



Physician Practice Compliance Conference

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Physician Enforcement: What Doctors Need to Know

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Topics for Today

- Civil Monetary Penalty Authority
- Program Exclusion
- OIG's Industry Guidance Branch
- Physician Relationships with Hospitals
- Physician Relationships with Drug & Medical Device Manufacturers



OIG Civil Monetary Penalties

42 U.S.C. § 1320a-7a | 42 C.F.R. Part 1003

- Alternative/Supplement to Civil Action
- Litigated by OCIG
- FCA Burden of Proof (generally)
- 6 Year Statute of Limitations
- DOJ Authorization
- Program Exclusion
- Intent ... mostly “knows or should know”



OIG Civil Monetary Penalties

- False or fraudulent claims
- Violations of the Federal AKS
- Violations of the Stark Law
- Billing While Excluded
- Part D & Managed Care
- Select Agents & Toxins
- About 40 other OIG CMPs



OIG Civil Monetary Penalties

- Applies to “Any person (including an organization, agency or other entity, but excluding a beneficiary ...)”
- Not limited to providers/practitioners



CMP Authorities for False or Fraudulent Claims

- False or Fraudulent Claims
- Items/Services not provided as claimed
 - Including a pattern of upcoded claims
- Pattern of Medically Unnecessary Items or Services
- Billing While Excluded
 - Excluded Person/Entity
 - Employer or Contractor



CMP Remedies for False or Fraudulent Claims

- Up to \$10,000 for each item or service improperly claimed
- Up to *3 times* the amount improperly claimed
- Exclusion



CMP Authority for Kickbacks

(42 USC § 1320a-7a(a)(7))

- Conduct that violates the Anti-Kickback Act
 - Knowing and willful offer, payment, solicitation, or receipt of remuneration to induce Federal program referrals
- No need to prove damages
- Penalty up to \$50,000 for each act
- Assessment of up to *3 times* the total remuneration
- Exclusion



CMP Authority for Stark

(42 USC § 1395nn(g)(3))

- Submits claims that knows or should know should not be paid because provider has improper financial relationship with physician referral source
- Penalty of up to \$15,000 for each service improperly claimed
- Assessment of up to *3 times* the amount improperly claimed
- Exclusion



CMP Authority for Billing While Excluded

- Arranges or contracts with a person that is excluded
- Knew or should have known that the person was excluded
- Subject to:
 - Penalties of up to \$10,000 per claim
 - Assessments of up to *3 times* the amount claimed
 - Exclusion



CMP Authority for Billing While Excluded, cont.

- Excluded Person –
 - Strict Liability

- Employer/Contractor –
 - Knew or should have known

- Excluded Person with an Ownership or Control Interest in an Entity
 - Penalty for each day of relationship



Program Exclusions

42 USC § 1320a-7 | 42 CFR Part 1001

- **Mandatory Exclusions (§ 1320a-7(a))**
 - Based on Convictions (4)
 - Minimum period of exclusion is 5 years

- **Permissive Exclusions (§ 1320a-7(b))**
 - 15 Bases for Exclusion, mostly derivative
 - Period of exclusion varies based on authority and aggravating/mitigating factors



Mandatory Exclusions

- Conviction of program-related crimes
- Conviction relating to patient abuse
- Felony conviction relating to health care fraud
- Felony conviction relating to controlled substance



Permissive Exclusions

■ Derivative Exclusions

- Convictions for fraud; obstructing an investigation; controlled substances (misdemeanor)
- License revocation or suspension
- Failure to disclose/supply information
- Sanctioned Entity/Sanctioned Individual
- Others ...



Permissive Exclusions

■ Affirmative Exclusions

- Quality of Care – 42 USC § 1320(b)(6)
 - Failure to meet professionally recognized standards of care
 - Substantially in excess of patients' needs

- Fraud – 42 USC § 1320(b)(7)
 - Relevant in ALL FCA cases involving Federal health care programs



Permissive Exclusion Criteria

62 Fed. Reg. 67392 (December 24, 1997)

- Fraud - 42 USC § 1320a-7(b)(7)
 - Circumstances of misconduct and seriousness of offense
 - Defendant's response to allegations/determination of unlawful conduct
 - Likelihood that offense or similar abuse will occur again
 - Financial responsibility



Industry Guidance Branch

- Helps you navigate the Fraud & Abuse laws
- Of particular interest for physician compliance ...
 - Supplemental CPG for Hospitals
 - CPG for Pharmaceutical Manufacturers
 - CPG for Individual and Small Group Physician Practices



Physician Relationships with Hospitals

- Space & Equipment Leases
- Physician Compensation Arrangements
- “Under Arrangement”
- A word about Joint Ventures ...



Physician Relationships with Manufacturers

- Consultant or Advisory Services
- Research Grants
- Device Royalties
- Physicians Investment in Device Companies



HHS-OIG's Website

www.oig.hhs.gov

- Guidance Documents
 - Compliance Program Guidance (“CPG”)
 - Advisory Opinions
 - Safe Harbor Regulations
 - Fraud Alerts & Special Advisory Bulletins
- List-Serve notification of new guidance



THANK YOU. QUESTIONS?

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