Federal Administrative Sanctions: Exclusion and Civil Monetary Penalties

HCCA Healthcare Enforcement Compliance Institute
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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

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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)

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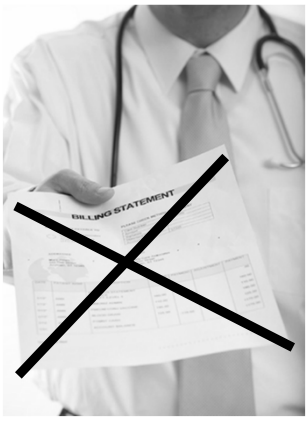
What is Exclusion?

- 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

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Revised Exclusion Criteria

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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

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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

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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?

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OIG's Civil Monetary Penalties Law

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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

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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

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FCA vs. CMPL Remedies

FCA	**CMPL**

• Civil Penalty of no less than $5,500 and not more than $11,000
  • Inflation Adjusted: $10,781 - $21,563
	• Monetary Penalty up to $10,000 for each item or service improperly claimed
	  • Inflation Adjusted: $15,024
	  • Violation occurred AFTER 11/2/15

• 3 times damages sustained by the U.S.	• Up to 3 times the amount improperly claimed
• No Exclusion	• Exclusion
• Statute of Limitations can be up to 10 years	• Statute of Limitations 6 years

CMPL Investigations

- When do they start?
  - Parallel Investigations with USAO
    - Criminal and Civil
  - OCIG Only
- When does a person or entity know that 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

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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.

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FCA v. CMP Litigation

FCA Litigation	**CMPL/Program Exclusion**

• Formal Trial
  • Finder of Law: Judge
  • Finder of Fact: Judge or Jury
	• Administrative Hearing
	  • Finder of Fact and Law: ALJ

• Burden of Proof: preponderance of the evidence	• Burden of Proof: preponderance of the evidence
• Evidence and testimony presented in court during hearing	• Most evidence and testimony is presented pre-hearing
• Hearsay is inadmissible	• Hearsay Admissible • FRE is serves as a "guideline"
• Resolution at end of trial	• 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.
- A tool that:
  - Identifies abnormalities;
  - Identifies patterns and trends of abuse;
  - Identifies cost-saving areas; and
  - Allows for assessment of quality of care.

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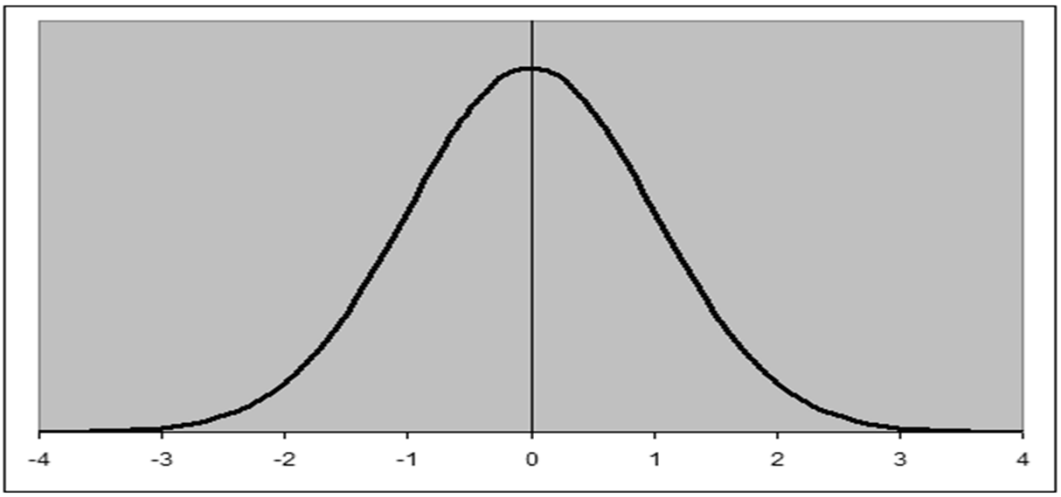
Investigation Techniques: The Bell Curve



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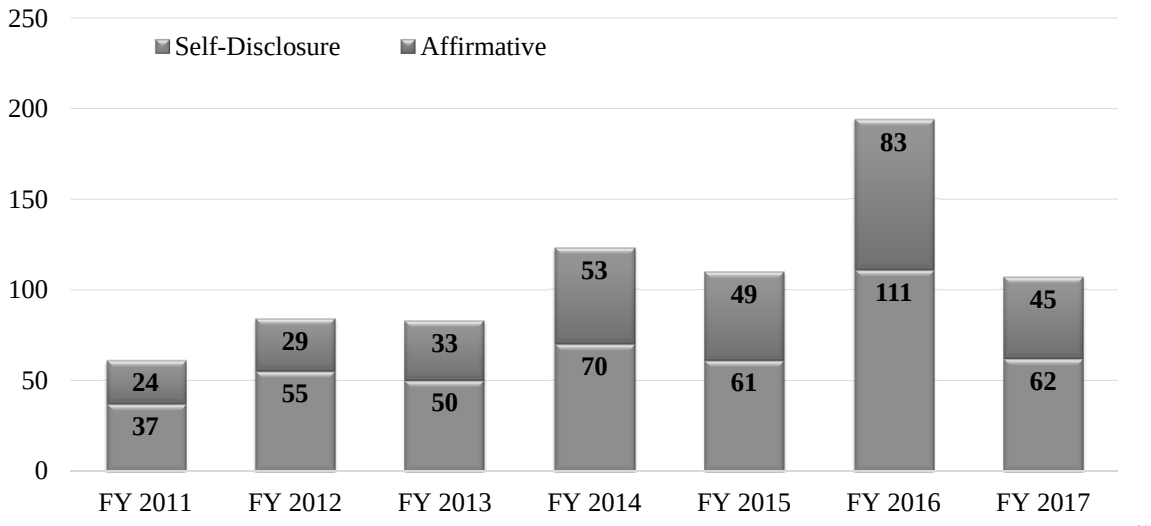
Number of CMP Settlements



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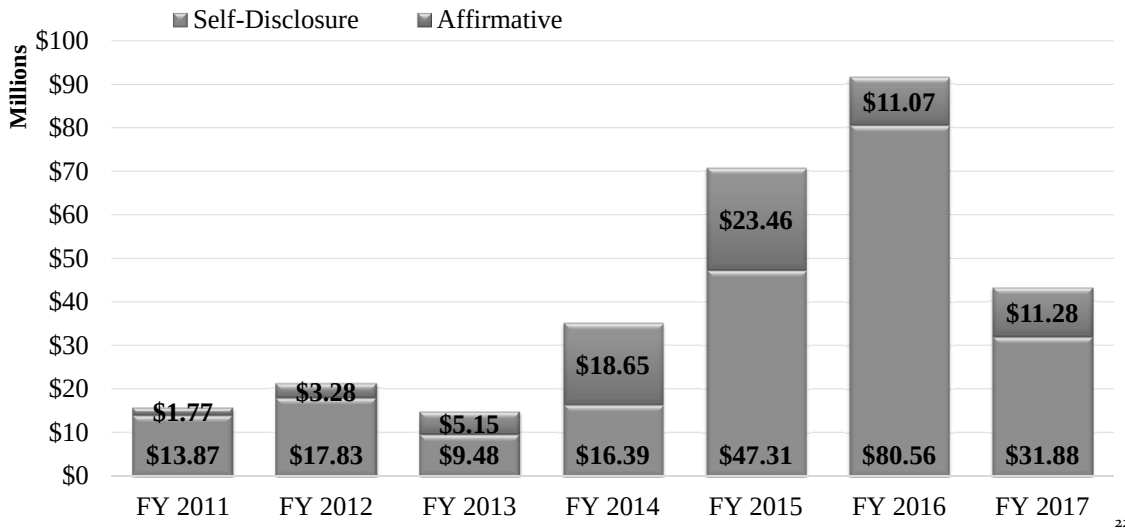
CMP Recoveries



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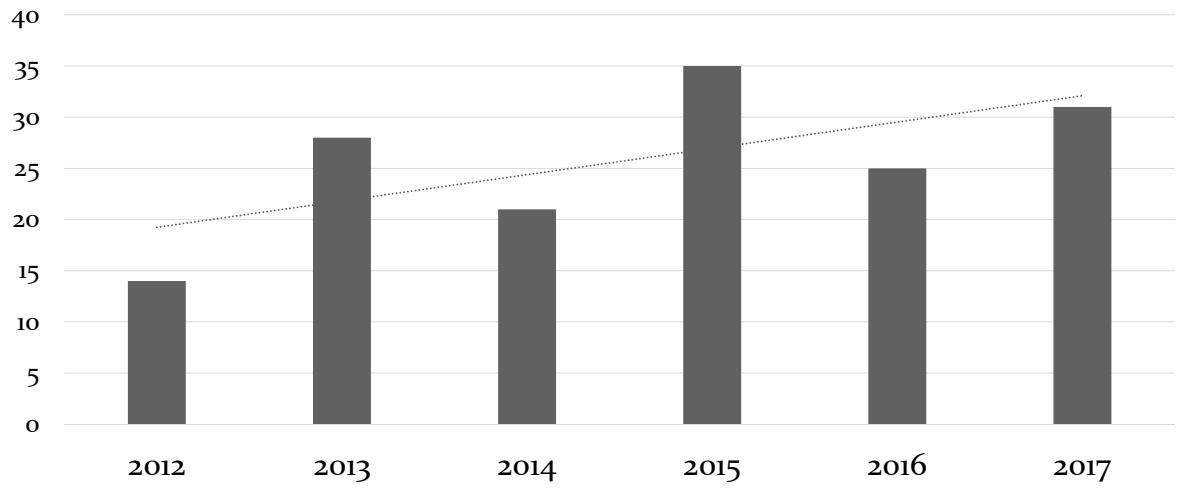
OIG Affirmative Exclusions



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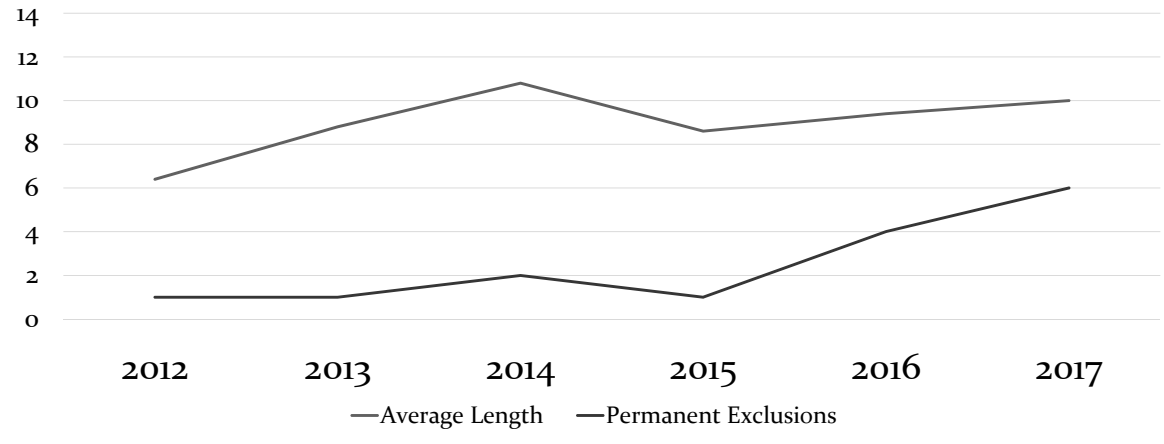
Average Length of Affirmative Exclusion



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OIG Enforcement Trends

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

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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.

Diagnostic Codes	Physical Therapy Codes	E&M Code
91122 (ARM)	97110 (therapeutic procedure)	99211 (office visit)
51784 (EMG Study)	97032 (E-Stim)	* 5 min
	97550 (therapeutic activity)	
	97550 (physical performance test)	
	*Each 15 minutes	

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 documents services; and
6. Billing for unreasonable and unnecessary diagnostic tests.

20 Year Exclusion


Report on MEDICARE COMPLIANCE
Volume 25, Number 43 • December 5, 2016
Weekly News and Compliance Strategies on CMS/OIG Regulations, Enforcement Actions and Audits

Doctor and His Third-Party Biller Are Excluded From Medicare and Fined


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

Posted by CJ Wolf
Nov 28, 2016 2:50:11 PM

On November 15, 2016, the HHS OIG announced that New Jersey OB/GYN, Dr. Labib Riachi, agreed to be excluded from participation in Federal healthcare programs for 20 years.

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


BNA's Health Care Daily Report™
November 18, 2016

Fraud and Abuse

Doctor's 20-Year Exclusion Signals Renewed Crackdown on Fraud

BNA Snapshot

- Twenty-year exclusion one of longest under OIG's permissive exclusion authority
- Signals agency will pursue exclusions following FCA settlements

By James Swann

Nov. 17 — The government's 20-year exclusion of a New Jersey doctor over false billing allegations represents a heightened focus on provider conduct, an HHS official told Bloomberg BNA Nov. 17.

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.

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Section 1128A of the Act

The CMPL Case

OIG's Investigation of Dr. Joseph Raia

- SGS Referral to OI
  - 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 = $4,247,461.64
    - 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
  - Jan. 1, 2006-Nov. 22, 2011
  - Claims Presented: 3,034
  - Total Claimed Amount: $379,283.44

Resolution

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

The Spin Offs

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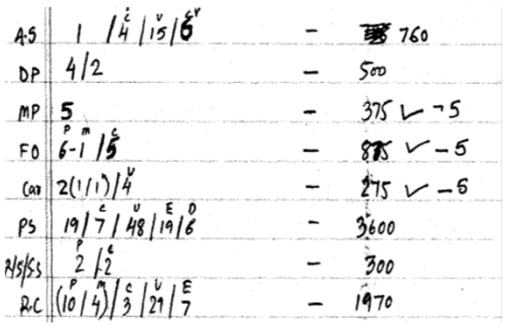
Operation Orange Squeeze

New Jersey Criminal Investigation
18 Criminal Convictions



Orange MRI Doctors

Dr. Robert Collin
Settlement = $111,415

Dr. Ansar Sharif
Settlement: $52,280

Dr. Rajan Shah
Settlement: $104,950

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

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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

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

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Questions and Comments

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