

OIG Announces Intent to Limit Stark Law Violation Self Disclosure Protocol

In an Open Letter to Healthcare Providers on March 24, 2009, the Office of the Inspector General (OIG) stated its intention, effectively immediately, to no longer use its Provider Self-Disclosure Protocol (SDP) to resolve issues that involve only physician self-referral violations.¹

The SDP, created by the OIG in 1998, currently gives providers the opportunity to disclose potential violations of Stark and/or Anti-kickback laws to the OIG. Providers who raise the concern about potential violations and submit the necessary SDP materials to the OIG (e.g., detailed disclosure of issue, list of parties involved, etc), receive the OIG's guidance on resolving the potential conflicts of interest. While participation in the now narrowed SDP would not result in provider immunity to the investigations by the Department of Justice (DOJ), cooperation in the proactive investigation would reduce penalties incurred as a result of any illegal activity.² Additionally, providers who submit evidence of potential fraud avoid the likely (and lengthy) government-directed investigation of fraudulent actions.³

The OIG last updated the SDP in 2006 when it announced the OIG's intention to provide guidance on resolving matters that involved civil monetary penalties (CMP). While CMPs fall on a continuum, participation in the SDP and proactive cooperation with the OIG would likely denote receiving a CMP on the lower end of the continuum.⁴

Although the SDP initially accepted a broad scope of disclosures (including both Stark Law and Anti-kickback violations), the March 24, 2009 Open Letter from the OIG stated its intention to narrow the SDP's scope and focus towards violations of the Anti-kickback statute that provide fraudulent kickbacks to reward or incentivize physicians for referrals. In the letter, the OIG stated it would no longer accept disclosures that *only* involved Stark Law violations. Disclosures that involve a Stark Law violation as well as an Anti-kickback violation (or violations related only to the Anti-kickback statute) will continue to be accepted. Inspector General Daniel R. Levinson stated that the purpose of the more defined scope was to better allocate OIG resources, as well as to more effectively fulfill the mission of the OIG.

⁵ However, questions have arisen as to whether the exclusion of Stark-only violations defeats the SDP's

original purpose of encouraging providers with *any* potential violations to come forward "*without fear of further litigation.*" With the elimination of the ability to disclose Stark-only violations, providers could either treat potential violations as overpayments and pay restitution to the affected parties, or they can alert the DOJ. Unfortunately, neither of these options provides guidance on resolving the matter and would not guarantee the absence of further legal ramifications.⁶

In addition to narrowing the scope of the SDP, the OIG also established a "*minimum settlement amount of \$50,000 to resolve the matter,*" a minimum consistent with the OIG's maximum penalty of \$50,000 for *each* violation of the Anti-kickback statute. Despite the OIG's letter sets a minimum settlement amount, Levinson stressed the OIG's commitment to settle CMPs on the lower end of the continuum for cooperating providers.⁷

Significantly, the letter cautioned that providers should not interpret the SDP's focus on Anti-kickback violations as any indication of relaxed enforcement of Stark Law violations.⁸

¹ "An Open Letter to Healthcare Providers: March 24, 2009," Office of the Inspector General, March 24, 2009, <http://www.oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf> (Accessed 4/7/09)

² "Publication of the OIG's Provider Self-Disclosure Protocol," 63 FR. 58399

³ "Self-Disclosure Information," Office of the Inspector General, 2009, <http://oig.hhs.gov/fraud/selfdisclosure.asp> (Accessed 4/7/09)

⁴ "An Open Letter to Healthcare Providers," Office of the Inspector General, April 24, 2006, <http://oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Pr%20viders%202006.pdf> (Accessed 4/7/09)

⁵ "An Open Letter to Healthcare Providers: March 24, 2009," Office of the Inspector General, March 24, 2009, <http://www.oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf> (Accessed 4/7/09)

⁶ "OIG Open Letter Leaves Providers with Self-Disclosure Questions," By Ben Amirault, Health Leaders Media, April 14, 2009, http://www.healthleadersmedia.com/content/231506/topic/WS_HLM2_HOM/OIG-Open-Letter-Leaves-Providers-with-SelfDisclosure-Questions.html (Accessed 4/15/09)

⁷ "An Open Letter to Healthcare Providers: March 24, 2009," Office of the Inspector General, March 24, 2009, <http://www.oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf> (Accessed 4/7/09)

⁸ "An Open Letter to Healthcare Providers: March 24, 2009," Office of the Inspector General, March 24, 2009, <http://www.oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf> (Accessed 4/7/09)



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