these Stark exceptions is the in-office ancillary services (IOAS) exception. The IOAS exception permits physicians to furnish DHS that are ancillary to the physician's practice where certain supervision, location and billing requirements are satisfied.

Section 6003 of PPACA amends the IOAS exception by requiring additional disclosures to patients with respect to referrals for magnetic resonance imaging (MRI), computed tomography (CT), positron emission tomography (PET), and any other DHS specified under Stark. This new patient disclosure mandate requires the physician to:

- (a) inform a patient in writing at the time of the referral that the patient may obtain the service from a person other than the referring physician or someone in the physician's group practice, and
- (b) provide the patient with a list of suppliers who furnish the service in the area in which the patient resides.

The Center for Medicare and Medicaid Services (CMS) has now issued proposed regulations in response to PPACA and these regulations, as amended, will become effective January 1, 2011. Notably, the proposed CMS regulations would require a physician's disclosure at the time of the referral and such disclosure will need to be acknowledged by the patient's signature. Issues remain as to situations where the patient is incapacitated or not present at the time to execute an acknowledgement. The proposed regulations also require the physician's disclosure to identify ten alternate suppliers (this designation of suppliers, rather than providers, does not include hospitals) within a 25-

mile radius. If there are not ten suppliers within this geographic radius, physicians would be required to identify all suppliers located within a 25 mile radius. Additionally, CMS is proposing making it mandatory that the physician provide certain information about the listed suppliers, including the name, address, phone number, and distance from the physician's office location at the time of the referral.

As mentioned above, these new disclosure requirements promulgated by CMS will not take effect until January 1, 2011. While this represents a change in policy for physicians, now is the time to begin implementing new policies, and developing procedures, forms, and documentation for these new rules in order to ensure a smooth transition.