

Federal Administrative Sanctions: Exclusion, Revocation, and Civil Monetary Penalties

2015 HCCA Healthcare Enforcement Compliance Institute

Julie E. Kass, Ober|Kaler
jekass@ober.com

Katie Fink, OIG
katie.fink@oig.hhs.gov

1

Introduction: Exclusion, Revocation, and Civil Monetary Penalties

- **OIG Exclusion and CMS Billing Revocation**
 - Overview of authorities
 - Discussion of the differences
 - Comparison of CMS' revocation process
- **OIG Civil Monetary Penalties**
 - OIG priority areas
 - Overview of authorities
 - Recent case results

2

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



Mandatory Exclusions – § 1128(a) of the SSA

- Based on convictions for:
 - Medicare/Medicaid Fraud
 - Patient Abuse/Neglect
 - Felony Health Care Fraud
 - Felony Relating to Controlled Substances
- Conviction is broadly defined in § 1128(i) of the SSA
- Minimum 5 year exclusion term
 - Aggravating and mitigating circumstances

Permissive Exclusions — § 1128(b) of the SSA

- 16 bases, most are derivative and include:
 - Misdemeanor health care (non-Medicare/Medicaid) fraud conviction;
 - Obstruction of investigation/audit;
 - Misdemeanor controlled substances conviction;
 - License revocation or suspension;
 - Individuals controlling a sanctioned entity;
 - Failure to supply payment information or grant immediate access;
 - Knowing false statements or misrepresentations on enrollment applications

- Term of exclusion varies based on grounds for permissive exclusion
 - Adjustments to term based on aggravating and mitigating factors

5

Affirmative Permissive Exclusions

- **OIG must prove the elements of the underlying offense before an Administrative Law Judge**
 - **Fraud/Kickbacks – §1128(b)(7)**
 - Right to pre-exclusion hearing for proposed (b)(7) exclusion

 - **Quality of Care – §1128(b)(6)(B)**
 - Failure to meet professionally recognized standards of care
 - Items or services substantially in excess of patients' need
 - Not just Federal health care program beneficiaries

6

Criteria for Implementing an Affirmative Exclusion Under 1128(b)(7)

- Seriousness of the underlying misconduct
- Defendant's response to the allegations
- Likelihood that an offense or similar abuse will occur again
- Financial responsibility

7

Top 6 Exclusions by Type

- License revocation or suspension – 1128(b)(4)
- Program-related conviction – 1128(a)(1)
- Patient abuse or neglect – 1128(a)(2)
- Felony health care (non-Medicare/Medicaid) fraud conviction – 1128(a)(3)
- Health Education Assistance Loan default – 1128(b)(14)
- Felony controlled substance conviction – 1128(a)(4)

8

Exclusion Procedure – 42 C.F.R. Part 1001

- Derivative Exclusions
 - Notice of Intent to Exclude and opportunity to respond in writing
 - Notice of Exclusion
 - Exclusion goes into effect 20 days after Notice of Exclusion
 - Right to appeal and request an ALJ hearing
 - Can request a hearing online at <https://dab.efile.hhs.gov/>

9

Exclusion Procedure – 42 C.F.R. Part 1001

- Affirmative exclusions under § 1128(b)(7)
 - Pre-Demand Letter and opportunity to respond in writing
 - The parties reach an agreement or OIG issues a Demand Letter, which may lead to a hearing
- Affirmative exclusions under § 1128(b)(6)(B)
 - Have opportunity to meet with OIG before OIG imposes exclusion
 - Exclusion goes into effect 20 days after Notice of Exclusion

10

Waiver of Exclusion

- OIG has the authority to waive an individual's or entity's exclusion as a provider from Federal health care programs
- Waivers are available only for those excluded providers who are the sole community physician or the sole source of essential specialized services in a community
- A waiver may be requested only by **the administrator of a Federal or State health program**
- Excluded individuals or entities may not request a waiver from the OIG

11

Reinstatement

- Reinstatement into the Federal health care programs is not automatic at the end of the exclusion period
- Individuals must apply to OIG for reinstatement
- OIG has discretion to grant or deny reinstatement petition
- No judicial review of OIG's decision to deny petition
- Billing while excluded is a common reason for denial

12

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

13

New OIG Regulations



- Proposed Revisions to OIG's Exclusion Authorities (May 9, 2014)
 - Expansion of waiver authority
 - New affirmative exclusion authority
 - Investigational inquiries
 - Obstruction of an audit
 - Failure to supply payment information
 - Technical Changes

14

CMS Revocation Rules

15

CMS Enforcement Efforts Increasing

- Effective June 2006: Change in regulations to allow the imposition of sanctions for failing to provide timely updates:
 - Deactivation of billing privileges
 - Revocation of billing privileges
- Effective August 2008: Implemented a *one- to three-year bar to Medicare re-enrollment* following a revocation

16

Sanctions for Failing to Comply

- Deactivation – temporary suspension of billing privileges without termination of the provider or supplier agreement
 - May need to submit new CMS 855 form to obtain reactivation
- Revocation – automatic termination of the provider or supplier agreement:
 - Generally, effective 30 days following notice
 - Exception if based on final adverse action, then effective date of the action
 - Becomes reportable event – Medicare, Medicaid and other third party payers, licensing agencies after all appeals are exhausted or time to file appeal has lapsed

17

Bases for Revocation

- Reporting Adverse Actions
- CHOW
- Change in practice location
- Failure to respond to request for revalidation
- Certifying info as true that is false or misleading
- Knowingly allowing another individual or entity to use a Medicare billing number
- Billing for services that could not have been provided on a particular date of service
- Failure to maintain documents

18

Bases for Revocation

- Exclusion from Medicare/Medicaid or other Federal health care programs
- Debarred, suspended, or excluded from any other Federal procurement or nonprocurement program
- Felonies by provider, supplier or any owner within 10 years of enrollment or revalidation that CMS determines to be detrimental to best interests of programs and beneficiaries
- Failure to report adverse legal actions

19

Reporting Changes to Enrollment Data

- Final adverse actions means:
 - A Medicare-imposed revocation of any Medicare billing privileges;
 - Suspension or revocation of a license to provide health care by any State licensing authority;
 - Revocation or suspension by an accreditation organization;
 - A conviction of certain Federal or State felony offenses within the last 10 years preceding enrollment, revalidation, or re-enrollment; or
 - An exclusion or debarment from participation in a Federal or State health care program.

20

Reporting Changes to Enrollment Data

- Final adverse actions – Federal or State Felony Offenses include:
 - Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions
 - Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions
 - Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct
 - Any felonies that would result in mandatory exclusion under section 1128(a) of the Act

21

Sanctions for Failing to Comply

- The letter revoking billing privileges must contain:
 - A legal basis of each reason for revocation;
 - A clear explanation including the facts or evidence used by the contractor in making the revocation determination;
 - An explanation of why the enrollment criteria or program requirement were not satisfied;
 - The effective date of the revocation;
 - Procedures for submitting a Corrective Action Plan (CAP); and
 - Complete and accurate information about further appeal rights.

22

Sanctions for Failing to Comply

- Appeals Process:
 - Request for Reconsideration filed within 60 days of the notice of the revocation
 - CMS or its contractor, or the provider or supplier dissatisfied with a Reconsideration Determination may request an ALJ Hearing within 60 days from receipt of the Reconsideration Decision
 - CMS or its contractor, or the provider or supplier dissatisfied with the ALJ Hearing Decision may request Board review by DAB within 60 days from receipt of the ALJ's Decision
 - Provider or supplier dissatisfied with the DAB Decision may seek judicial review in District Court by filing a civil action within 60 days from receipt of the DAB's Decision

23

Sanctions for Failing to Comply

- Bar to re-enrollment:
 - Bar is not discretionary
 - Length of bar is discretionary for most revocations and is to be based on the severity of the basis for revocation
 - Exceptions:
 - Failure to report final adverse action: 1-year if already enrolled, 3-years if new enrollee
 - Failed site visit: 2-year bar
 - Submitting claims after license suspension or felony conviction or falsification of information: 3-year bar
 - Must reapply as a new provider/supplier

24

Other important Notes on Revocation

- Revocation is effective 30 days after notice
 - Except for exclusion/debarment, which is when the exclusion or debarment was effective OR when CMS determined no longer operational
- Similar to exclusion by OIG, if adverse activity is due to sanction of an individual, severing ties with individual can lead to reversal of revocation if proved within 30 days of revocation notification
- If a provider/supplier is revoked, CMS reviews all other associated business arrangements

25

OIG's Civil Monetary Penalties Law

26

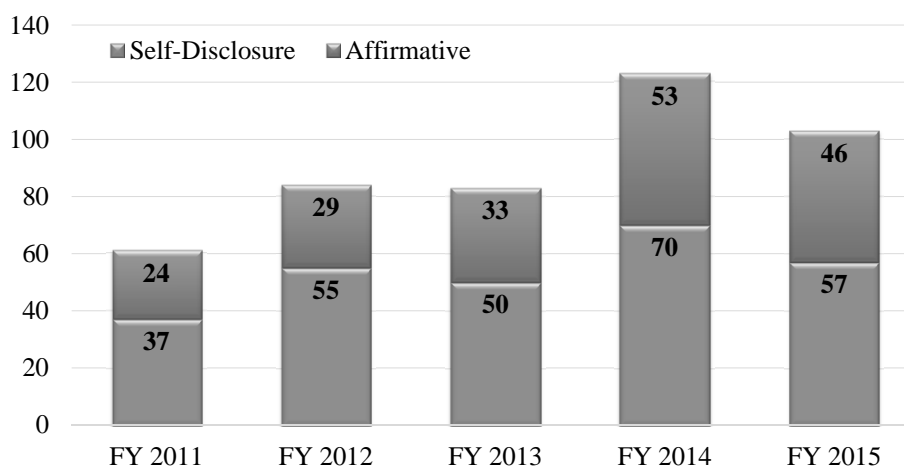
What is the Civil Monetary Penalties Law?

- Administrative fraud remedy
 - Affirmative cases initiated by ACRB
 - Can recover money damages + penalties + exclusion
- Alternative or companion case to a civil action
 - Physicians, owners, or executives
- Burden of Proof
 - Preponderance of the evidence (same as civil)
- Statute of Limitation
 - 6 years (same as civil)
- Intent: generally “knows or should know”
 - Actual knowledge
 - Deliberate ignorance or reckless disregard

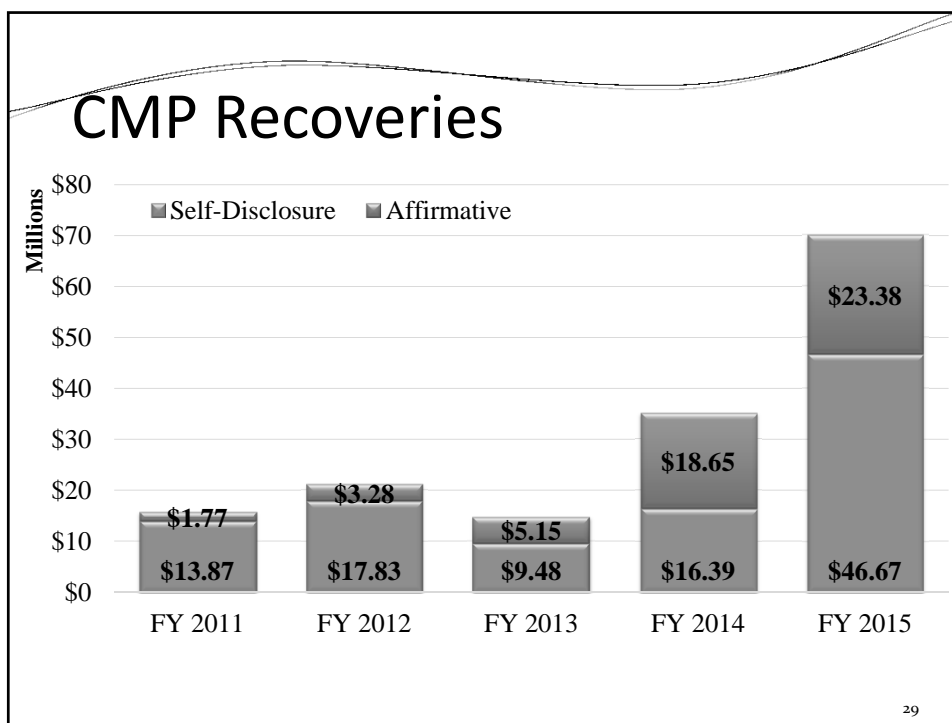


27

Number of CMP Settlements



28



Factors Favoring CMP Cases

- No explicit civil remedy
 - False or Fraudulent Claims
 - Kickbacks
 - Billing while excluded
 - Violation of an assignment agreement
 - Failure to properly report required drug pricing information
- Opportunity to hold individuals accountable
- Exclusion sought
- Jury appeal issues
- Good evidence of fraud, but U.S. Attorney's Office declined

30

Criminal Spin-Off Cases *Orange Community MRI*

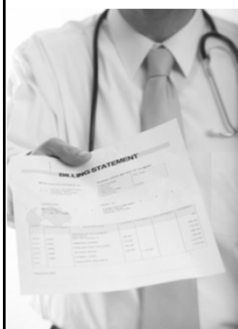


Conduct: Referring physicians received cash kickbacks for referrals; amount or remuneration per referral was based on the procedure ordered

Result: Settlement with Dr. Sharif for \$52,280 and Dr. Shah for \$104,950

31

Criminal Spin-Off Cases *Mississippi PT Doctors*



Conduct: Physicians failed to personally render or directly supervise physical therapy services billed under their provider numbers

Result: Settlements with nine physicians for a total of \$630,375

32

Fraud Alert to Physicians



OIG ALERT

OIG alerted physicians that if they reassign their right to bill the Medicare program and receive Medicare payments by executing the CMS-855R application, they may be liable for false claims submitted by entities to which they reassigned their Medicare benefits.

33

Civil FCA Spin-Off Cases

*Jack Baker Fairmont Diagnostic Center
and Open MRI, Inc.*

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



34

Second Fraud Alert to Physicians



DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
 WASHINGTON, DC 20201



**Fraud Alert: Physician Compensation Arrangements
 May Result in Significant Liability**

June 9, 2015

OIG alerted physicians that compensation arrangements may violate the Anti-Kickback Statute if even one purpose of the arrangement is to compensate a physician for his or her past or future referrals of Federal health care program business.

35

Office of Investigations Referral— *Dr. Raia and Jennan*



Conduct: Dr. Raia failed to perform or directly supervise physical therapy services billed under his provider number while he was out of the country or the state

Result: \$1.5 million settlement and 15 year exclusion



Conduct: Jennan submitted claims under Dr. Raia's provider number for services he failed to perform or supervise

Result: \$694,887 settlement and divestiture of physical therapy practice

36

Office of Investigations Referral *Heritage Medical Partners*

Conduct: Heritage sent a letter to its 5,474 Medicare patients requesting payment of an annual \$50 administrative fee, which was in violation of the physicians' assignment agreements with Medicare



Result: \$170,000 settlement, which included a penalty and a partial refund of the administrative fees to patients

37

Office of Investigations Referral *Harper's Hospice*

Conduct: Harper's Hospice paid a medical directorship fee to a physician in exchange for the physician referring patients to Harper's Hospice for hospice services and pre-signing blank prescription forms for patients

Result: \$150,000 settlement



38

Office of Audit Services Referral *CVS Pharmacy*

Conduct: CVS knowingly filed duplicate claims for immunosuppressant drugs both to Medicare Part B and to Medicare Part D plan sponsors for the same beneficiary on the same date of service

Result: \$1.2 million settlement



Office of Audit Services Referrals *Urine Drug Testing Initiative*

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

Results:

- Nine settlements totaling more than \$13 million
- Gainesville Pain Management & Dr. Britton- \$1.58 million settlement and five year CIA
- Medicus- \$5 million settlement and five year CIA



40

Office of Evaluation and Inspections Referral – *Hyundai Drugs*

Conduct: Pharmacy billed Part D for drugs they did not have in stock

Result: \$1.34 million settlement for billing for drugs not dispensed



41

Office of Evaluation and Inspections Referral – *Sandoz*

Conduct: Sandoz failed to submit accurate drug pricing information to CMS, which uses the information to determine payment amounts for drugs reimbursed by Medicaid

Result: \$12.64 million settlement



42

Enforcement of CIA

OIG excluded Church Street Health Management, LLC for material breaches of its CIA, including:

- Failure to report quality-of-care reportable events to OIG and State dental boards
- Failure to make corrective actions
- Failure to implement and maintain quality-related policies and procedures
- Submission of a false certification from its Compliance Officer regarding its compliance with CIA obligations



43

CIA Monitor Referral


Robert E. Hackley, DDS

Conduct: Small Smiles dentist performed medically unnecessary dental procedures, failed to treat existing dental conditions, and performed dental procedures that were below professionally recognized standards of care

Result: 3 year exclusion



44




New OIG Regulations

- Proposed Revisions to OIG's CMP Rules (May 12, 2014)
- New Authorities
 - Failure to grant timely access to OIG
 - Ordering or prescribing while excluded
 - Making false statements, omissions, misrepresentations in an enrollment application
 - Failure to return an overpayment
 - Making or using a false record or statement that is material to a false or fraudulent claim
 - Medicare Advantage and Part D plan sponsor misconduct

45


OIG Compliance Resources

<http://oig.hhs.gov/compliance/>

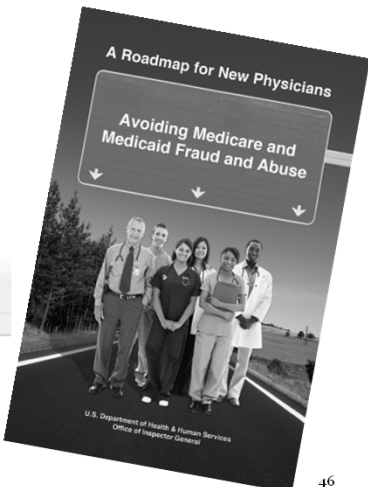


Special Fraud Alert

RENTAL OF SPACE IN PHYSICIAN OFFICES BY PERSONS OR ENTITIES TO WHICH PHYSICIANS REFER



HHS-OIG Compliance Training
oig.hhs.gov



A Roadmap for New Physicians
Avoiding Medicare and Medicaid Fraud and Abuse

U.S. Department of Health & Human Services
Office of Inspector General

46

QUESTIONS?

