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Possible Stark Violation? What Providers Should Do Now

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In recent years, hospitals, physicians and other providers have wrestled with the question of how to remedy violations of the dauntingly technical and complicated physician self-referral law, or "Stark Law."[1] The Stark Law prohibits accepting Medicare payments for services provided while a violation exists, but provides little guidance on the steps providers should take when they discover a violation and offers no mechanism to mitigate disproportionately harsh financial effects of minor, non-abusive violations. The Patient Protection and Affordable Care Act (PPACA)[2] and the Centers for Medicare and Medicaid Services' (CMS) new self-disclosure protocol have changed the landscape related to such situations.

PPACA Section 6402(d) mandates that a provider who identifies an "overpayment" must, within the later of 60 days after the overpayment is "identified" or any corresponding cost report is due: (1) report and return the overpayment to the government and (2) notify the relevant government agency of the reason for the overpayment.[3] PPACA further links retention of an overpayment, *i.e.*, "[Medicare or Medicaid] funds that a person receives or retains… to which the person, after applicable reconciliation, is not entitled," to the federal False Claims Act (FCA). The FCA imposes potential civil liability for knowingly concealing or knowingly and improperly avoiding an "obligation" to pay or transmit money to the government under the FCA (the "reverse false claims" provision).[4] Thus, overpayments retained beyond PPACA's 60-day "report and return" deadline could subject a provider to civil liability under the FCA,[5] as well as criminal liability under a separate statute.[6]

This mandate initially left providers in a difficult position, as it defined no procedure to "report and return" overpayments or to determine whether a violation led to an overpayment. On September 23, 2010, CMS unveiled its long-awaited Medicare Self-Referral Disclosure Protocol (SRDP), which describes <u>how</u> providers and suppliers should self-disclose actual or potential Stark Law violations, and offers <u>some</u> opportunity for providers to avoid excessive penalties.[7] The SDRP, like the Department of Health and Human Services Office of Inspector General protocol, requires the self-disclosure to describe the disclosing entity, the questionable conduct, the provider's investigation, potential causes of the disclosed conduct, and steps taken to ensure such conduct does not recur.

Under the SRDP, the disclosure must provide a legal analysis of the problematic conduct, and a financial analysis of the amount due and owing—but the SRDP pro-

vides no specific guidance on how to perform this analysis. Thus, providers should obtain legal advice from qualified counsel familiar with Stark issues to confirm the existence of a disclosable Stark issue and assist in drafting the disclosure. The SDRP does not provide guidance as to when an overpayment is "identified," but a provider who becomes aware of a potential Stark violation should act promptly to quantify the overpayment and should consult with counsel about how to do so.

CMS will not accept repayments before it has reviewed the disclosure, so the repayment period is stayed pending review. CMS will require access to the provider's documentation related to the violation, and may refer a provider to law enforcement based on the disclosure. Importantly, CMS may, but is not required to, reduce any amount due resulting from a Stark violation.[8] The factors CMS may consider in reducing the amount owed include the: (1) nature and extent of the improper practice; (2) timeliness of self-disclosure; (3) cooperation in providing information; (4) litigation risk associated with the matter disclosed; and (5) financial position of the disclosing party. Providers who settle with CMS will lose the right to appeal a finding of a violation. If CMS does not settle with the provider, CMS may be able to reopen the disclosed claims.[9] Finally, providers should not disclose the same conduct under both the SRDP and the OIG's protocol, even if the conduct raises enforcement issues (such as civil monetary penalties) addressed by both protocols—leaving providers to decide which protocol to rely upon.

Unfortunately, the SRDP is silent as to how CMS will assess "technical" Stark violations, *e.g.*, a missing signature, that do not involve program abuse but nonetheless may result in significant overpayment liability. Therefore, providers and their counsel must carefully assess a possible violation and then seek a settlement by making a compelling case that the "nature and extent" of the conduct they self-disclose does not warrant significant repayment liability. More importantly, providers and suppliers have a continuing incentive to comply with the Stark Law and a new avenue to remedy compliance issues under the Stark Law.

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[1] 42 U.S.C. § 1395nn.

[2] Pub. L. No. 111-148, 124 Stat. 119 (2010).

[3] PPACA § 6402(d).

[4] 31 U.S.C. §§ 3729-3733.

[5] PPACA § 6402(d)(3).

[6] 42 USC § 1320a-7b(a)(3).

[7] A copy of the SRDP is available at http://www.cms.gov/PhysicianSelfReferral.

[8] PPACA, Section 6409(b).

[9] 42 C.F.R. §§ 405.980 - 405.986.

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