

OIG Narrows Self-Disclosure Protocol

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The U.S. Department of Health and Human Services Office of Inspector General (OIG) narrowed the scope of issues that may be resolved through its Self-Disclosure Protocol (SDP) in an Open Letter to Health Care Providers dated March 24, 2009. Citing a need to prioritize its work and resources, the OIG announced it will no longer accept disclosures of matters that involve only liability under the physician self-referral (Stark) statute. The OIG will continue to accept submissions related to conduct involving colorable violations of both the anti-kickback statute and the physician self-referral statute. In addition, the OIG announced a new minimum penalty floor of \$50,000 to resolve anti-kickback matters.

This guidance represents a significant shift from the OIG's Open Letter dated April 24, 2006. That letter announced an initiative "that promotes the use of the SDP to resolve civil monetary penalty (CMP) liability under the physician self-referral and anti-kickback statutes for financial arrangements between hospitals and physicians." The letter noted that the SDP "is one vehicle to resolve this [Stark] type of administrative liability." This is no longer true, unless the reported conduct also involves a colorable anti-kickback claim.

This change closes the door on the most attractive option for healthcare providers seeking to disclose colorable Stark-only violations. Providers are now left with the choice of disclosing to another agency, such as the U.S. Department of Justice/U.S. Attorney's Office, the Centers for Medicare and Medicaid Services, or a State Medicaid Fraud Control Unit, or making a refund to a fiscal intermediary/carrier. Each of these alternatives has significant challenges and risks. For instance, only the Department of Justice option offers the chance to obtain a False Claims Act release for Stark-only compliance issues.

For conduct that gives rise to colorable anti-kickback liability, the SDP remains the most attractive self-disclosure option. Even with the new minimum \$50,000 penalty, the SDP offers the best opportunity for a reasonable settlement. For those who meet the applicable requirements, the SDP holds out the promise of resolution with reduced penalties and without the imposition of an onerous Corporate Integrity Agreement or, worse yet, exclusion from participation in federal health programs. For all these reasons, healthcare providers and entities will continue to benefit from the SDP in appropriate cases.

The March 24, 2009 Open Letter may be found here on the OIG website. Further information about the SDP may be found here.

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