

# Recent Government Enforcement and Compliance Guidance Affecting Healthcare



**Lila M. Bateman**  
Assistant U.S. Attorney  
Civil Healthcare Fraud  
Coordinator

**Anna Edgar**  
Assistant U.S. Attorney  
Criminal Healthcare Fraud  
Coordinator

The points of view expressed are those of the authors and do not reflect the official view of the Department of Justice

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## Agenda

- Civil and Criminal Enforcement Trends and Results
- Whistleblower Assessments and Parallel Proceedings
- Criminal and Civil Compliance Review Guidance



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# Civil and Criminal Enforcement Trends and Results

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## Civil Enforcement Remains Aggressive

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- **2018:** healthcare recovery increased over FY 2017
- **First half of 2019:** approximately *three times higher* than same period 2018

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# Civil FCA Enforcement: Common Focus Areas

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- Billing/up coding
- Waived co-pays
- Medical necessity
- Medicare Advantage / risk adjustment coding
- Healthcare fraud cases against individuals and doctors
- Joint ventures with physician practices
- AKS violations

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## Civil Enforcement: Electronic Health Records Vendors

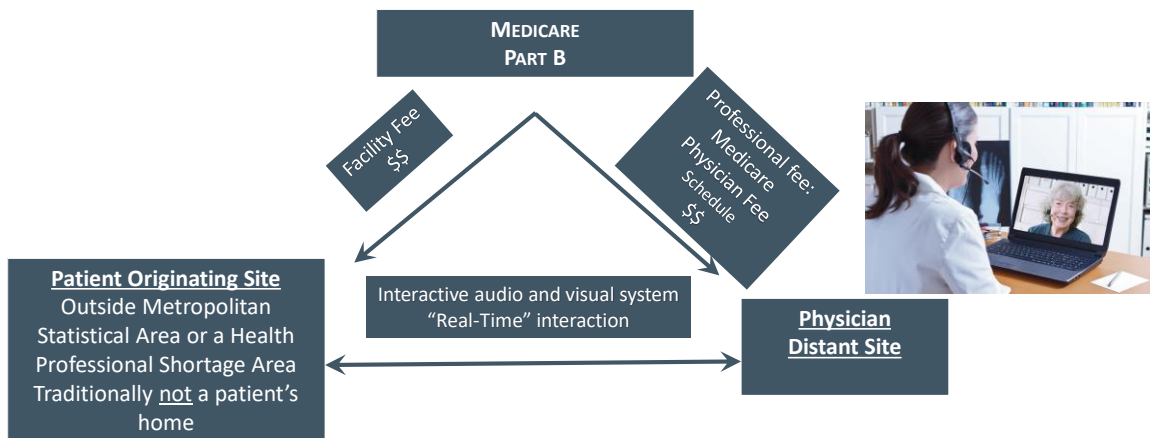
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**Third-party EHR vendor(s) who  
caused others to  
submit false  
claims**



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## Civil Enforcement: Telemedicine / Telehealth Services



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## Civil Enforcement Telemedicine: Where's the Fraud?

Claims from non-rural or unauthorized originating sites

Claims for services provided by an unallowable means of communication

Claims for ineligible institutional providers

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# Civil Enforcement Telemedicine: Where's the Fraud?

## Kickbacks

### Part D and DME Fraud Schemes premised on telemedicine visits

Call centers pay physicians to prescribe, by telemedicine, braces and pain creams that are not medically necessary. Prescriptions are sold to DME providers and pharmacies

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**“Telemedicine is a valuable service for our citizens, but it must not be abused.”**

**August 2019:**

Telemarketer and Marketing Companies Pay \$2.5 Million to Settle Allegations That They Operated Telemedicine Schemes Involving Illegal Kickbacks and Unnecessary Prescriptions

United States Department of Justice

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FOR IMMEDIATE RELEASE Thursday, August 1, 2019

**Telemarketer And His Companies Agree To Pay \$2.5 Million To Settle Allegations That They Operated Telemedicine Schemes Involving Illegal Kickbacks And Unnecessary Prescriptions**

United States Attorney Maria Chapa Lopez and U.S. Attorney J. Douglas Overbey for the Eastern District of Tennessee announce that Scott Rois, together with several entities through which he ran his telemarketing business, including HealthRight, LLC, Health Savings Solutions, LLC, Vici Marketing, LLC, and Vici Marketing Group, LLC (hereinafter collectively referred to as "marketing companies"), have agreed to pay \$2.5 million to resolve allegations that Rois and these marketing companies violated the False Claims Act by causing the submission of false claims to federal healthcare programs in connection with telemedicine health care fraud schemes.

The government alleged that: (1) Rois and his marketing companies fraudulently obtained insurance coverage information from consumers across the country to arrange for them to receive prescription pain creams and other similar products, (2) these prescriptions were not medically necessary and did not arise from a valid doctor-patient relationship, and (3) Rois and his marketing companies sold these prescriptions to pharmacies under the guise of marketing services, and the payments solicited were based on the volume and value of the prescriptions.

"The United States Attorney's Office is committed to protecting TRICARE and other federal health care programs from improper practices that harm our nation's healthcare programs," said U.S. Attorney Chapa Lopez. "Those who generate prescriptions for profit and violate the Anti-Kickback Statute will be held accountable."

"Prescriptions and other medical services resulting from kickbacks undermine the integrity of our health care system," said U.S. Attorney Overbey. "Telemedicine is a valuable service for our citizens, but it must not be abused. We will take action against individuals who break the law to make a profit at the expense of our federal healthcare programs and ultimately at the expense of the American taxpayer."

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# Civil Enforcement: Some Stark Law in 2019

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- *United States ex rel. Long v. Wheeling Hospital*, No. 2:17-cv-01654 (W.D.P.A. Mar. 25, 2019).
- *United States ex rel. Herbold v. Doctor's Choice Home Care, Inc.*, No. 8:15-cv-1044 (M.D. Fl. May 24, 2019).
- Various Settlements

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## Criminal Enforcement: Common Health Care Fraud Schemes

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Common frauds include:

- Billing for services that were not provided
- Billing for unnecessary services
- Misidentifying services as covered when providing non-covered services
- Upcoding
- Misrepresenting providers of services
- Paying kickbacks for patient referrals

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# Criminal Enforcement: Results

## ➤ 2016 National Health Care Fraud Takedown

- 301 defendants charged across 36 federal districts
- 61 defendants were doctors, nurses, and other licensed medical professionals
- Charges in connection with over \$900 million in fraudulent billings

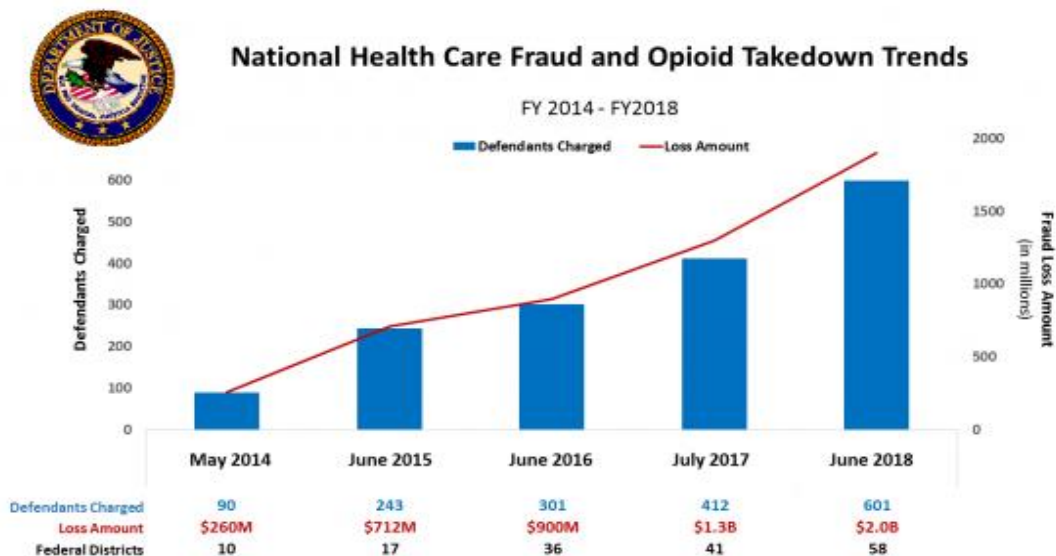
## ➤ 2017 National Health Care Fraud Takedown

- 400 individuals charged across 41 federal districts
- 115 defendants were doctors, nurses, and other licensed medical professionals
- Charges against 120 defendants involved in the distribution of opioids
- Charges in connection with \$1.3 billion in fraudulent billing

## ➤ 2018 National Health Care Fraud Takedown

- 601 defendants charged across 58 federal districts in connection with \$2 billion in fraudulent billing
- 165 doctors, nurses, and other licensed medical professionals were charged
- 162 defendants charged in connection with the opioid epidemic; 132 defendants charged in cases involving pharmacy-related fraud

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# Criminal Enforcement: Recent Examples

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## **Telemedicine and Recruiting Frauds**

- Operation Brace Yourself – 24 individuals charged in \$2 billion Medicare fraud
- Genetic Testing – Recruiters, telemedicine, medically unnecessary tests, and kickbacks

## **Kickbacks**

- Speaker programs, sham contracts, PODs

## **Criminal HIPPA Violations**

### **Industries Susceptible to Fraud**

- Home Health, Hospice

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# Whistleblowers and Parallel Proceedings

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# Sources for Civil Cases

## What do we investigate:

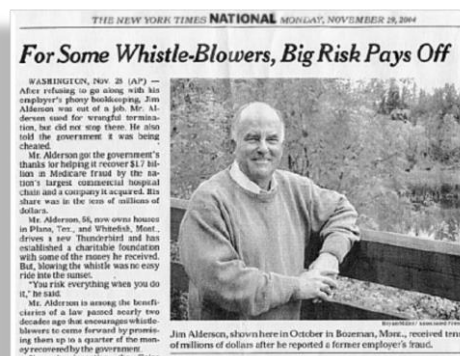
- *Qui tams*
- Non *qui tams* (DOJ investigations)
- Voluntary disclosures
- Agency referrals
- Parallel cases

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## Civil Qui Tam Considerations



Realtor



Relator

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# DOJ Considerations of Relator's Pre-Filing

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- **Facts:** Knowledge of clear violation?
- **Evidence:** What are the documents, other proof of fraud, "who, what, when, where?," specific examples of fraud?
- **Damages:** Sufficient damages to justify risk to Relator?
- **Initial assessment of Government's interest in the area of law and type of fraud:** Is it material to the government?

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## Civil Investigative Tools: Ways To Get Information

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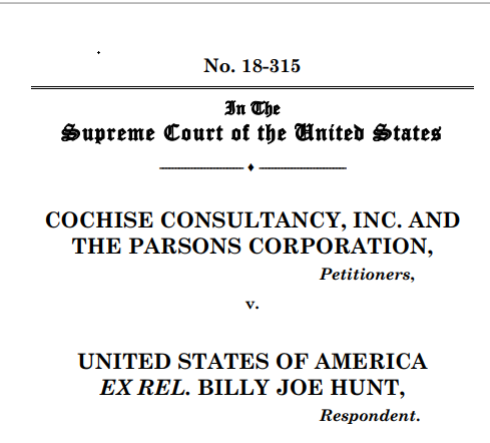
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# Civil Legal Framework

- False Claims Act (FCA)
- Anti-Kickback Statute (AKS)
- Stark Law
- Controlled Substances Act (CSA)

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## Civil FCA Update: Will This Qui Tam Ever End?



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## Sources for Criminal Investigations

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- *Qui tams*
- Data-identified targets
- Voluntary disclosures
- Agency referrals (including those derived from hotline tips)
- Unified Program Integrity Contractors (UPIC) referrals
- Collaboration with state agencies

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## Criminal Investigative Tools

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- Grand Juries
- HIPAA subpoenas
- Agency subpoenas
- Search Warrants
- Process under the Electronic Communications Privacy Act – 2703(d) orders
- Undercover Investigations
- Witness cooperation

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# Criminal Legal Framework

- Healthcare Fraud, 18 U.S.C. § 1347
- Mail and Wire Fraud, 18 U.S.C. §§ 1341, 1343
- Anti-Kickback Statute, 42 U.S.C. § 1320a-7b
- Eliminating Kickbacks in Recovery Act, 18 U.S.C. § 220
- False Claims, 18 U.S.C. §§ 286, 287
- Conspiracy statutes, 18 U.S.C. §§ 371, 1349
- Travel Act, 18 U.S.C. §1952
- Title 21: Controlled Substances Act

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## Criminal Sanctions for Healthcare Violations: How Bad is Bad?

**Individuals:** Sentences dependent on harm to the patients or public and amount of loss

- United States Sentencing Guidelines, Chapter 2, Section 2B1.1

Loss (apply the greatest)	Increase in Level
(A) \$6,500 or less	no increase
(B) More than \$6,500	add 2
(C) More than \$15,000	add 4
(D) More than \$40,000	add 6
(E) More than \$95,000	add 8
(F) More than \$150,000	add 10
(G) More than \$250,000	add 12
(H) More than \$550,000	add 14
(I) More than \$1,500,000	add 16
(J) More than \$3,500,000	add 18
(K) More than \$9,500,000	add 20
(L) More than \$25,000,000	add 22
(M) More than \$65,000,000	add 24
(N) More than \$150,000,000	add 26
(O) More than \$250,000,000	add 28
(P) More than \$550,000,000	add 30.

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# Criminal Sanctions for Healthcare Violations: How Bad is Bad?

**Organizations:** United States Sentencing Guidelines: Chapter 8

➤ **Part B: Remedying Harm from Criminal Conduct** (restitution, remedial orders, community service, notice to victims)

- Not part of punishment, but of making victims whole.
- 8B1.1 provides requirements for an *effective compliance and ethics program*

➤ **Part C: Fines:** Based on seriousness of the offense and culpability of the organization.

- If the organization operated primarily for a criminal purpose or primarily by criminal means, the fine shall be set at an amount (subject to statutory maximum) sufficient to divest the organization of all of its assets.
- Otherwise, the base fine is the greatest of: (1) the amount from the table provided at right (based on Offense Level calculated from applicable Chapter 2 Guideline), (2) the pecuniary gain to the organization, or (3) the pecuniary loss from the offense caused by the organization, to the extent the loss was caused intentionally, knowingly, or recklessly. U.S.S.G. § 8C2.4(d).
- Fine is increased or decreased from the "base" by culpability score that results in a multiplier.
  - Multiplier ranges from 0.05 for culpability score 0, to 4 for culpability score 10 or more. Fine is multiplier times fine amount in table associates with offense level. Anything below culpability score 5 yields a discount in the fine.

➤ **Part D: Organizational Probation**

- Appropriate when needed to ensure another sanction will be fully implemented or that steps will be taken within the organization to reduce the likelihood of future criminal conduct (e.g., paying the fine or restitution, implementation of CIA)

Offense Level	Amount
6 or less	\$8,500
7	\$15,000
8	\$25,000
9	\$50,000
10	\$75,000
11	\$250,000
12	\$750,000
13	\$1,000,000
14	\$150,000
15	\$200,000
16	\$300,000
17	\$450,000
18	\$600,000
19	\$850,000
20	\$1,000,000
21	\$1,500,000
22	\$2,000,000
23	\$3,000,000
24	\$3,500,000
25	\$5,000,000
26	\$6,500,000
27	\$8,500,000
28	\$10,000,000
29	\$15,000,000
30	\$20,000,000
31	\$25,000,000
32	\$30,000,000
33	\$40,000,000
34	\$50,000,000
35	\$65,000,000
36	\$80,000,000
37	\$100,000,000
38 or more	\$150,000,000

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## Parallel Proceedings

JM 1-12.000 (January 2012): Criminal prosecutors and affirmative civil enforcement attorneys must consider parallel proceedings between criminal, civil, administrative, and regulatory investigations at every stage of the investigation and prosecution.

Justice Manual (4-3.100) (previously the Yates memo): focuses on individual accountability in corporate wrongdoing

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# Criminal and Civil DOJ Compliance Guidance



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## KEY DEVELOPMENTS

- **Headline news**
  - Criminal Guidance on Corporate Compliance Programs
  - Individual Accountability
  - Civil FCA Guidance



**Rules  
of  
the  
Road**

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# Update #1: Criminal Division Guidance on Corporate Compliance

## Background: Principles of Federal Prosecution of Business Organizations (USAM 9-28.000)

- Two Factors focus on corporate compliance: (1) existence and effectiveness of pre-existing compliance program; and (2) remedial actions, including efforts to implement an adequate and effective compliance program or to improve an existing one.
- Also emphasizes the focus on individual wrongdoers: “Prosecution of a corporation is not a substitute for the prosecution of criminally culpable individuals within or without the corporation. Because a corporation can act only through individuals, imposition of individual criminal liability may provide the strongest deterrent against future corporate wrongdoing.”
- Directs prosecutors to review Chapter 8 of the U.S.S.G., which identifies features of an effective compliance program.

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# Criminal Division Guidance on Corporate Compliance

## March 2018 –FCPA Corporate Enforcement Policy as “nonbinding guidance”

- When there is (1) voluntary self-disclosure, (2) full cooperation, and (3) timely and appropriate remediation, in accordance with the policy, there presumption that the company will receive a declination absent aggravating circumstances
- If a criminal resolution is warranted, the government:
  - Will recommend 50% reduction off low end of the U.S.S.G. fine range, except for a criminal recidivist; and
  - Will not require a monitor if the company has, at the time of resolution, implemented an **effective compliance program**.
  - To qualify, the company must pay all disgorgement, forfeiture, and restitution.
- If no initial self-disclosure but later cooperation, 25% recommended reduction off low end U.S.S.G.
- Compliance program is evaluated in context of determining whether there was timely and appropriate remediation.

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# Criminal Division Guidance on Corporate Compliance

## October 2018: Benczkowski Memorandum

In general, the Criminal Division should favor the imposition of a monitor only where there is a demonstrated need for, and clear benefit to be derived from, a monitorship relative to the projected costs and burdens. Where a corporation's compliance program and controls are demonstrated to be effective and appropriately resourced at the time of resolution, a monitor will likely not be necessary."

Factors:

(a) whether the underlying misconduct involved the manipulation of corporate books and records or the exploitation of an inadequate compliance program or internal control systems; (b) whether the misconduct at issue was pervasive across the business organization or approved or facilitated by senior management; **(c) whether the corporation has made significant investments in, and improvements to, its corporate compliance program and internal control systems;** and **(d) whether remedial improvements to the compliance program and internal controls have been tested to demonstrate that they would prevent or detect similar misconduct in the future.**

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# Criminal Division Guidance on Corporate Compliance

## May 2019: Evaluation of Corporate Compliance Programs

Purpose of the Guidance: Assist prosecutors in determining whether a compliance program was and is effective, for purposes of determining appropriate (1) form of any resolution or prosecution, (2) monetary penalty, if any, and (3) compliance obligations in any criminal resolution.

2019 Guidance focuses on 3 questions:

1. **Design:** Is the corporation's compliance program well designed?
2. **Implementation** - Is the program being applied earnestly and in good faith? That is, is the program implemented effectively?
3. **Results** - Does the corporation's compliance program work in practice?

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# Criminal Division Guidance on Corporate Compliance

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## Design

Assess whether the program is designed for maximum effectiveness to prevent and detect wrongdoing, and whether corporate management is enforcing the program or tacitly encouraging or pressuring employees to engage in misconduct

Design Factors:

- Internal Corporate Risk Assessment: tailored to detect misconduct likely to occur in business and regulatory environment, periodically updated, and should include revisions based on lessons learned.
- Policies and Procedures: Give effect to ethical norms and reduce identified risk
  - Code of Conduct setting forth commitment to full compliance that is accessible to all employees
  - Incorporate culture of compliance into day-to-day operations
- Training and Communication: appropriately tailored and integrated into the organization; implemented to be “truly effective”
- Confidential Reporting Structure and Investigation Process: anonymous or confidential process
- Third Party Management: risk-based due diligence of third party relationships
- Mergers and Acquisitions (M&A): comprehensive due diligence of acquisition targets

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# Criminal Division Guidance on Corporate Compliance

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## Effective Implementation

- Commitment by Senior and Middle Management – create and foster a culture of ethics and compliance
- Autonomy and Resources – sufficient personnel and resources with autonomy from management, such as direct access to board or board’s audit committee
- Incentives and Disciplinary Measures – clear procedures, consistently enforced, discipline commensurate with violation

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## Criminal Division Guidance on Corporate Compliance

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### Does the program work in practice?

- Continuous Improvement, Periodic Testing, and Review – evolve to adjust to changes in company, environment, and law
- Investigation of Misconduct – timely, well-funded, and thorough
- Analysis and Remediation – root cause analysis of misconduct

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## A Culture of Compliance?

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## Update #2: Pursuing Claims Against Individuals (JM 4-3.100)

- September 2015: Yates Memo
- November 2018: Justice Manual
- DOJ will hold individuals accountable for corporate wrongdoing.



### 4-3.100 – Pursuit of Claims Against Individuals

The Department of Justice prioritizes fighting corporate fraud and other misconduct because effective pursuit of civil claims protects citizens, the government, and the nation's economy, and because expeditious and vigorous civil enforcement provides a strong deterrent to misconduct. Holding individuals who perpetrate wrongdoing accountable, in addition to corporations or business entities, is one of the most effective ways of combatting corporate misconduct. Doing so deters future illegal activity, incentivizes changes in corporate behavior, holds the proper parties responsible for their actions, and promotes the public's confidence in our justice system.

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## Update #2: Pursuing Claims Against Individuals (JM 4-3.100(3))

1. Focus on individuals from the inception of the investigation
2. Communicate during parallel investigations
3. Corporations must provide “meaningful assistance” to be eligible for “cooperation credit”
4. Don't release individuals from liability when resolving with a company, unless further action isn't necessary or in public interest
5. Have a plan for individuals and memorialize any declinations

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## Update #3: Civil FCA Disclosure, Cooperation and Remediation Guidance (JM 4-4.112)

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### What not to do...



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## Update #3 Civil FCA Disclosure, Cooperation and Remediation Guidance: How?

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1. Voluntary Self-Disclosure
2. Cooperate in Ongoing Government Investigation: 9 examples
3. Undertake Remedial Measures in Response to Violation: 4 examples

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## Update #3 Civil FCA Disclosure, Cooperation and Remediation Guidance: Potential Upsides?

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1. Reduction in penalties
2. Administrative agencies notified of cooperation
3. Public acknowledgement of cooperation
4. Assistance with *qui tam* resolution