OIG Updates Self Disclosure Protocol

On April 17, 2013, the Health and Human Services, Office of Inspector General (OIG) updated its Provider Self Disclosure Protocol (SDP). The updated SDP replaces OIG’s original SDP, published in October 1998, and supersedes OIG’s related open letters from 2006, 2008 and 2009. The original SDP was to “establish a process for healthcare providers to voluntarily identify, disclose, and resolve instances of potential fraud involving the Federal health care programs;” and to provide guidance on how to investigate this conduct, quantify damages and report the conduct to OIG to resolve the provider’s liability under OIG’s civil monetary penalty (CMP) authorities. The updated SDP generally affirms OIG’s past positions regarding voluntary disclosure; but it also makes some important changes including:

- **SDP Availability:**
  - The SDP applies not only to health care providers; but also to drug and device manufacturers (e.g., disclosing parties);
  - The SDP applies to disclosing parties that may already be subject to a government inquiry; and
  - The SDP is only available for matters subject to CMPs under federal criminal, civil or administrative law (not matters violating the Stark law [these errors must be processed through the CMS Self-Referral Disclosure Protocol] or that exclusively involve overpayments and errors [these must be processed through the Medicare Administrative Contractor]).
- **Affordable Care Act (ACA) Changes:**
  - The ACA requires that providers report and rectify any Medicare and Medicaid overpayments within 60 days after the overpayment is identified. If a disclosing party is involved in an SDP; the 60-day deadline is tolled.
- **SDP Submission Requirements:**
  - The disclosing party must complete an internal investigation within 90 days of their initial submission to OIG, and acknowledge a potential violation of the federal laws.
- **Damage Calculations:**
  - The SDP provides a detailed methodology for calculation of damages from false billing, employment of excluded persons and the federal Anti-Kickback law; and reaffirms OIG’s general practice to require a minimum multiplier of 1.5 times the single damages as a condition of settlement under the SDP;
- **Resolution:**
  - The SDP offers an incentive for self-disclosure, and reaffirms its presumption against a Corporate Integrity Agreement (CIA) for settlements reached under the SDP; and
  - The SDP is not a fast process.