Fraud and Abuse Statutes, Administrative Authorities, and Self-Disclosures

1. The False Claims Act
2. Civil Monetary Penalties Law
3. The Anti-Kickback Statute
4. The Prohibition on Certain Physician Referrals (Stark Law)
5. The Inspector General’s Exclusion Authority
6. The Self-Disclosure Process
Presenter

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Civil Cases

RELATIONSHIPS
• Anti-Kickback Statute
• Prohibition on Certain Physician Referrals (Stark)
• Civil Monetary Penalties Law
• Exclusion

BILLING
• False Claims Act
• Civil Monetary Penalties Law
• Exclusion
The False Claims Act

31 U.S.C. Sections 3729-3733
The Federal False Claims Act

• 31 U.S.C. Sections 3729 *et. seq.*
• Prohibitions on knowingly making--
  • False claim;
  • False record or statement;
  • Reverse false claim; or
  • Conspiracy.
• Treble damages.
• Per claim penalties.
The False Claims Act

Common Issues:

- Medical necessity
- Arrangements
- Worthless services
- 60 day repayment
- Data-driven cases
Civil Monetary Penalties Law

42 U.S.C. Section 1320a-7a
Types of Civil Monetary Penalties (CMP) Cases

- Kickbacks
- Physician referral (Stark) violations
- False or Fraudulent Claims
- Billing while excluded
- Select Agents
- Patient dumping (EMTALA)
- About 40 other OIG CMPs
Civil Monetary Penalties Law – Key Points

• Aside from 42 U.S.C. 1320a-7a, there are other CMPs are codified outside the CMPL, but incorporate the CMPL intent standards and procedures.

• CMPL is most often used by OIG as an alternative to civil action under the False Claims Act.

• DOJ authorization is required for a CMPL action, 42 U.S.C. § 1320a-7a(c)(1).

• OIG must prove the elements of a CMP action by preponderance of the evidence; Respondent has the burden to prove any mitigating factors and affirmative defenses.

• Six Year Statute of Limitations, 42 U.S.C. § 1320a-7a(c)(1).

• CMP, Assessments, and Exclusion available for most CMP cases.

• Administrative Law Judge Proceeding/Hearing, 42 U.S.C. § 1320a-7a(c)(2).
The Anti-Kickback Statute

42 U.S.C. § 1320a-7b(b)
The Anti-Kickback Statute

• Offer, Payment, Solicitation, or Receipt
• Remuneration
• Referrals
• Knowingly and Willfully
• Safe Harbors
Violations of the Anti-Kickback Statute

• Criminal
• Civil Monetary Penalties
• Exclusion
• False Claims Act Liability
• Non-Payment
• Refunds to Beneficiaries
The Prohibition on Certain Physician Referrals (Stark Law)

42 U.S.C. Section 1395nn
Three Questions

• Is there a referral by a physician for a Medicare designated health service (DHS)?

• Does the physician have a financial relationship with the entity furnishing DHS?

• Does the financial relationship fit in an exception?
  • If not, there’s probably a violation
Violations of Stark Law

• Non-payment
• Refunds to beneficiaries
• Civil Monetary Penalties
• Exclusion
• False Claims Act Liability
Nutshell Stark

• Technical violations matter.

• Fair Market Value (FMV) matters even more.

• Evolving case law.

See CMS Advisory Opinions at:
cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html
The Inspector General’s Exclusion Authorities

Section 1128A of the Social Security Act
42 U.S.C. Section 1320a-7
Exclusion from Federal Health Care Programs
Section 1128 of the Social Security Act

Mandatory – Section 1128(a)
• Conviction of “program related” crime;
• Conviction of patient abuse and neglect;
• Felony conviction of health care fraud; and
• Felony conviction relating to controlled substances.
• Five year minimum.

Permissive – Section 1128(b)
• 16 authorities, including:
  • Certain misdemeanor convictions;
  • Loss of state license to practice;
  • Failure to repay health education loans; and
  • Failure to provide quality care.
Length of Exclusion

Generally defined period, but certain may be indefinite in length.

Must apply for and be granted Reinstatement.

Directions for application can be found at www.oig.hhs.gov.
What can you do?

Contact the OIG.

Negotiate a voluntary exclusion. Effective upon signing.
Procedure for Exclusions

Derivative Exclusions – Implemented and then the excluded individual or entity has a right to a hearing.

Affirmative Exclusions – By agreement or hearing.

See 42 C.F.R. sections 1001 et. seq. and www.hhs.gov/dab
Self-Disclosure

• Should I disclose?

• Where should I disclose?
  • Contractor
  • OIG
  • DOJ
  • CMS

• Get some advice.
Resolution

- OIG - Civil Monetary Penalties Law settlement.

- DOJ - False Claims Act settlement.

- No Corporate Integrity Agreement (if cooperative).
Self-Disclosure Information

The Office of Inspector General (OIG) has several self-disclosure processes that can be used to report potential fraud in Department of Health and Human Services (HHS) programs. Choose the one that applies to you from the following descriptions to learn more.

**Self-disclosures should not be reported to the OIG Hotline.**

**Health Care Provider Self-Disclosures**
- Health care providers, suppliers, or other individuals or entities subject to Civil Monetary Penalties can use the Provider Self-Disclosure Protocol, which was created in 1999, to voluntarily disclose self-discovered evidence of potential fraud. Self-disclosure gives providers the opportunity to avoid the costs and disruptions associated with a Government-directed investigation and civil or administrative litigation. Visit the Provider Self-Disclosure Protocol webpage for more information.

**HHS Contractor Self-Disclosures**
- Contractors are individuals, businesses, or other legal entities that are awarded government contracts, or subcontracts, to provide services to the Department of Health and Human Services (HHS). OIG's contractor self-disclosure program enables contractors to self-disclose potential violations of the False Claims Act and various Federal criminal laws involving fraud, conflict of interest, bribe, or gratuity violations. This self-disclosure process is available for those entities with a Federal Acquisition Regulation-based contract. Visit the Contractor Self-Disclosure webpage for more information.

**HHS Grantee Self-Disclosures**
- HHS grantees or subrecipients may voluntarily disclose evidence of potential violations of Federal criminal law involving fraud, bribery, or gratuity violations, potentially affecting the Federal award. 45 C.F.R. 75.113 notes mandatory disclosure of criminal offenses that non-Federal entities must make with respect to HHS grants. Recipients submitting disclosures in connection with this requirement should include the subject reference line “Mandatory Grant Disclosure.” Recipients choosing to disclose conduct that may not fall within the scope of offenses described in 45 C.F.R. 75.113, should include the following subject reference line: "[Other]" to prompt OIG staff to consider the matter outside the Federal False Claims Act or grant regulations.
On-Line Submission
OIG Self-Disclosure Protocol

- Make sure the submission is complete.
- Consult OIG’s website at: oig.hhs.gov
Benefits of Self-Disclosure

• Cooperative Process.

• Likely a smaller settlement amount.

• Usually no integrity obligations.
Questions?