

Physician, Disclose Thyself: CMS Updates Stark Law Protocol



The Stark Law (also known as the physician self-referral law)

prohibits doctors and their immediate family members who have a financial relationship with a business from referring patients to that entity for designated health services (DHS) covered by Medicare. Furthermore, should services occur that violate the Stark Law, the entity in question is not allowed to submit claims to Medicare or another payer for reimbursement. Penalties for violating the Stark Law range roughly from \$11,000 to \$22,000.

The broad strokes of the law's history, as described on the website of the Centers for Medicare & Medicaid Services (CMS): "Section 6409 of the Patient Protection and Affordable Care Act (ACA) was signed into law on March 23, 2010. Section 6409(a) of the ACA required the Secretary of the Department of Health and Human Services, in cooperation with the Inspector General of the Department of Health and Human Services, to establish a Medicare self-referral disclosure protocol that sets forth a process to enable providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute."

Revision to CMS's Voluntary Self-Referral Disclosure Protocol

Late last month the CMS released its revised requirements for [Voluntary Self-Referral Disclosure Protocol \(SRDP\)](#) which gives the Department of Health and Human Services (HHS) the right to consider how much is owed the practitioner or healthcare supplier (known as the "Disclosing Party") as well as the amount of Stark Law penalties that have been accrued, and adjust payments accordingly.

Regarding the revisions to protocol recently released by the CMS, a notable update comes in the shape of the new SRDP Disclosure Form CMS-10328, an electronic submission which will be a required piece for any Disclosing Party from June 1st on. In addition, a non-electronic Certification, ink-signed by the Disclosing Party, must accompany the disclosure. The form asks the Disclosing Party to furnish information that shows how pervasive the non-compliance in question was.

From new guidance to a longer lookback period

Other revisions to the SRDP include:

- New guidance about how to identify and report self-referral non-compliance, not only when potential issues are brought to light in the behavior of individual practitioners, but in group practices as well;

- The instructions for the Disclosing Party to send the CMS emailed notification in the event of the Party making a change to the designated representative, entity ownership, or files for bankruptcy;
- A removal of the previous SRDP requirements of the submission of information that describes the financial benefit of a non-compliant relationship to the practitioner in question and an evaluation of the Disclosing Party's preexisting compliance program;
- A widening of CMS's "lookback period," the timeframe in which a Disclosing Party must identify a potential Stark Law violation, now expanded to six years;
- A revision to the Physician Information Form that previously only included the instructions for the Disclosing Party to provide "detailed explanations of noncompliance" with new check-boxes that "allow parties to quickly identify those elements of an applicable exception that a financial relationship satisfied and those elements that the relationship failed to satisfy";
- And the aforementioned Physician Information Form includes one of two specific directions that the Disclosing Party's disclosure must take; the disclosure must either: "(a) certify that the applicable financial relationship was noncompliant (or that the services failed to satisfy an applicable exception at 45 C.F.R. § 411.355), or (b) state that, because it cannot confirm that the financial relationship complied with the physician self-referral law, it is certifying noncompliance with the law."

\$23 million in Stark Law settlements from 2011 to 2016

According to Lisa Ohrin Wilson, Senior Technical Advisor for CMS, from the SRDP's inception in 2011 through the end of 2016, the CMS had received nearly 900 disclosures and settled more than 200 Stark Law violations totaling over \$23 million (individually, the settlements ranged widely, from \$60 to nearly \$1.2 million. But not every disclosure of self-referral non-compliance culminates in settlement: nearly 100 were closed without being settled, settled by law enforcement, or withdrawn entirely.

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