Introduction:
Exclusion and Civil Monetary Penalties

- OIG Exclusion
  - Overview of authorities
  - Differences between exclusion and CMS revocation authority

- OIG Civil Monetary Penalties
  - OIG priority areas
  - Overview of authorities
  - Recent case results

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

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
Revised Exclusion Criteria

Risk Spectrum

Highest Risk  
Exclusion  
High Blood Pressure  
Hypertension  
No Further Action  
Release (Self-Disclaimer)

Lower Risk

Procedure for Exclusions – 42 C.F.R. Part 1001

- Derivative exclusions (mandatory and permissive):
  - Notice of Intent to Exclude (opportunity to respond)
  - Notice of Exclusion (goes into effect 20 days from letter)
  - any appeal of exclusion (basis and/or length) is before HHS Departmental Appeals Board Administrative Law Judge (https://dab.efile.hhs.gov/)

- “Affirmative” exclusions:
  - OIG notifies individual/entity of proposed exclusion and length via letter
  - Generally* goes into effect AFTER hearing before ALJ (or 60 days from letter if provider doesn’t appeal to ALJ)

* (b)(6)(B) exclusions go into effect before hearing, but opportunity to meet with OIG before exclusion imposed

Screening for Excluded Persons

- Best practices
  - Screen at hiring with employee/contractor certification
  - Screen monthly

- OIG List of Excluded Individuals and Entities (LEIE)
  - http://exclusions.oig.hhs.gov
  - Updated monthly
Screening Pitfalls

- Former or Maiden Names
  - Make sure employment agreements request this information

- Criminal Background Checks
  - Look for the mandatory exclusion triggers.

- Spelling Mistakes

- 3rd Party Screening
  - Who's responsible for mistakes?

OIG’s Civil Monetary Penalties Law

What is the Civil Monetary Penalties Law?

- Administrative fraud remedy (42 U.S.C. § 1320a-7a)
  - 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
  - Ownership, control or management while excluded
  - Ordering or prescribing while excluded
  - Knowing false statement on application, bid or contract to participate or enroll
  - Knowing retention of overpayment
  - Provision of untimely or false information by a drug manufacturer with rebate agreement
  - Self-Disclosure Protocol

FCA vs. CMPL Remedies

<table>
<thead>
<tr>
<th>FCA</th>
<th>CMPL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Civil Penalty of no less than $5,000 and not more than $10,000</td>
<td></td>
</tr>
<tr>
<td>Monetary Penalty up to $10,000 for each item or service improperly claimed</td>
<td></td>
</tr>
<tr>
<td>3 times damages sustained by the U.S.</td>
<td></td>
</tr>
<tr>
<td>Up to 3 times the amount improperly claimed</td>
<td></td>
</tr>
<tr>
<td>No Exclusion</td>
<td></td>
</tr>
<tr>
<td>Exclusion</td>
<td></td>
</tr>
<tr>
<td>Statute of Limitations can be up to 10 years</td>
<td></td>
</tr>
<tr>
<td>Statute of Limitations 6 years</td>
<td></td>
</tr>
</tbody>
</table>

CMPL Investigations

- When do they start?
  - Parallel Investigations with USAO
  - Criminal and Civil
  - OGIS Only

- When does a person or entity know that they are subject to a CMPL investigation?

- What are the OIG's Investigative Tools?
  - Document Subpoenas
  - Investigational Inquiries (Testimonial Subpoena)
  - Data Analysis
Potential Life Span of Agency Actions

- Investigation
- Agency Action
- Administrative Hearing (ALJ Review)
- Administrative Appellate Review
- Federal District Court
- Federal Appeals Court
- The Supreme Court

The Initiation of a CMPL Hearing

- DOJ/USAO Declination
- Demand Letter
  - Notice of Proposed Agency Determination

Factors to determine Penalty and Assessment
- Nature and Circumstances of the Incident;
- Degree of Culpability;
- Prior Offenses;
- Other Wrongful Conduct;
- Financial Condition; and
- Other Matters as Justice May require.

FCA v. CMP Litigation

FCA Litigation
- Formal Trial
  - Finder of Law: Judge
  - Finder of Fact: Judge or Jury
- Burden of Proof: preponderance of the evidence
- Evidence and testimony presented in court during hearing
- Hearsay is inadmissible
- Resolution at end of trial

CMPL/Program Exclusion
- Administrative Hearing
  - Finder of Fact and Law: ALJ
- Burden of Proof: preponderance of the evidence
- Most evidence and testimony is presented pre-hearing
- Hearsay Admissible
  - FRE is serves as a “guideline”
- Resolution after post hearing exchanges
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.

- **Advantages:**
  - Identifies abnormalities;
  - Identifies patterns and trends of abuse;
  - Identifies cost-saving areas; and
  - Allows for assessment of quality of care.

Investigation Techniques: The Bell Curve

Number of CMP Settlements
OIG Enforcement Trends

- Prescription Drug Fraud
- Data Analysis
- Kickbacks (DME, Labs, Ambulance)
- Patient Harm
- Individual Accountability
- Physicians and Individual Providers
- Post FCA Settlement Exclusions

Section 1128(b)(7) of the Act

The Permissive Exclusion

"Sometime $$$ just isn't enough"

Labib Riachi, M.D.
The Investigation

- 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

Pelvic Floor Therapy

- Early adopter of Pelvic Floor Therapy (PFT) to treat female incontinence.
- Riachi’s PFT treatment included a mix of diagnostic testing and physical therapy services.

<table>
<thead>
<tr>
<th>Diagnostic Codes</th>
<th>Physical Therapy Codes</th>
<th>E&amp;M Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>97122 (ARM)</td>
<td>97120 (therapeutic procedure)</td>
<td>99211 (office visit)</td>
</tr>
<tr>
<td>51784 (EMG Study)</td>
<td>97550 (therapeutic activity)</td>
<td>97550 (physical performance test)</td>
</tr>
<tr>
<td></td>
<td>*Each 15 minutes</td>
<td></td>
</tr>
</tbody>
</table>

Exclusion Notice

Issued May 18, 2016

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
20-Year Exclusion

Deeper Than the Headlines: Exclusions for Doctors, Billers and Suppliers... Oh My!

Report on Medicare Compliance

Doctor and His Third-Party Biller Are Excluded from Medicare and Medicaid

New Jersey OB/GYN Settles Fraudulent Billing Allegations, Agrees to 20-Year Exclusion from Medicare, Medicaid

Other Notable Exclusions

- **Phillip Minga**: owner of DME company excluded for 10 years after billing for diabetes supplies that were not delivered, were the result of telemarketing rules violations, or were tainted by kickbacks.
- **Alexander Khavash**: chiropractor excluded for 40 years after submitting claims for chiropractic services that were not provided as claimed and were not medically necessary.
- **Eugene Fox**: podiatrist excluded for 30 years after he billed for podiatric services that were not rendered or were rendered by unqualified personnel.
- **Michael Esposito**: physician excluded for 5 years after forging another physician's signature on prescriptions for himself and another person.

Section 1128A of the Act

The CMPL Case
OIG’s Investigation of Dr. Joseph Raia

- SGS Referral to OIG
- Billing for services not rendered;
- Billing for medically unnecessary services; and
- Use of Unqualified People.

Investigative Findings

1. "Incident to" PT claims rendered by a chiropractor;
2. Claims submitted while traveling;
3. Inaccurate time based procedures;
4. Impossible Days;
5. Unqualified people rendering PT; and
6. Group therapy billed as 1-on-1.

Demand Letter

- Issued on June 28, 2013
- CMP & Assessment = $4,247,416.64
- CMP - $2,495,900
- Assessment - $1,751,561.64
- Exclusion = 20 Years

- CMP Theory #1: Chiropractic rendered PT
  - Jan. 1, 2006 - June 24, 2009
  - Claims Presented: 2,943
  - Total Claimed Amount: $383,558.14

- CMP Theory #2: Travel Dates/Lack of Supervision
  - Claims Presented: 2,012
  - Total Claimed Amount: $379,185.44
Resolution

- Raia Appealed the Demand
- Agreed to resolution after Discovery
- February 2014 Settlement
  - $1.5 million
  - 15 year exclusion

The Spin Offs

Operation Orange Squeeze

New Jersey Criminal Investigation
18 Criminal Convictions
Orange MRI Doctors

Dr. Robert Collins
Settlement: $42,455

Dr. Anar Shafiee
Settlement: $64,180

Dr. Raja Shah
Settlement: $114,995

Jennan Comprehensive Medical

- Physician Practice in NYC.
- Hired Raia to head its PMR unit.
  - April 2006 – February 2012
  - Raia present 1 day week
- All claims submitted for PT identify Raia as rendering provider.
- December 2014: Settlement
  - $694,887
  - Divestiture of the physical therapy practice

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
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:** $17.8 million in settlements with 8 companies, including $12.64 million settlement with Sandoz

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

OIG Compliance Resources

http://oig.hhs.gov/compliance/
Questions and Comments

David M. Blank
Office of Inspector General
Telephone: 202-205-0578
Email: David.Blank@oig.hhs.gov

Edgar D. Bueno
Morris Manning & Martin, LLP
Telephone: (912) 232-7182
Email: ebueno@mmmlaw.com