Office of Inspector General Updates and Clarifies its Self-Disclosure Protocols

The government urges business and individuals to self-disclose potential violations of law. A substantial obstacle to self-disclosure is that the consequences are often unpredictable. With an updated protocol issued by the Office of Inspector General, health care entities have obtained a bit more certainty.

On April 17, 2013, the Office of Inspector General (“OIG”) of the Department of Health and Human Services published an Updated Provider Self-Disclosure Protocol (“Updated SDP”) for health care entities who wish to voluntarily disclose potential violations of law to OIG. The Updated SDP is the first complete revision to the self-disclosure process since the original 1998 Federal Register, and it supersedes and replaces the original protocol, as well as the three subsequent Open Letters that provided additional guidance.

The Updated SDP revises the process for submitting a self-disclosure and provides guidance on how to investigate and report such conduct to resolve exposure under OIG’s civil monetary penalty authorities. Among other things, the Updated SDP:

- Clarifies that all health care-related providers and companies subject to the OIG’s civil monetary penalty authorities, including pharmaceutical and device manufacturers, are eligible for the SDP process;
- Acknowledges that OIG’s general practice is to use a minimum penalty multiplier of 1.5 times single damages when an entity self-discloses (as opposed to upwards of treble damages plus penalties);
- Notes a pending regulatory proposal to suspend the 60-day clock for reporting overpayments, as soon as OIG acknowledges receipt of a timely self-disclosure;
- Requires that the self-disclosing party complete its damages calculation within 90 days of the initial self-disclosure (as opposed to 90 days of OIG’s acceptance of the self-disclosure);
- Acknowledges that OIG has instituted a presumption against requiring corporate integrity agreement obligations in exchange for the entity’s release of OIG’s permissive exclusion authorities in resolving the self-disclosed matter;
- Warns that disclosures should explicitly acknowledge and identify potential criminal, civil, or administrative violations and should not state, for instance, that the “government may think there is a violation, but we disagree”;
- Establishes minimum settlement amounts of at least $50,000 for self-disclosures involving kickbacks and $10,000 for all other disclosures;
- Institutes specific submission and damages guidelines for false billing, conduct involving excluded persons, and Anti-Kickback Statute self-disclosures;
- Generally requires a minimum sample size of 100 units;
Clarifies that the Updated SDP is not appropriate for potential violations that only involve the physician self-referral law ("Stark Law"), which should be disclosed directly to CMS through its separate Self-Referral Disclosure Protocol; and

Specifically recognizes that OIG will consider inability-to-pay arguments, and provides guidance about raising those issues early in the self-disclosure process.

HSE’s Health Care and Government & Internal Investigations attorneys are available to guide you and your organization through the process of self-disclosure. Please contact any of us at (585) 232-6500.