

Three Competing Perspectives on Federal Health Care Enforcement Trends: Federal Prosecutor, In-House Counsel, Outside Counsel

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Update: Department of Justice Priorities



Self-Report?



Consideration: Required by Law

▪ Affordable Care Act Regulatory Requirements

- 42 C.F.R. § 422.326—Reporting and Returning of Overpayments

▪ Securities Exchange Act of 1934

- Section 10A, 15 U.S.C. § 78j-1
- Requires issuers and auditors to report certain illegal conduct to the SEC

Federal Acquisition Regulations

- Reg. 52.203-13, 48 C.F.R. § 52.203-13—Contractor Code of Business Ethics and Conduct
- Affirmative duty for federal contractors to report violations of False Claims Act and other laws



Voluntary Disclosure of Violations of Health Care Laws

- Centers for Medicare & Medicaid Services (CMS)
 - *CMS Self-Referral Disclosure Protocol*
 - Solely for Stark Law violations
- U.S. Department of Health & Human Services, Office of the Inspector General (HHS-OIG)
 - *OIG's Provider Self-Disclosure Protocol*
- U.S. Department of Justice (DOJ)
 - *No Protocol*

Disclosure Benefits

- **CMS**
 - Release from administrative liability
 - But not from CMP liability, which is province of OIG
 - Recommendation to OIG and DOJ for favorable resolution of CMP and False Claims Act liability
- **HHS-OIG**
 - Multiplier of 1.5 times damages, instead of 2 to 3
 - Avoid Corporate Integrity Agreement
- **DOJ**
 - Non-Prosecution Agreement or Deferred Prosecution Agreement
 - Reduced criminal fine
 - Release from False Claims Act liability

□ Disclosure Risks: “Poking the Bear”



□ Disclosure Risks (cont.)

▪ Poking the Bear

- Likelihood of detection vs. certainty of payment
- Broader areas of inquiry
 - Hard to fend off new inquiry when cooperating

▪ Collateral Consequences

- Other federal entities
- States
- Private lawsuits

□ **Federal Compliance Guidance**



□ **Recent Compliance Program Guidance**

▪ **DOJ Fraud Section**

- “Evaluation of Corporate Compliance Programs”
 - Neither a checklist nor a formula
 - But in reality . . .

▪ **HHS-OIG**

- “Measuring Compliance Program Effectiveness: A Resource Guide” “Measuring Compliance Program Effectiveness: A Resource Guide”
 - How to use/implement?



Corporate Monitorships



Corporate Monitorships

RISK & COMPLIANCE JOURNAL | COMPLIANCE

U.S. to Reduce Use of Monitors in Corporate Settlements

Policy change comes amid a broader review of corporate criminal enforcement



The U.S. Department of Justice building is seen in Washington. PHOTO: JIM BOURG/REUTERS



□ **Corporate Monitorship Benefits**

- Opportunity to learn from established Compliance professionals
- Partnership with monitor to strengthen Compliance controls and build “first-in-class” program
- Lasting impact on company and strengthening of internal view of compliance
- Department of Justice perspective

□ **Corporate Monitorship Problems and Risks**

- Conflicts of interest; lack of true independence
- Lack of familiarity with the company and its culture
- Lack of formal training and experience as monitors
- “Scope creep”
 - Ambiguity regarding monitor’s role and concerns that monitor will exceed appropriate scope

□ Corporate Monitorship Problems and Risks (cont.)

- Disruption of company operations
 - Diverts time and resources from corporate functions
 - General intrusiveness of monitoring process
- Expense
 - The company is responsible for monitor costs
- Insufficient oversight of monitors

□ Questions?

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