

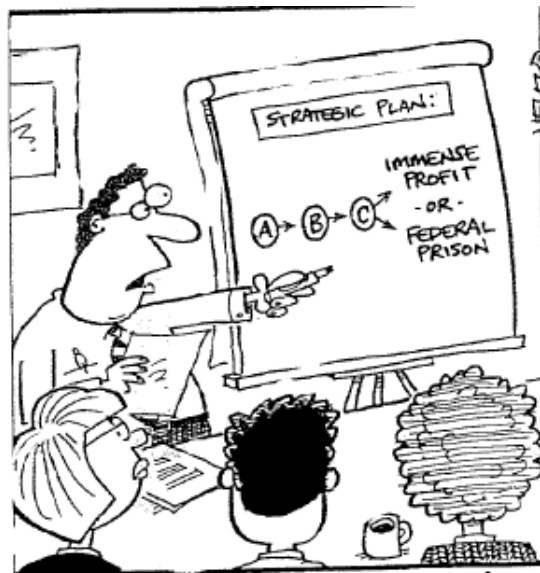
Enforcement Highlights

November 2021



Fraud and Abuse Laws

- Anti-Kickback Statute
- Stark Laws
- False Claims Act
- Civil Monetary Penalties



"Stay with me now, people, because in step C, things get a bit delicate."

The Yates Memo

“It’s only fair that the people who are responsible for committing the crimes be held accountable”

Accountability:

- Deter illegal activity
- Incentivize changes in behavior
- Parties are held responsible for their actions
- Promote confidence in the federal justice system



U.S. Department of Justice


Office of the Deputy Attorney General

The Deputy Attorney General

Washington, D.C. 20530

September 9, 2015

MEMORANDUM FOR THE ASSISTANT ATTORNEY GENERAL, ANTI-TRUST DIVISION
THE ASSISTANT ATTORNEY GENERAL, CIVIL DIVISION
THE ASSISTANT ATTORNEY GENERAL, CRIMINAL DIVISION
THE ASSISTANT ATTORNEY GENERAL, ENVIRONMENT AND
NATURAL RESOURCES DIVISION
THE ASSISTANT ATTORNEY GENERAL, NATIONAL
SECURITY DIVISION
THE ASSISTANT ATTORNEY GENERAL, TAX DIVISION
THE DIRECTOR, FEDERAL BUREAU OF INVESTIGATION
THE DIRECTOR, EXECUTIVE OFFICE FOR UNITED STATES
TRUSTEES
ALL UNITED STATES ATTORNEYS

FROM: Sally Quillian Yates 
Deputy Attorney General

SUBJECT: Individual Accountability for Corporate Wrongdoing

Fighting corporate fraud and other misconduct is a top priority of the Department of Justice. Our nation's economy depends on effective enforcement of the civil and criminal laws that protect our financial system and, by extension, all our citizens. These are principles that the Department lives and breathes—as evidenced by the many attorneys, agents, and support staff who have worked tirelessly on corporate investigations, particularly in the aftermath of the financial crisis.

One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing. Such accountability is important for several reasons: it deters future illegal activity, it incentivizes changes in corporate behavior, it ensures that the proper parties are held responsible for their actions, and it promotes the public's confidence in our justice system.





JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Thursday, January 14, 2021

Justice Department Recovers Over \$2.2 Billion from False Claims Act Cases in Fiscal Year 2020

The Department of Justice obtained more than \$2.2 billion in settlements and judgments from civil cases involving fraud and false claims against the government in the fiscal year ending Sept. 30, 2020, Acting Assistant Attorney General Jeffrey Bossert Clark of the Department of Justice's Civil Division announced today. Recoveries since 1986, when Congress substantially strengthened the civil False Claims Act, now total more than \$6.4 billion.

"Even in the face of a nationwide pandemic, the department's dedicated employees continued to investigate and litigate cases involving fraud against the government and to ensure that citizens' tax dollars are protected from abuse and are used for their intended purposes," said Acting Assistant Attorney General Clark. "The continued success of the department's False Claims Act enforcement efforts are a testament to the dedication of the civil servants who pursue these important cases as well as to the fortitude of whistleblowers who report fraud."

Of the more than \$2.2 billion in settlements and judgments recovered by the Department of Justice this past fiscal year, over \$1.8 billion relates to matters that involved the health care industry, including drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians. The amounts included in the \$1.8 billion reflect only federal losses, and, in many of these cases, the department was instrumental in recovering additional tens of millions of dollars for state Medicaid programs.

In addition to combating health care fraud, the False Claims Act serves as the government's primary civil tool to redress false claims for federal funds and property involving a multitude of other government operations and functions. The act helps to support our military and first responders by ensuring that government contractors provide equipment that is safe, effective, and cost efficient; to safeguard American businesses and workers by promoting compliance with customs laws, trade agreements, visa requirements, and small business protections; and to protect other critical government programs ranging from the provision of disaster relief funds to nutrition benefits for needy families.

In 1986, Congress strengthened the act by increasing incentives for whistleblowers to file lawsuits alleging false claims on behalf of the government. These whistleblower, or *qui tam*, actions comprise a significant percentage of the False Claims Act cases that are filed. If the government prevails in a *qui tam* action, the whistleblower, also known as the relator, typically receives a portion of the recovery ranging between 15 and 30 percent. Whistleblowers filed 672 *qui tam* suits in fiscal year 2020, and this past year the department recovered over \$1.6 billion in these and earlier-filed suits.

RELATED LINKS

[Speeches and Press Releases](#)

[Videos](#)

[Photos](#)

[Blogs](#)

[Podcasts](#)



“When healthcare providers submit improper claims to Medicare and Medicaid, they do two bad things: they unjustly enrich themselves, and they drain money needed for legitimate patient care”

-Nathaniel R. Mendell
Acting US Attorney



“Our federal healthcare system relies on the basic premise that providers abide by the rules and bill properly, and the American taxpayers who fund the Medicare and Medicaid programs deserve nothing less”

**-Phillip Coyne
Special Agent in Charge, Office of the
Inspector General**



What is Fraud & Abuse

- **Fraud**
 - Intentional act of deception or misrepresentation that is knowingly false
 - Acting with actual knowledge or in “reckless disregard” of the laws or regulations
- **Abuse**
 - Unintentional act resulting in higher payment
- Submitting inaccurate or misleading claims for services provided.
- Submitting claims for services not provided.
- Submitting claims for medically unnecessary services or services not covered by the payer.
- Making false statements or representations to obtain payment for services or to gain participation in a health care program.
- Concealing or improperly avoiding an obligation to repay a health care program.
- Offering or paying money, goods, or anything of value to encourage or reward the referral of patients to a health care provider.



Anti-Kickback Statute

- Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals
- Examples
 - Arrangements between physicians and healthcare providers to induce referrals
 - Rewarding business in exchange for referrals
 - Giving money or gifts to patients



Stark Law

- Prohibits physicians from referring patients to other entities or providers in which the referring physician or his immediate family has a financial interest unless:
 - An exception applies
 - Employment Agreement
 - Medical Director Contracts
 - Professional Services Agreement
 - Office space rental
 - Giving anything of value



Stark vs Anti-Kickback

Stark

- Penalties
 - Denial of payment
 - Refund of payment
 - False Claims Liability
 - Civil Monetary Penalties
 - Exclusion

Anti-Kickback

- Penalties
 - Fines
 - Prison
 - False Claims Liability
 - Civil Monetary Penalties
 - Criminal Penalties
 - Exclusion



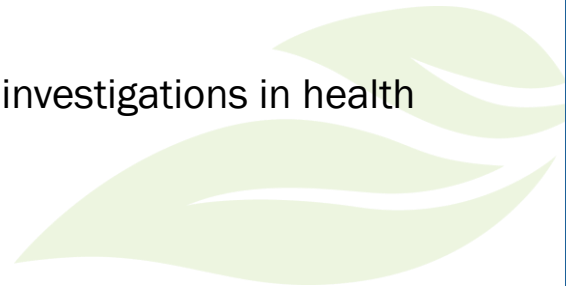
False Claims Act

- Federal crime to knowingly make a false record or file a false claim involving a federal healthcare program
- Penalties
 - Repayment
 - Civil Monetary Penalties
 - Fines from \$11,000 to \$22,000/claim
 - Treble damages
 - Criminal penalties
 - Exclusions
 - Corporate Integrity Agreements



Qui Tam Lawsuits

- Allows individuals with information concerning fraud to file lawsuits on behalf of government
- Individuals can receive a percentage of any recoveries
- False Claims laws provide protections for individuals against retaliation
- Who can be a Whistleblower?
 - Employees
 - Suppliers
 - Consultants
 - Physicians
 - Competitors
- Whistleblower lawsuits are the leading source of regulatory investigations in health care





WARNING

Anytime you want to:

- **Give anything to induce or reward referrals, or**
- **Do any deal with a referral source.**

Best Defense is a Good Offense

- Ensure arrangements with physicians, patients and other referral sources are appropriate:
 - Beware of free or discounted items to referring physicians
 - Written contracts with referring physicians
 - Paying Fair Market Value
 - Do not condition payments on referrals
- Respond to suspected problems
- Repay as necessary



What's Happening in HIPAA

- Cyber attacks
- Snooping
- Social Media
- Business Associate Agreements



Breach Report Results							
Expand All	Name of Covered Entity	State	Covered Entity Type	Individuals Affected	Breach Submission Date	Type of Breach	Location of Breached Information
	The Urology Center of Colorado	CO	Healthcare Provider	137820	11/05/2021	Hacking/IT Incident	Network Server
	Maxim Healthcare Group	MD	Healthcare Provider	65267	11/04/2021	Hacking/IT Incident	Email
	Putnam County Memorial Hospital	MO	Healthcare Provider	6916	11/03/2021	Hacking/IT Incident	Network Server
	JEV Plastic Surgery & Medical Aesthetics	MD	Healthcare Provider	1620	11/03/2021	Hacking/IT Incident	Network Server
	Utah Imaging Associates, Inc.	UT	Healthcare Provider	583643	11/03/2021	Hacking/IT Incident	Network Server
	Doctors Health Group, Inc.	AR	Healthcare Provider	47660	11/02/2021	Hacking/IT Incident	Network Server
	Pottawatomie County Health Department	KS	Healthcare Provider	6000	10/30/2021	Hacking/IT Incident	Network Server
	Surecare Specialty Pharmacy	TX	Healthcare Provider	8412	10/29/2021	Hacking/IT Incident	Network Server
	NHS Management, LLC	AL	Business Associate	501	10/29/2021	Hacking/IT Incident	Network Server
	Viverant PT, LLC	MN	Healthcare Provider	6540	10/29/2021	Hacking/IT Incident	Email
	Nationwide Laboratory Services	FL	Healthcare Provider	33437	10/28/2021	Hacking/IT Incident	Network Server
	Professional Healthcare Management, Inc.	TN	Healthcare Provider	12306	10/28/2021	Hacking/IT Incident	Network Server
	Anthem, Inc.	IN	Business Associate	5505	10/27/2021	Theft	Other Portable Electronic Device, Paper/Films
	California Physicians' Services d/b/a Blue Shield of California	CA	Health Plan	2841	10/27/2021	Hacking/IT Incident	Network Server
	Blue Cross of California	IN	Health Plan	672	10/27/2021	Hacking/IT Incident	Network Server
	Seneca Family of Agencies	CA	Healthcare Provider	2470	10/26/2021	Hacking/IT Incident	Network Server
	Walmart, Inc.	AR	Healthcare Provider	828	10/26/2021	Loss	Laptop
	Foundation for Medical Care of Tulare and Kings Counties	CA	Business Associate	1835	10/26/2021	Theft	Other Portable Electronic Device
	Painters District Council No. 30 Health and Welfare Fund	IL	Health Plan	2157	10/25/2021	Hacking/IT Incident	Email
	Bryan Health	NE	Healthcare Provider	2753	10/25/2021	Unauthorized Access/Disclosure	Electronic Medical Record
	Throckmorton County Memorial Hospital	TX	Healthcare Provider	3136	10/22/2021	Hacking/IT Incident	Network Server
	Educators Mutual Insurance Association	UT	Health Plan	51446	10/22/2021	Hacking/IT Incident	Network Server
	QRS, Inc.	TN	Business Associate	319778	10/22/2021	Hacking/IT Incident	Network Server
	Missouri Delta Medical Center	IL	Healthcare Provider	500	10/21/2021	Hacking/IT Incident	Network Server
	Lavaca Medical Center	TX	Healthcare Provider	48705	10/21/2021	Hacking/IT Incident	Network Server
	UNC Hospitals	NC	Healthcare Provider	719	10/19/2021	Unauthorized Access/Disclosure	Desktop Computer, Electronic Medical Record
	Redwoods Rural Health Center	CA	Healthcare Provider	2306	10/18/2021	Unauthorized Access/Disclosure	Email
	Family of Woodstock	NY	Healthcare Provider	8214	10/17/2021	Hacking/IT Incident	Network Server
	Limeade, Inc.	WA	Business Associate	2287	10/15/2021	Unauthorized Access/Disclosure	Desktop Computer, Other Portable Electronic Device
	UMass Memorial Health Care, Inc.	MA	Business Associate	209048	10/15/2021	Hacking/IT Incident	Email

I'm looking for...

[A-Z Index](#)HIPAA for
IndividualsFiling a
ComplaintHIPAA for
Professionals

Newsroom

[HHS](#) > [HIPAA Home](#) > [For Professionals](#) > [HIPAA Compliance and Enforcement](#) > [Enforcement Data](#) > Enforcement Highlights - Current

HIPAA for Professionals

Regulatory Initiatives

Privacy



Security



Breach Notification



Compliance & Enforcement



Enforcement Rule

Enforcement Process

Enforcement Data

Resolution Agreements

Case Examples

Audit

Reports to Congress

State Attorneys General

Text Resize **A A A**

Print

Share



Enforcement Highlights

For information on the history of and details about each of the HIPAA Rules, please visit <https://www.hhs.gov/hipaa-for-professionals/index.html> and click on "Privacy," "Security," or "Breach Notification" from the left-hand tool-bar.

Enforcement Results as of September 30, 2021

Since the compliance date of the Privacy Rule in April 2003, OCR has received over 275,871 HIPAA complaints and has initiated over 1,103 compliance reviews. We have resolved ninety-eight percent of these cases (269,886).

OCR has investigated and resolved over 29,149 cases by requiring changes in privacy practices and corrective actions by, or providing technical assistance to, HIPAA covered entities and their business associates. Corrective actions obtained by OCR from these entities have resulted in change that is systemic and that affects all the individuals they serve. OCR has successfully enforced the HIPAA Rules by applying corrective measures in all cases where an investigation indicates noncompliance by the covered entity or their business associate. To date, OCR has settled or imposed a civil money penalty in 101 cases resulting in a total dollar amount of \$131,060,482.00. OCR has investigated complaints against many different types of entities including: national pharmacy chains, major medical centers, group health plans, hospital chains, and small provider offices.

In another 13,359 cases, our investigations found no violation had occurred.

Additionally, in 49,751 cases, OCR has intervened early and provided technical assistance to HIPAA covered entities, their business associates, and individuals exercising their rights under the Privacy Rule, without the need for an investigation.



Enforcement Highlights

- From the compliance date to present, the compliance issues most often alleged in complaints are:
 - Impermissible uses and disclosures of PHI
 - Lack of safeguards of PHI
 - Lack of patient access to their PHI
 - Lack of administrative safeguards of ePHI
 - Use of disclosure of more than the minimum necessary

