

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

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## 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

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## Overview

- 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



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## 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

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## 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

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## 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

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## 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

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## 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/>

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## 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

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## CMS Revocation Rules

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## 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

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## 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

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## 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

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## 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

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## 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.

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## 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

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## 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.

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## 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

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## 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

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## 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

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## OIG's Civil Monetary Penalties Law

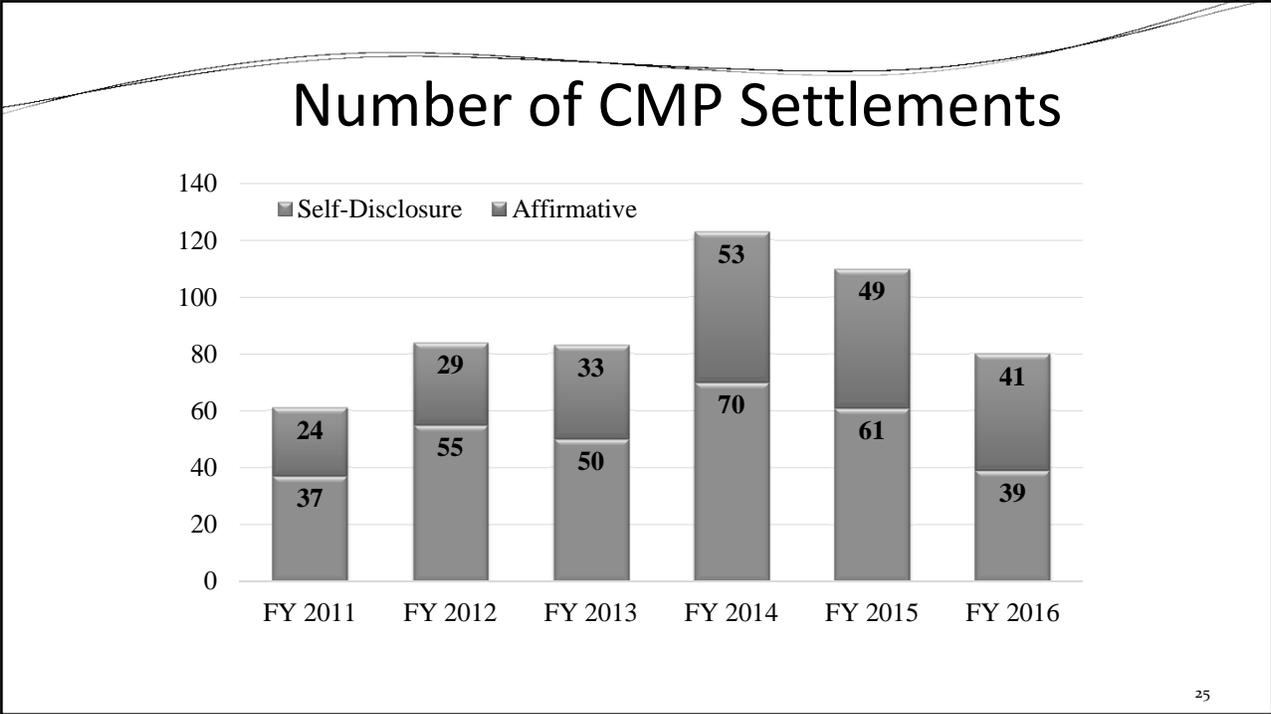
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## What is the Civil Monetary Penalties Law?

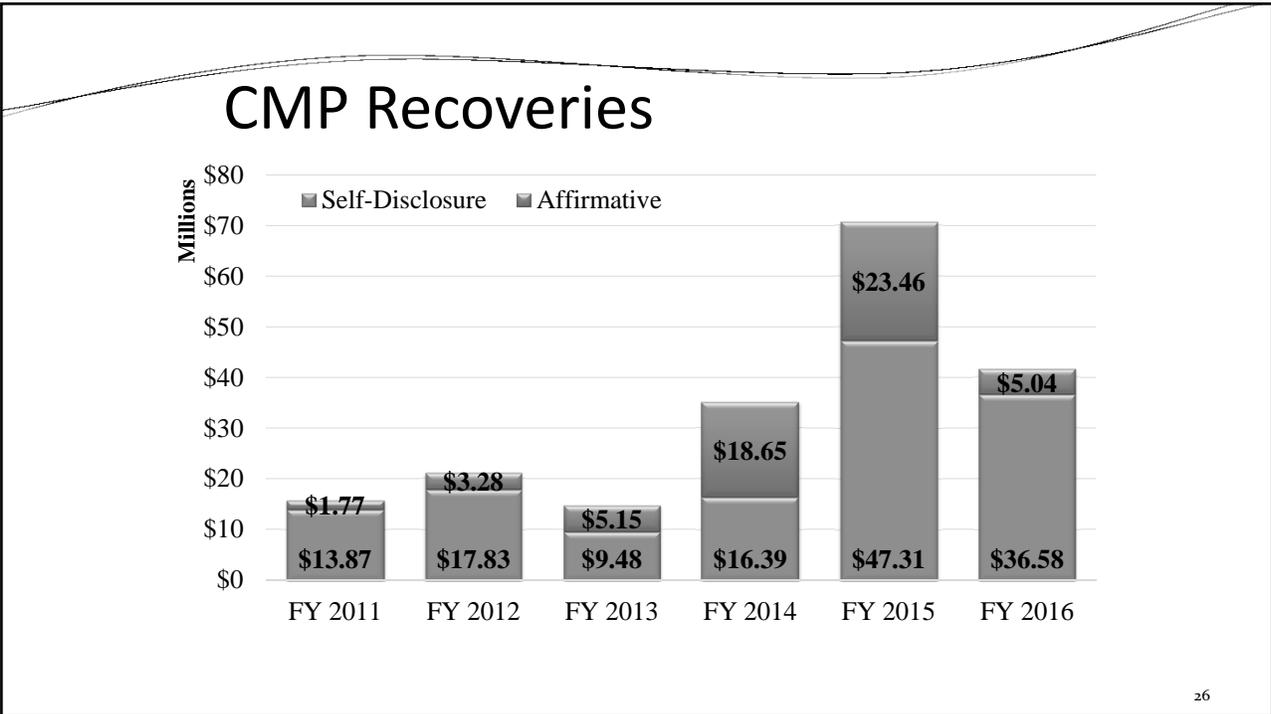
- Administrative fraud remedy
  - Affirmative cases initiated by ACRB
  - Can recover money damages + penalties + exclusion
- Alternative or companion case to a civil action
  - Physicians, owners, or executives
- Burden of Proof
  - Preponderance of the evidence (same as civil)
- Statute of Limitation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



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## 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
- Good evidence of fraud, but U.S. Attorney's Office declined

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## 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

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## 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

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## 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.

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## Civil FCA Spin-Off Cases

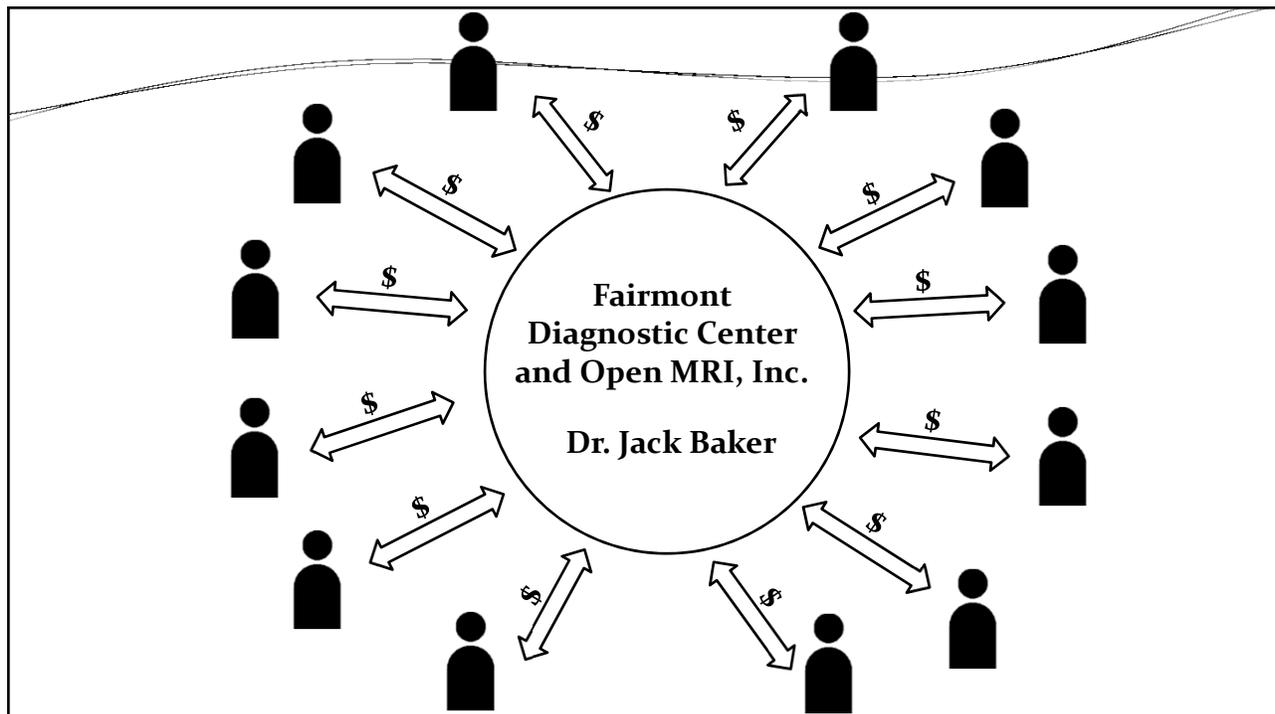
*Jack Baker Fairmont Diagnostic Center  
and Open MRI, Inc.*

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



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## 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.

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## 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

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## 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

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## 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



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## 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



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## 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:

- Ten settlements totaling more than \$8.9 million
- Gainesville Pain Management & Dr. Britton- \$1.58 million settlement and five year CIA
- Medicus- \$5 million settlement and five year CIA



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## 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



## 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



## 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



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## Data Mining - *Ambulance Referrals*

Conduct: Emergency ambulance transportations to inappropriate destinations such as skilled nursing facilities or residences.

Result: Nine settlements for over \$1.1 million



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## Exclusions

- Nemerofsky
- Synthes executives
- Malik
- Hackley

## OIG Compliance Resources

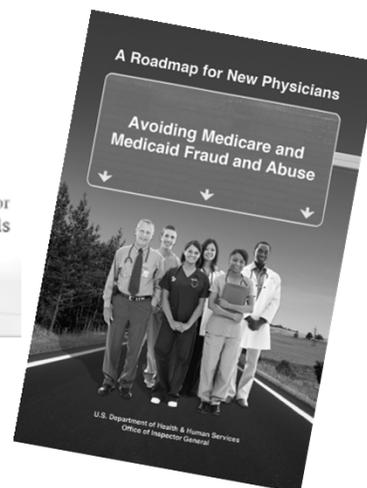
<http://oig.hhs.gov/compliance/>



### Special Fraud Alert

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

### GUIDANCE for Health Care Boards



# QUESTIONS?

