How to Get in Trouble Without Really Trying; Practical Advice for When a Regulator Comes Knocking

GRAY PLANT MOOTY

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Agenda

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- **Part One**: An Overview of State and Federal Enforcement
- **Part Two**: The Current State of Enforcement
- **Part Three**: Hypotheticals
  - Hypo One: Anonymous letter & a disgruntled employee
  - Hypo Two: Responding to a Civil Investigative Demand ("CID") from the Minnesota Attorney General's Office
  - Hypo Three: Responding to a subpoena from the DEA
  - Hypo Four: Responding to a search warrant

Part One: An Overview of State and Federal Enforcement

The Players

- Center for Medicare & Medicaid Services (and its contractors)
  - Medicare and Medicaid "program integrity "
    - Enrollment scrutiny, payment suspensions, enrollment moratoria, etc.
- Office of Inspector General (OIG)
  - Part of Department of Health & Human Services (HHS)
  - Charged with identifying, auditing, and investigating fraud, waste, and abuse in Medicare and Medicaid and more than 100 other HHS programs
  - Also primary source of education and guidance for providers
  - Just added new litigation team
- Department of Justice (DOJ)
  - Responsible for federal law enforcement
    - Health care fraud is a priority
    - Criminal and civil fraud cases

The Players—Continued

- *Qui Tam* Relators
  - Private party (called relator or whistleblower) brings a False Claims Act case on the government's behalf
    - The government considered the real plaintiff
  - If the government/relator succeeds, the relator receives a share of the award
  - The experienced whistleblower
    - Cecelia Guardiola, RN (worked in clinical documentation and case management)
    - Successful 3-time relator
      - Christus Spohn Health System (2012, $5 million)
      - Renown Health (2016, $9.5 million)
      - Banner Health (2018, $18 million)

The Players—Continued

- Agency cross-coordination:
  - Many examples, such as: 2018 HHS and VA announced partnership to address F&A between programs
  - Focus on data driven arrangements
    - One Program Integrity Data Analysis
    - Integrated Data Repository
- State regulatory agencies
  - State Attorneys General
  - State Medicaid Fraud Units
  - Professional licensing boards
- Health Plans
  - Medicare Advantage Organizations
  - Medicare Part D Plans
  - Medicaid Managed Care Organizations

The False Claims Act: A Regulator's Best Weapon

- Traditionally used for billing for services that health care provider did not, in fact, perform
- For many years, FCA used against providers who fail to comply with technical requirements
- Numerous enforcement theories:
  - Overpayments or "reverse false claims"
  - "Implied certification" theory
  - "Worthless service" theory
  - Stark Law, Anti-kickback violations
  - Fair market value standard
- Technical violations do not get a "pass"

Tools Used by Regulators

- Informal request for information
- Civil Investigative Demand
- Subpoena
- Search warrant
- Investigations/Audits
  - E.g., vulnerable adult maltreatment investigations, licensing site visits, etc.

OIG Exclusions

- Updates to permissive and mandatory exclusion rules in 2015 and 2016
- OIG continues to be active. In FYs 2013/ 2014/ 2015/ 2016:
  - Individuals and entities excluded—
    - 3,214/ 4,017/ 4,112/ 3,635
      - Medicare or Medicaid crimes—1,132/ 1,310/ 1,329/ 1,362
      - Other crimes—311/ 432/ 424/ 262
      - Patient abuse or neglect—180/ 189/ 302/ 299
      - Licensing actions—1,324/ 1,744/ 1,743/ 1,448
  - HCFAC 2016 Report indicated few resources for DOJ, FBI, HHS and OIG as a result of sequestration

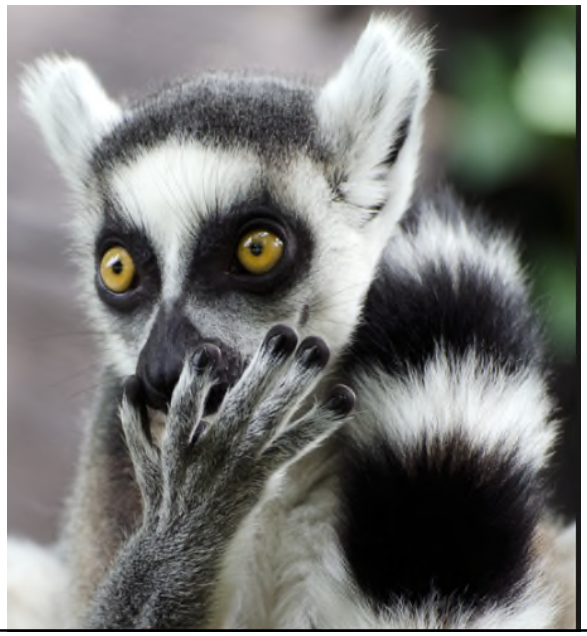
Fixing the Problem: OIG and CMS Self Disclosure Update

- OIG Self-Disclosure Protocol (created in 1998)
  - More than $35 million in 2017 self-disclosures; $63 million in 2018
- Stark Law SRDP (created in 2010)

Calendar Year	Number of Disclosures Settled	Range of Amounts of Settlements	Aggregate Amount of Settlements
2011	3	$60 - $579,000	$709,060
2012	14	$1,600 - $584,700	$1,236,200
2013	24	$760 - $317,620	$2,468,348
2014	41	$3,322 - $463,473	$5,175,168
2015	49	$5,081 - $815,405	$6,706,458
2016	102	$80-$1,195,763	$6,913,988
2017	47	$83-$575,680	$3,876,588
Totals	**280**	**$60 - $1,195,763**	**$27,085,810**

- 2018 Update—36 SRDP disclosures; total settlements of $3.66 million

Part Two: Statistics Continue to Shock!!



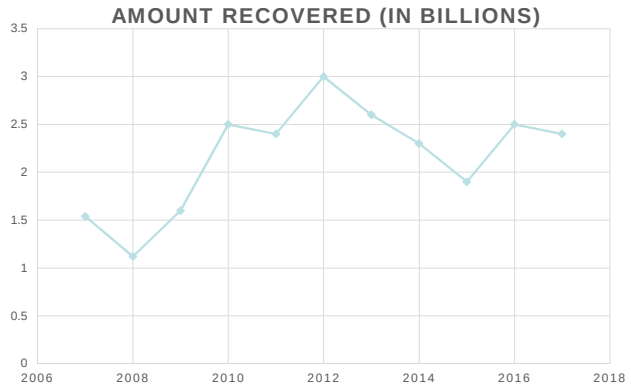
Increases to Civil Monetary Penalties

On February 9, 2018, new penalty amounts became effective under the CMP Law:

CMP Section	Previous Penalty	Current Penalty
1320a-7a(a)(1), (2), (5), (6),	$10,000 / item or service	$20,000 / item or service
1320a-7a(a)(3)	$15,000 / individual given false or misleading info	$30,000 / individual given false or misleading info
1320a-7a(a)(4)	$10,000 / day	$20,000 / day
1320a-7a(a)(7)	$50,000 / act	$100,000 / act
1320a-7a(a)(8)	$50,000 / record	$100,000 / record
1320a-7a(a)(9)	$15,000 / day	$30,000 / day
1320a-7a(a)(9)	$50,000 / false statement	$100,000 / false statement

Increases to Civil Monetary Penalties

The increases will likely increase the amount DOJ will recover in the future.



Average Recovery: $2.17 bil

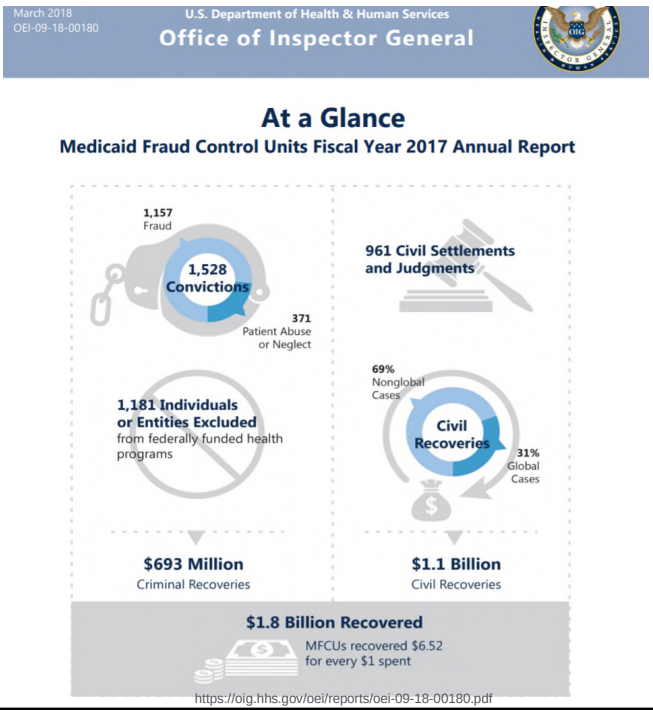
Department of Justice Annual News Bulletins regarding False Claims Act Recovery, 2007-2017

In 2017:

- **Enforcement Actions**
  - DOJ opened 967 new criminal health care fraud investigations
    - Filed criminal charges in 439 cases involving 720 defendants
    - Convicted 639 defendants of health care fraud-related crimes
  - DOJ opened 948 new civil health care fraud investigations
    - 1,086 civil health care fraud matters were pending at the end of the year
  - OIG investigations resulted in:
    - 788 criminal actions related to Medicare and Medicaid
    - 818 civil actions (including false claims, CMP settlements, and administrative recoveries related to provider self disclosure)
  - HHS-OIG excluded 3,244 individuals and entities from participation in Medicare, Medicaid, and other federal health care programs

In 2017:

- **Monetary Results**
  - Federal Government won/negotiated over 2.4 billion in health care fraud judgements
    - Attained additional administrative impositions in health care fraud cases/proceedings
  - Due to this, and efforts from previous years, and $2.6 billion was recouped by the Federal Government or paid to private persons
  - 8th consecutive year with more than $2 billion in recoveries by DOJ
  - Implications of Yates Memo:
    - Number of FCA settlements involving individual personal provider liability:
    - Approximately 33 in 2017
    - Compared to 8 in 2016, 6 in 2015



https://oig.hhs.gov/oei/reports/oei-09-18-00180.pdf

In 2018:

- The DOJ obtained more than $2.8 billion in settlements and judgments from FCA cases in the fiscal year ending Sept. 30, 2018
  - $2.5 billion of this involved the health care industry
  - $2.1 billion was from qui tam cases
  - Of that $2.1 billion, $2 billion from cases where DOJ intervened.
  - Relators took home approximately $301 million.
- The largest recoveries involving the health care industry this past year came from the drug and medical device industry.
  - AmerisourceBergen Corporation and certain of its subsidiaries paid $625 million to resolve allegations
  - Alere paid $33.2 million to resolve allegations

Any Good News?

- Total of 645 new *qui tam* cases filed in 2018, a slight decrease from 680 cases filed in 2017!
- Granston Memo (Jan. 10, 2018)
  - Outlines 7 factors DOJ attorneys should use to determine whether to seek dismissal of declined *qui tam* cases (e.g., preserving govt. resources and curbing meritless *qui tams*)
  - Memo formally incorporated into DOJ Justice Manual
  - In 2018, DOJ filed 16 motions to dismiss non-intervened *qui tam* cases
  - Significant increase over previous years
  - But 11 of the 16 cases involved the same relator filing what appear to be "copycat" *qui tam* suits

Fraud Statistics—Health and Human Services

October 1, 1986 - September 30, 2018

Civil Division, U.S. Department of Justice

FY	NEW MATTERS[1]		SETTLEMENTS AND JUDGMENTS[2]					RELATOR SHARE AWARDS[3]		
	NON QUI TAM	QUI TAM	NON QUI TAM	QUI TAM			TOTAL QUI TAM AND NON QUI TAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
			TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL				
TOTAL	1,022	7,633	6,733,728,753	30,390,264,925	1,671,775,748	32,062,040,673	38,795,769,426	4,905,856,887	407,901,364	5,313,758,251

NOTES:

0. The information reported in this table covers matters in which the Department of Health and Human Services is the primary client agency.
1. "New Matters" refers to newly received referrals, investigations, and qui tam actions.
2. Non qui tam settlements and judgments do not include matters delegated to United States Attorneys' offices. The Civil Division maintains no data on such matters.
3. Relator share awards are calculated on the portion of the settlement or judgment attributable to the relator's claims, which may be less than the total settlement or judgment. Relator share awards do not include amounts recovered in subsection (h) or other personal claims. See 31 U. S. C. 3730(h).

Criminal Enforcement Actions

Criminal Enforcement Actions

Medicaid Fraud Control Units Fiscal Year 2017 Annual Report of Indictment versus Conviction Rates

KEY PERFORMANCE INDICATORS	FY 2015 (ACTUAL)	FY 2016 (ACTUAL)	FY 2017 (ACTUAL)	FY 2018 TARGET	FY 2019 TARGET
Indictment rate	17.8%	17.2%	18.4%	18.5%	19.0%
Conviction rate	91.2%	89.7%	88.6%	91.0%	91.0%

Suzanne Murrin, Deputy Inspector General "Medicaid Fraud Control Units Fiscal Year 2017 Annual Report" Office of Inspector General (Dec. 2017) https://oig.hhs.gov/oei/reports/oei-09-18-00180.pdf

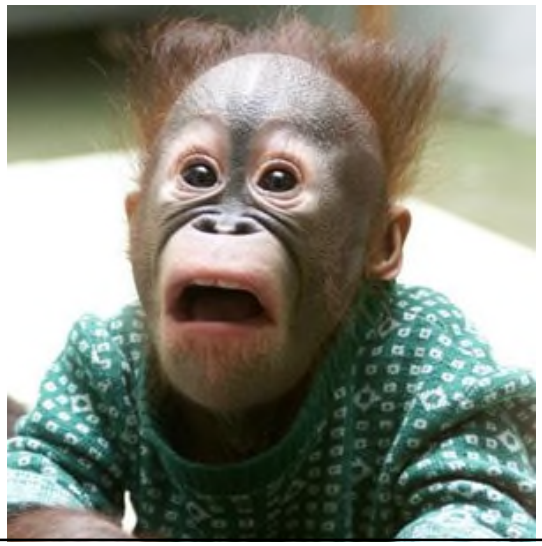
Criminal Enforcement Actions

- In 2018, Criminal Enforcement Action continues to focus on individual bad actors in different areas
- Crackdown in Medical Transportation
  - In May 2018, the Department of Justice indicted 13 individuals from 10 medical transport companies which allegedly fraudulently charged New York's Medicaid program $7.3 million.
    - *See, e.g.*, *United States v. Gondal et al.*, (N.D. N.Y. 18-cr-00190-TJM)
  - September 27, 2018, Dept. of Justice entered into a settlement for over $21 million with seven ambulance industry defendants located in Texas to settle allegations of unlawful kickbacks and improper financial relationships.

The Risk is Real!

- In June 2018, the DOJ announced its largest ever health care fraud enforcement action, which involved charges against 600 individuals who were alleged to be responsible for over $2 billion in fraudulent billings to the Medicare and Medicaid programs;
- Minnesota Attorney General's focus on agencies providing PCA services
  - E.g. Your Way Home, a home health care agency, in 2017 alleging that the agency was responsible for nearly $7 million in fraudulent Medical Assistance billings
- In 2014, the Minnesota Department of Health announced that stepped up enforcement efforts had resulted in a doubling of recoveries of fraudulent overpayments of Medicaid funds, from $1.8 million to $3.9 million.

Part 3: Hypotheticals



Hypo One: Anonymous Letter & the Disgruntled Employee

- You are the executive director of Homeways, a company that provides home health care services for elderly clients, including numerous Medicare beneficiaries.
- You have received an anonymous letter that alleges that several of Homeways' employees have falsified documents to make it appear that they have completed more client visits than is actually the case.
- Based on the content of the letter, you believe that the anonymous source is an employee who was recently put on a two week unpaid leave because the employee was witnessed verbally abusing a client and that the employee wrote the letter to retaliate against Homeways.
- The letter says that if Homeways does not fire the employed case managers, the author will publish an article on his or her blog identifying some of Homeways' patients "so that they can protect themselves because Homeways won't".

Hypo Two: Civil Investigative Demand from the Minnesota Attorney General's Office

- Homeways has received in the mail a letter from the Minnesota Attorney General's Office enclosing a Civil Investigative Demand that contains 30 separate document requests relating to Homeways' marketing practices and its relationships with referring physicians.
- The CID requires that Homeways produce documents covering the time period of January 1, 2010, through the present. The letter accompanying the CID says that the CID is being issued in connection with an investigation of potential fraud.
- The Civil Investigative Demand states the all documents responsive to the Demand are to be produced within 15 days of receipt of the Demand and also requests that a the clinic designate a representative to be informally interviewed by an Assistant Attorney General regarding the documents being produced.

Hypo Three (part 1): Subpoena from the DEA

- Homeways has been served with a subpoena from the DEA requesting the personnel file of a former employee and "all records" relating to any client who received care from that former employee. The subpoena requests that all responsive documents be produced within 15 days.
- You immediately contact Homeways' lawyer who contacts the DEA agent who signed the subpoena.
- The DEA agent tells your lawyer that the DEA has reason to believe that the former employee has been involved in selling drugs that he has taken from Homeways' clients.

Hypo Three (part 2): Responding to a subpoena from the DEA

- In reviewing the employment files to be provided to the DEA, you realize that the former employee at issue never went through Homeways "Employee Onboarding" process, which includes things like OIG exclusion searches.
- When you ask Homeways compliance leader about this individual, he tells you:
- "we always had some concerns about his recordkeeping and documentation practices, but I never got a chance to look into it much. It shouldn't matter anyway, since he doesn't work here anymore and this DEA stuff doesn't have anything to do with Medicare".

Hypo Four: Responding to a search warrant

- FBI agents are waiting for you when you arrive at work. The agent in charge hands you a search warrant relating to assistance that Homeways' employees have provided to Homeways' clients relating to prescription opiods.

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