

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

November 6, 2018

**Presenters:**

**Scott B. McBride**  
Partner  
Lowenstein Sandler LLP  
973-597-6136  
[smcbride@lowenstein.com](mailto:smcbride@lowenstein.com)

**Joseph G. Mack**  
Senior Compliance Counsel  
Bayer U.S.  
[Joseph.mack@bayer.com](mailto:Joseph.mack@bayer.com)

**Bernard J. Cooney**  
Assistant U.S. Attorney  
District of New Jersey  
[Bernard.Cooney@usdoj.gov](mailto:Bernard.Cooney@usdoj.gov)



48075558

---

---

---

---

---

---

---

---

# 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

 13

---

---

---

---

---


---

---

---

**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*

 14

---

---

---

---

---


---

---

---

**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

 15

---

---

---

---

---

---

---

---

□ **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?

LS Lowenstein Sandler | 9

---

---

---

---

---

---

---

---

Corporate Monitorships

LS Lowenstein Sandler

---

---

---

---

---

---

---

---

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



PHOTO: U.S. DEPARTMENT OF JUSTICE BUILDING IN WASHINGTON, DC. PHOTO: JEFF BOUJG/REUTERS

LS Lowenstein Sandler | 11

---

---

---

---

---


---

---

---

**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

 | 12

---

---

---

---

---


---

---

---

**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

 | 13

---

---

---

---

---


---

---

---

**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

 | 14

---

---

---

---

---

---

---

---

**Questions?**

**Scott B. McBride**  
Partner  
Lowenstein Sandler LLP  
973-597-6136  
[smcbride@lowenstein.com](mailto:smcbride@lowenstein.com)

**Joseph G. Mack**  
Senior Compliance Counsel  
Bayer U.S.  
862-404-7099  
[Joseph.mack@bayer.com](mailto:Joseph.mack@bayer.com)

**Bernard J. Cooney**  
Assistant U.S. Attorney  
District of New Jersey  
[Bernard.Cooney@usdoj.gov](mailto:Bernard.Cooney@usdoj.gov)



---

---

---

---

---

---

---

---