

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

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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?

First Amendment Developments

□ First Amendment Considerations

- FDA Memorandum in January
 - Alternatives considered and rejected
 - FDA arguably “doubling down” on historical theories
 - BUT then . . .

□ First Amendment Considerations

- Consistent Communications Draft Guidance
 - 3-factor test and examples provided
- Commissioner Gottlieb comments (September 2017):
 - “It’s very clear right now that the courts recognize commercial free speech as constitutionally protected, and it’s very clear that the agency has lost a series of First Amendment challenges . . . What I want to make sure is that we have a legally enforceable set of rules that we’re operating from that we’re able to use to promote our public health goals. So we need to have clear regulation that is legally sustainable and we need to enforce against that vigorously.”
 - “To the extent that we have certain regulatory parameters that either we feel or others feel is in conflict with the court’s interpretation of what constitutes commercially protected speech and the scope of FDA’s ability to regulate that, we need to resolve that. We can’t be operating from a platform where our regulations might be in perpetual conflict with the courts and then we are reluctant to take action for fear that we might run afoul of the courts. We need to have clear regulation that is aligned with the interpretations of the courts around what is and what isn’t permissible and we need to enforce vigorously against that.”

Questions?

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