

## Summary of Stark Law White Paper

The Stark law white paper discusses potential changes to section 1877 of the Social Security Act, 42 U.S.C. § 1395nn, also referred to as the Stark law, to remove barriers to implementing health care reform and to distinguish technical violations from substantive violations.

Congress enacted the Stark law to curb the influence of financial relationships on physician referrals. Under a fee-for-service (FFS) payment model, physicians have a financial incentive to provide more services. When a physician has a financial stake in an entity to which he or she refers patients, there is an incentive to make more referrals to that entity. The Stark law addresses this incentive by prohibiting a physician from referring Medicare patients for “designated health services” to an entity with which the physician (or an immediate family member) has a financial relationship, unless an exception applies.

The prohibition has grown into a complex set of regulations that has continually expanded since its initial publication in 1995. There is no requirement of an intent to violate the statute. Congress believed that given a bright line rule, providers would self-police their arrangements with physicians. Despite this intent, the Stark law has become increasingly complex and confusing, creating a number of challenges for the health care industry through its strict liability standard, significant fines and compliance costs, and its challenging and inflexible nature.

To better understand these concerns, in December 2015, the Senate Committee on Finance, along with the House Committee on Ways and Means, invited stakeholders and legal experts to a round table to discuss the Stark law. The Committees heard feedback on the current Stark law environment, impediments to health care reform implementation and possible fixes under both FFS and alternative payment models, compliance and disclosure costs, and the Center for Medicare & Medicaid Services’ (CMS) limited authority to create exceptions and to issue advisory opinions.

Following the round table, a more widespread call for comments was issued and nearly 50 comments were received. The key areas of comment were:

- Changes to the Stark law to allow providers to implement new payment models, including potential new waivers or exceptions, expansion of existing waivers or exceptions, broadening CMS’s regulatory authority, repealing the compensation arrangement prohibition, or repealing the law in its entirety.
- Changes to implement the Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10 (MACRA), with options for payment systems that include both FFS and alternative payment models.
- The need to amend Stark law definitions such as fair market value, volume and value of referrals, and commercial reasonableness.
- Technical violations (of form rather than substance) of the law should be subject to separate sanctions and limited liability.
- General frustrations with the difficulties and expense of complying with the Stark law.