Recent Developments in Voluntary Self-Disclosure

Tamar V. Terzian
Deputy Chief, Administrative & Civil Remedies Branch
Office of Counsel to the Inspector General
Department of Health & Human Services

OIG Provider Self-Disclosure Protocol

- OIG’s commitment to voluntary compliance
- Protocol sets out recommended investigative and audit measures
- Protocol found on OIG website at oig.hhs.gov
Why Self-Disclose?

- Requirement to return identified overpayments
  42 U.S.C. § 1320a-7b(a)(3)
- Control investigation and presentation of issue
- Possibility of protection against *qui tam* suit under the False Claims Act
- Possibility of mitigating penalties
- CIA requirements generally waived

When Should a Provider Use the Self-Disclosure Protocol?

- Distinguish ordinary overpayments from potential civil or criminal violations
- Ordinary overpayments should be resolved through the relevant Medicare contractor
Open Letters

- April 24, 2006
- April 15, 2008
- March 24, 2009

April 2006: Open Letter to Health Care Providers

- Protocol is a vehicle for resolving improper arrangements under the Physician Self Referral law
- Conduct that might subject the provider to CMP liability
- “Multiplier of the value of the financial benefit conferred by the hospital”
April 2008: Open Letter to Health Care Providers

- In initial submission to OIG, provider must include:
  - Complete description of conduct
  - Description of internal investigation (or commitment regarding completion of investigation)
  - Estimate of damages and methodology of calculation
  - Statement of laws potentially violated
- Without these elements, providers won’t be admitted
- Uncooperative providers will be removed

April 2008: Open Letter to Health Care Providers

- OIG’s internal process streamlined
- Expect full cooperation during verification
- Complete and informative disclosure, quick responses to OIG requests, and performance of an accurate audit
April 2008: Open Letter to Health Care Providers

Benefits to Provider

- Expedited resolution of matter
- With provider’s cooperation, presumed release of permissive exclusion in settlement, without integrity obligations

March 2009: Open Letter to Health Care Providers

- Refines initiative announced in 2006 Open Letter by narrowing Protocol’s scope regarding violations of the Stark Law
- OIG will no longer accept matters that involve liability only under the Stark CMP in the absence of a colorable kickback violation
- OIG will continue to accept matters that raise both kickback and Stark issues as well as matters that only implicate the kickback CMP
- Open Letter establishes a minimum settlement amount of $50,000 for kickback disclosures
March 2009: Open Letter to Health Care Providers

What we are NOT saying:

- We are not saying that kickbacks under $50,000 are okay
- We are not saying Stark enforcement is unimportant
- We are not saying that DOJ is bound by anything we are saying
- The Open Letter should not be seen as a statement about the Government’s legal rights to seek remedies for violations of the Stark law

Internal OIG Process for Protocol Submissions

- OIG receives disclosure and verifies if provider is already under investigation

- Agent and Attorney are assigned to:
  - Verify submission
  - Request missing information
  - Interviews of parties involved
Internal Process (con’t)

- Agent and attorney review the disclosure and determine resolution:
  - FCA settlement
  - CMP settlement
  - CIA (rebuttable presumption)
  - Referral to contractor for refund
  - Closed with no recoveries or settlement

Results To Date

- In last three years, over 200 submissions to the Protocol
- Settled approximately 185 since 1998
- Almost $200 million returned to Medicare Trust Fund