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The Centers for Medicare and Medicaid Services (CMS) issued its long-awaited Medicare self-referral disclosure protocol (SRDP) on September 23, 2010. The SRDP provides a vehicle for healthcare providers and suppliers to resolve actual or potential violations of the Stark Self-Referral Statute (Stark). Congress directed the Secretary of Health and Human Services (HHS) to develop the SRDP following the Office of Inspector General's (OIG) announcement on March 24, 2009, that it would not accept "Stark-only" disclosures into the OIG Self-Disclosure Protocol (OIG Protocol). See Affordable Care Act (ACA) at §6409.

There are no guarantees of favorable treatment for disclosing parties who come forward through the SRDP. So why consider it? Three reasons:

- The government can recover all payments made for claims tainted by a Stark violation. When an improper arrangement has been in place for years, this recovery can threaten the financial viability of the practice or entity involved. Congress gave HHS authority to compromise the amount owed. The prospect of compromise is a powerful incentive even without a guaranteed reduction. Past experience involving hybrid Stark/anti-kickback disclosures under the OIG Protocol suggests there may be the opportunity for meaningful reductions, particularly for "technical" Stark violations.
- The ACA requires that overpayments be returned by the later of: (1) 60 days after the date of identification, or (2) the due date of the corresponding cost report. Improper retention of an overpayment beyond the deadline may create a False Claims Act violation. The SRDP provides an escape valve, because the deadline is suspended by the submission of a disclosure under the SRDP.
- Disclosure may be better than the alternatives. The penalties for Stark violations include significant civil monetary penalties and potential exclusion from participation in federal health programs. While it remains to be seen whether the SRDP will effectively eliminate those risks for most disclosing parties, deliberately avoiding disclosure only serves to heighten those risks.

Bear in mind that the purpose of the SRDP is narrow: to resolve colorable Stark violations. It is not available to resolve conduct that implicates both Stark and the anti-kickback statute or to obtain an advisory opinion regarding the underlying conduct or arrangement.

When considering your options, remember that a disclosure may have the unintended consequence of triggering an expanded inquiry. Per the SRDP, CMS reserves the right to refer a disclosed matter to another agency to

resolve False Claims Act, civil monetary penalty, or other liability. Due to this and many other risks, each matter should be carefully evaluated to determine whether disclosure is not only appropriate, but desirable.

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