

OIG Administrative Enforcement Update

2018 HCCA Compliance Institute

David M. Blank
Partner
Quarles & Brady LLP

Mariel Filtz
Program Analyst
Office of Inspector General

OIG Organization

- ▶ Office of Audit Services (OAS)
- ▶ Office of Evaluation and Inspections (OEI)
- ▶ Office of Investigations (OI)
- ▶ Office of Counsel to the Inspector General (OCIG)
- ▶ Office of Management & Policy (OMP)



What is Exclusion?

- ▶ Protects Federal health care programs from untrustworthy providers
- ▶ No Federal health care program payment may be made for items or services:
 - ▶ Furnished by an excluded individual or entity
 - ▶ Directed or prescribed by an excluded individual, where the person furnishing the item or service knew or had reason to know of the exclusion
- ▶ Exclusion applies to direct providers (e.g., doctors, hospitals) and indirect providers (e.g., drug manufacturers, device manufacturers)
- ▶ Special Advisory Bulletin on the Effect of Exclusion



Program Exclusion Law 42 U.S.C. § 1320a-7

- ▶ Mandatory v. Permissive Exclusion
 - ▶ Mandatory - § 1128(a) of the SSA
 - ▶ 4 Authorities
 - ▶ Permissive - § 1128(b) of the SSA
 - ▶ 16 Authorities
- ▶ 1128(b)(7) - Fraud, kickback, and prohibited activities
 - ▶ CMPL Violation
 - ▶ Kickback Violation



4

January 2018-to-Date Exclusion Stats

Authority	Count	Individual	Businesses
1128(a)(1)	859	834	25
1128(a)(2)	176	175	1
1128(a)(3)	201	201	
1128(a)(4)	111	109	2
1128(b)(1)	26	26	
1128(b)(2)	1	1	
1128(b)(3)	4	4	
1128(b)(4)	855	855	
1128(b)(5)	17	13	4
1128(b)(6)	2	2	
1128(b)(7)	14	10	4
1128(b)(8)	3		3
1128(b)(14)	30	30	
Settlement Agreement Breach/Default	1		1
Total	2300	2260	40

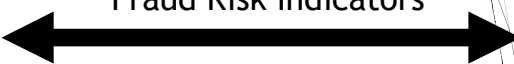
5

Revised Exclusion Criteria

- ▶ OIG updated policy statement (April 18, 2016):
 - ▶ (1) how it evaluates risk to federal health care programs; and
 - ▶ (2) the non-binding criteria it uses to assess whether to impose exclusion under section 1128(b)(7) of the Social Security Act.
- ▶ Four broad categories of factors:
 - ▶ Nature and circumstances of conduct
 - ▶ conduct during the Government's investigation
 - ▶ significant ameliorative efforts
 - ▶ and history of compliance

6

Fraud Risk Indicators



- Highest Risk - Exclusion
- High Risk - Heightened Scrutiny
- Medium Risk - CIAs
- Lower Risk - No Further Action
- Low Risk - Self-Disclosure

OIG's Civil Monetary Penalties Law

What is the Civil Monetary Penalties Law?

- ▶ Administrative fraud remedy (42 U.S.C. § 1320a-7a)
 - ▶ new regulations 81 Fed. Reg. 88,334 (Dec. 7, 2016)
 - ▶ Assessment (ex. 3x amount claimed) + penalties (ex. \$50k/act) + exclusion
 - ▶ Penalties updated annually for inflation, 45 CFR Part 102
- ▶ Alternative or companion case to a criminal or civil health care fraud action
 - ▶ Physicians, owners, or executives
- ▶ Intent: generally "knows or should know"
 - ▶ Actual knowledge, deliberate ignorance or reckless disregard

How does OIG use the CMPL?

- ▶ Enforcement actions on many different grounds, including:
 - ▶ False or fraudulent claims
 - ▶ AKS and beneficiary inducement
 - ▶ Arranging or contracting with excluded person
 - ▶ Ordering or prescribing while excluded
 - ▶ Knowing retention of overpayment
 - ▶ Provision of untimely or false information by a drug manufacturer with rebate agreement
 - ▶ Patient Dumping
 - ▶ Grant Fraud
- ▶ Self-Disclosure Protocol

10

CMPL Investigations

- ▶ When do they start?
 - ▶ Parallel Investigations with USAO
 - ▶ Criminal and Civil
 - ▶ OCIG Only
- ▶ When does a person or entity know they are subject to a CMPL investigation?
- ▶ What are the OIG's Investigative Tools?
 - ▶ Document Subpoenas
 - ▶ Investigational Inquiries (Testimonial Subpoena)
 - ▶ Data Analysis

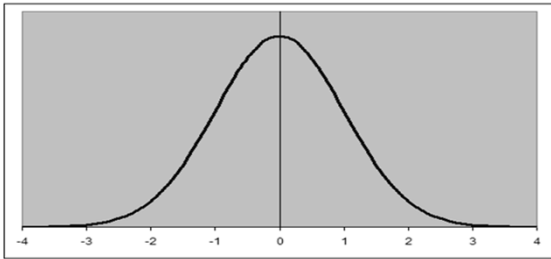
11

Forensic Data Analysis

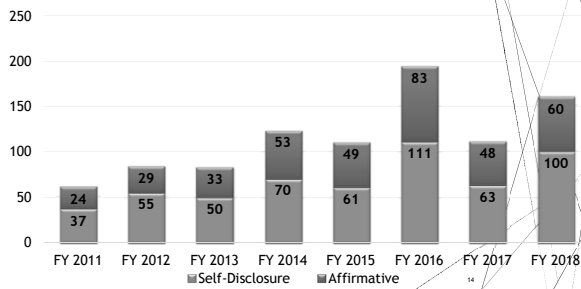
- ▶ What is it?
 - ▶ Data Mining:
 - ▶ Process of sorting through large amounts of data and extracting previously unknown information to identify aberrant billing trends that would otherwise remain hidden.
 - ▶ Advantages:
 - ▶ Allows for a flexible approach to fraud detection;
 - ▶ Uses a larger data warehouse;
 - ▶ Identifies a wide range of trends; and
 - ▶ Provides quicker results based on near real-time data.
- ▶ A tool that:
 - ▶ Identifies abnormalities;
 - ▶ Identifies patterns and trends of abuse;
 - ▶ Identifies cost-saving areas; and
 - ▶ Allows for assessment of quality of care.

12

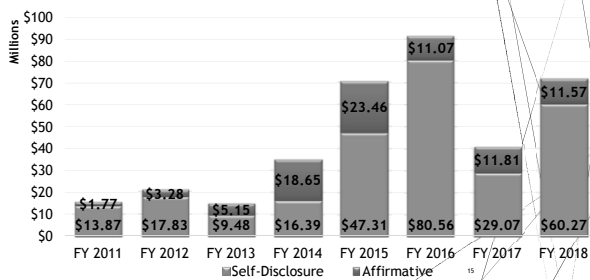
Investigation Techniques: The Bell Curve

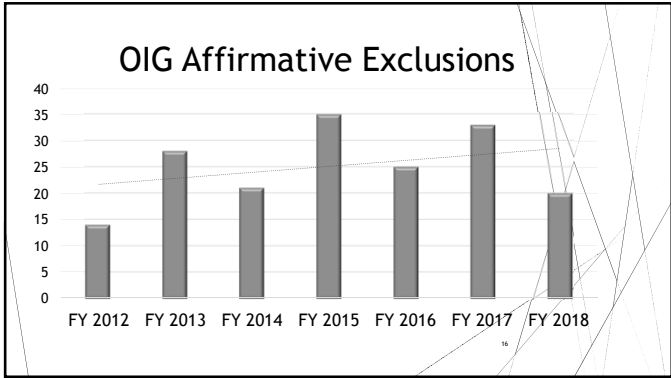


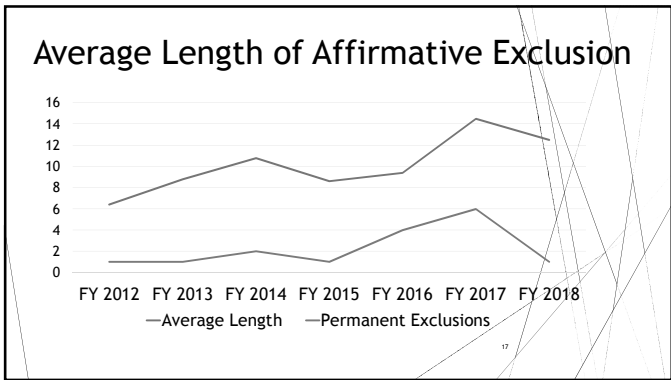
Number of CMP Settlements



CMP Recoveries







- ### OIG Enforcement Trends
- ▶ Opioids
 - ▶ Individual Accountability
 - ▶ Kickbacks
 - ▶ EMTALA
 - ▶ Diagnostic Providers
 - ▶ Employment of Excluded Individuals
 - ▶ Grant and Contracts
 - ▶ Hospital Billing
 - ▶ Managed Care
 - ▶ Home Health
 - ▶ Quality of Care

Section 1128(b)(7) of the Act

The Permissive Exclusion



"Sometime \$\$\$\$ just isn't enough"

Labib Riachi M.D.

- ▶ 2011 Data Analysis:
 - ▶ Highest biller in U.S. for anorectal manometry procedures (ARM) from 2008-2010.
 - ▶ Third in New Jersey for most physical therapy billed, despite being an OB/GYN physician.
- ▶ 2011-2013 Interviewed over 50 patients.
 - ▶ Patients denied receiving ARM procedure.
- ▶ 2012 Search Warrant
- ▶ 2011-2015 USAO Investigation

20

OIG Allegations

1. Failed to perform or supervise services while traveling;
2. Failed to personally supervise services;
3. Billing for services never provided;
4. Billing for PT provided unqualified people;
5. Failure to document services; and
6. Billing for unreasonable and unnecessary diagnostic tests.

Results: 20 year exclusion

21

Other Notable Exclusions

- ▶ Cindy Scott: APRM excluded for 10 years - excessively prescribing opioids
- ▶ Stephen Latman: physician excluded for 10 years - excessively prescribing opioids
- ▶ Anthony Vertino: psychologist excluded for 20 years - billing for psych testing in nursing homes when patients were in the hospital
- ▶ First Initiative and Shameika Amin: behavioral health service provider and owner excluded for 50 years - billing for group therapy when individual therapy was provided, and billing under the NPI of someone other than rendering provider

22

The Spin Offs



23

Susan Toy

- ▶ Owner of Millennium Billing
- ▶ July 2016: CMP Demand Letter Issued
 - ▶ 25 Counts
 - ▶ Demanded \$250,000 and 5 Year
- ▶ Settlement: Sept. 19, 2016
 - ▶ \$100,000
 - ▶ 5 Year Exclusion

24

Civil FCA Spin-Off Cases

Dr. Baker Fairmont Diagnostic Center and Open MRI

Conduct: Referring physicians received kickbacks in the form of medical directorship fees and office staff arrangements

Result: Settlements with 11 physicians for a total of \$1.4 million and one exclusion



25

Civil FCA Spin-Off Cases

Millennium Health

► **Conduct:** These entities accepted free urine drug testing (UDT) specimen cups that had test-strips built into the cups. These strips would give an “instant” indication of whether certain drugs were present in the urine, providing something of value in exchange for the referral to Millennium. Entities that received the free cups were contractually obligated to send confirmation testing to Millennium, otherwise they would be charged for the cups.

► **Result:** Settlements with 8 practices for a total of \$664,431.15

26

Employment of Excluded Individuals

27

Screening for Excluded Persons

- ▶ Best practices
 - ▶ Screen at hiring with employee/contractor certification
 - ▶ Screen monthly
 - ▶ Be aware of screening pit falls
- ▶ OIG List of Excluded Individuals and Entities (LEIE)
 - ▶ <http://exclusions.oig.hhs.gov>
 - ▶ Updated monthly
- ▶ Advisory Opinion 18-01: favorable opinion allowing an excluded individual to market emergency medication discounts to Long-Term Care pharmacies that participate in the federal health care programs. 28

Examples of Settlements Involving Excluded Persons

- ▶ Newark Community Health Center: Referral from NJ MCO that a physician was working at the CHC while excluded. \$98,750.36 settlement
- ▶ Community Dialysis Center: Self-disclosure that they employed an excluded tech. \$307,609.80 settlement
- ▶ UF Health Shands: Self-disclosure that they employed an excluded nurse. \$249,413 settlement
- ▶ Joseph Moon: Applied for reinstatement of his exclusion, disclosed he owned a pharmacy. \$96,259.57 settlement 29

Data Mining

30

Pelvic Floor Therapy Project

Project Description: Proactive data-analytics identified outliers for pelvic floor therapy.



Results: 7 settlements resulting \$2.88 million and 32 years of exclusion (total)

31

Rashmi Sandeep, MD

- ▶ **Conduct:** Referral from NJ MCO.
 - ▶ Failure to supervise services billed under her NPI because she was not in the United States or otherwise present.
 - ▶ Resubmission of previously denied claims, identified herself as the rendering provider when she was not.
 - ▶ Submitted claims for services rendered under her NPI for services performed by non-credentialed providers she did not supervise.

- ▶ **Results:** \$336,298.52 settlement

32

Urine Drug Testing Cases

Conduct: OAS identified providers who added Modifier-59 to claims for drug screening when only a single unit may be billed per patient encounter and general upcoding.

Results: 11 CMPL settlements and 1 FCA settlement totaling more than \$14 million

- Gainesville Pain Management & Dr. Britton- \$1.58 million settlement and CIA
- Medicus- \$5 million settlement and CIA
- Calloway- \$4.67 million and CIA
- Mohammad Siddique, M.D.- 10-year exclusion



33

E/M Outpatient Clinic Visits

Conduct: OAS identified hospitals that submitted claims for “new patient” evaluation and management (E/M) outpatient clinic visits using HCPCS codes 99203-99205 when the patients were “established patients” and the hospitals should have billed those claims using the lower-paying HCPCS codes 99213-99215.

Results: Four CMPL settlements with hospitals totaling \$2.6 million

- UCSF Medical Center
- Boston Medical Center
- UMass Memorial Medical Center
- Carilion



34

Operation Wheel and Deal

Conduct: CDAC conducted data analytics to identify ambulance companies that billed emergency ambulance transportations to inappropriate destinations, including skilled nursing facilities, residences, and dialysis facilities.

Results:

- 23 CMPL settlements with ambulance companies totaling more than \$4.4 million



35

Drug Pricing Cases

- ▶ Office of Evaluations and Inspections referral
- ▶ **Conduct:** Pharmaceutical companies failed to submit accurate drug pricing information to CMS, which uses the information to determine payment amounts for drugs reimbursed by Medicaid
- ▶ **Results:** \$18.1 million in settlements with 11 companies, including \$12.64 million settlement with Sandoz

36

Sub-standard Quality of Care *Dr. Bobby Merkle*

- ▶ Quality Improvement Organization (QIO) referral
- ▶ Conduct: Violated obligations to provide services to 5 Medicare beneficiaries through practices that violated professionally recognized standards of care.
- ▶ Results: 3 year exclusion under 42 USC § 1320c-5

37

And Beyond...



- ▶ **21st Century Cures Act - December 2016**
 - ▶ Grant and Contract Fraud
 - ▶ HHS given statutory authority to impose civil money penalties, assessments, and/or exclusion upon individual/entities engaging in fraudulent conduct involving HHS *grants, contracts and other agreements*.
 - ▶ Information Blocking
 - ▶ OIG given authority to impose civil money penalties upon parties (health information technology developers, health care providers, and other) that engage in information blocking

38

Grant and Contract Fraud

- ▶ CMP Authority: - Knowingly presenting a false or fraudulent *specified claim* under grant, contract, or other agreement.
 - ▶ "Specified claim" - application, request, demand for payment.
 - ▶ False statements in grant applications
 - ▶ Charging for costs not incurred or unallowable costs
 - ▶ Drawing down funds when not in compliance with grant terms
- ▶ Results: 2 settlements for \$152,716.30 related to unallowable draw downs of grant funds

39

Information Blocking

- ▶ What is Information Blocking?
 - ▶ A practice that inappropriately impedes the flow or use of information
- ▶ CMP Authority
 - ▶ OIG has the authority to investigate claims that health information technology developers, health care providers, or health information exchanges or networks engaged in information blocking.
 - ▶ For developers and exchanges or networks, OIG may impose civil monetary penalties not to exceed \$1 million per violation.

40

OIG Compliance Resources <http://oig.hhs.gov/compliance/>



Questions and Comments

David M. Blank
Quarles & Brady
Telephone: 202-780-2643
Email:
David.Blank@quarles.com

Marief Filtz
Office of Inspector General
Telephone: 202-329-9475
Email: Marief.Filtz@oig.hhs.gov

41
