

## **Avoiding Compliance Pitfalls: Stark Law**

*What is the Stark Law?*

It is a highly technical statute. Even Peter Stark, the statute's Congressional namesake, has expressed regrets that it passed!

The physician referral law prohibits a physician from referring patients to an entity for a Designated Health Service (DHS), if the physician or a member of his or her immediate family<sup>1</sup> has a financial relationship with the entity, unless an exception applies. The law also prohibits an entity from presenting a claim to Medicare or to any person or other entity for DHS provided under a prohibited referral. No Medicare payment may be made for DHS rendered as a result of a prohibited referral, and an entity must timely refund any amounts collected for DHS performed under a prohibited referral.

*See (42 CFR §411.350 et seq.).*

*See also:* [http://questions.cms.hhs.gov/app/answers/detail/a\\_id/1501/p/8%2C51%2C854](http://questions.cms.hhs.gov/app/answers/detail/a_id/1501/p/8%2C51%2C854)

Stark is a strict liability statute. Innocent violations are still violations and intent does not need to be shown. Even if you have the most innocent intentions, you are still subject to the grossest of penalties, as if you meant to violate the law.

*How Can You Navigate the Stark Law Minefield?*

In any Stark analysis there are three (3) key questions:

- Are the patients covered by Medicare or Medicaid?
- Are the services considered Designated Health Services (i.e. clinical laboratory services)?
- Does the physician or his/her immediate family member have a financial relationship with the entity<sup>2</sup> to which there is a referral? [i.e. either compensation or investment]

If the answer is “yes” to all three questions, there is a Stark Law issue.

<sup>1</sup>42 CFR §411.351 defines immediate family member as “husband or wife; birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild”.

<sup>2</sup>One exception to the referral prohibition is an investment interest in a publically traded company or investment in a corporation that has stockholder equity exceeding \$75M. *See* 42 CFR §411.356.

The Stark Law carries draconian penalties that are often grossly disproportionate to any harm. Possible consequences of Stark Law violations:

- An entity may be prohibited from presenting claims to Medicare;
- An entity may be required to refund all collected amounts to Medicare;
- Civil Monetary Penalties of \$15,000 per claim;
- Civil Monetary Penalties of \$100,000 for schemes to circumvent the law; and/or
- An entity may be excluded from all federal health care programs.

The goal is to avoid technical violations of the Stark law in the first place. We want to protect you, the company and our clients. Work with legal counsel on Stark law analyses if there are questions.

A useful online resource that discusses the Stark Law can be found at:

<http://oig.hhs.gov/fraud/PhysicianEducation/>.

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