

Federal Administrative Sanctions: Exclusion and Civil Monetary Penalties

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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



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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;
 - Entities controlled by a sanctioned individual.
- Term of exclusion varies based on grounds for permissive exclusion
 - Adjustments to term based on aggravating and mitigating factors

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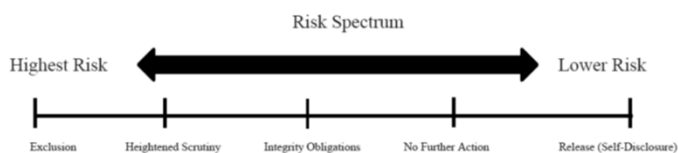
Affirmative Permissive Exclusions

- Fraud/Kickbacks – §1128(b)(7)
- Failure to meet professionally recognized standards of care – §1128(b)(6)(B)
- Failure to provide medically necessary services meeting professionally recognized standards of care - § 1156
- Knowing false statements or misrepresentations on enrollment applications – §1128(b)(16)
- Failure to grant immediate access - § 1128(b)(12)

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1128(b)(7) Criteria – Exercise of OIG Discretion

- 62 Fed. Reg. 67392 (Dec. 24, 1997), superseded and replaced by new policy published April 18, 2016:
<https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf>



- 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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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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Waiver of Exclusion

- OIG has the authority to waive an individual’s or entity’s exclusion as a provider from Federal health care programs
- A waiver may be requested only by **the administrator of a Federal or State health program**
- 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
- Excluded individuals or entities may not request a waiver from the OIG

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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

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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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CMS Revocation Rules

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Topics for Discussion

- Medicare Enrollment: Requirement to Maintain Accurate and Complete Data
- Mechanisms for Verifying Compliance with Enrollment Rules
- Increasing CMS Scrutiny – Medicare Sanctions
- Revocation Case Law Trends
- What can you do to prevent such actions?

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Medicare Enrollment

- Increasing efforts to combat fraud, waste and abuse through the enrollment rules and CMS sanctions
- Enrollment application is considered essential part of the agency's ongoing effort to combat fraud and abuse
- False or misleading information, or a simple omission, can lead to deactivation or revocation of Medicare billing privileges

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Complete and Accurate Data Required

- 42 C.F.R. § 424.510(d) requires all providers and suppliers to:
 - (1) Submit a complete enrollment application and supporting documentation which
 - (2)(i) includes complete, accurate, and truthful responses to all information requested.
 - (3) The certification statement found on the enrollment application must be signed by an individual who has the authority to bind the provider or supplier. The signature attests that the information is accurate.

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Medicare Enrollment – Updating Data

42 C.F.R. § 424.516(e) requires reporting of:

- Changes in Ownership or Control, or changes in authorized official(s) or delegated official(s) to be reported no later than 30 days after the effective date
- Any revocation or suspension of a federal or state license must be reported by no later than 30 days after the effective date.
- All other changes to enrollment within 90 days

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Medicare Enrollment – Updating Data

- 42 C.F.R. § 424.502 Final Adverse Action 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 reenrollment; or
 - An exclusion or debarment from participation in a Federal or State health care program.

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Medicare Enrollment – Updating Data

- 42 C.F.R. § 424.530(a)(3) Final Adverse Action includes certain federal or state felony convictions:
 - 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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Consequences for Non-Compliance

- When licensure or database issues are identified:
 - If attempting to enroll, under 42 C.F.R. § 424.530(a)(1) CMS may deny the enrollment if provider or supplier is determined to not be in compliance with the enrollment requirements in this subpart P or in the enrollment application.
 - If already enrolled, under 42 C.F.R. § 424.535(a)(1) CMS may revoke a currently enrolled provider's or supplier's Medicare billing privileges and any corresponding provider or supplier agreement.

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Sanctions for Failing to Comply

- Deactivation -- temporary suspension of billing privileges without termination of the provider or supplier agreement. 42 C.F.R. § 424.540
- Revocation -- automatic termination of the provider or supplier agreement. 42 C.F.R. § 424.535
 - Generally, effective 30 days following notice unless based on final adverse action or non-operational location, then effective as of the date of the adverse action or finding location to be non-operational.
 - Reportable event to Medicaid and other federal payers (mandated cross-termination), and other third party payers.

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CMS Sanctions -- Billing Privilege Revocation

Bar to Re-Enrollment

- Bar itself is not discretionary.
- Generally, length of bar is discretionary and is to be based on severity of the basis for revocation.
- Exceptions:
 - Failure to report final adverse action: 1-year bar 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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CMS Sanctions -- Billing Privilege Revocation

- Bases for Revocation – 42 C.F.R. § 424.535
 - (1) Not in compliance with the enrollment regulations or the applicable enrollment application requirements;
 - (2) Provider, any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel is excluded, debarred or otherwise not eligible to participate in federal health care programs;
 - (3) 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;

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CMS Sanctions -- Billing Privilege Revocation

- Bases for Revocation – 42 C.F.R. § 424.535:
 - (4) False or misleading information on the enrollment application
 - (5) Based on an on-site review or other reliable evidence, CMS determines that the provider is no longer “Operational” or otherwise fails to satisfy any Medicare enrollment requirement.
 - (6) Failure to pay the application fee or obtain an approved hardship exception to pay the fee.
 - (7) Misuse of billing number: The provider or supplier knowingly sells to or allows another individual or entity to use its billing number.

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CMS Sanctions -- Billing Privilege Revocation

- Bases for Revocation – 42 C.F.R. § 424.535:
 - (8) Abuse of billing privileges which includes either of the following:
 - Submission of claim for services that could not have been furnished to a specific individual on the date of service, such as when the beneficiary is deceased, a supervising physician or beneficiary is not in the state or the equipment necessary for testing is not present.
 - CMS determines that the provider has a “pattern or practice” of submitting claims that do not comply with Medicare’s claims completion rules.

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CMS Sanctions – Billing Privilege Revocation

- *Pattern or Practice* 42 C.F.R. § 424.535(a)(8)(ii)
 - Provides a basis when “CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements.
 - Factors that CMS is to consider include:
 - Percent of submitted claims that were denied,
 - Reason(s) for the claim denials,
 - History of a final adverse action and, if so, the nature of any such action,
 - Length of time over which the pattern occurred, and
 - How long the provider or supplier was enrolled.
 - However, when finalizing the rule, CMS commented that as little as 3 claims could be pattern or practice.

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CMS Sanctions -- Billing Privilege Revocation

- Bases for Revocation – 42 C.F.R. § 424.535:
 - (9) For physicians, non-physician practitioners and their organizations, failure to report change of ownership or control, or revocation or suspension of Federal or State license within 30 days; All other changes to enrollment data within 90 days;
 - (10) Failure to document or provide CMS access to documentation;
 - (11) For home health agencies, if HHA cannot provide supporting documentation verifying that the HHA meets the initial reserve operating funds requirement within 30 days of request; and
 - (12) Mandated cross-termination if terminated or revoked by a state Medicaid agency.

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CMS Sanctions – Billing Privilege Revocation

- 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 the 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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Increased Scrutiny: GAO & OIG Reports

- GAO Report, MEDICARE Program: Additional Actions Needed to Improve Eligibility Verification of Providers and Suppliers,” GAO-15-448 (June 2015)
- OIG Report, Enhanced Enrollment Screening of Medicare Providers: Early Implementation Results (April 2016)

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Revocation – No Longer Operational

- *AR Testing Corp. v. CMS*, HHS DAB, Docket No. A-15-69 (Mar. 10, 2016)
 - CMS MAC performed unannounced inspection of IDTF practice location identified in Medicare enrollment application. Unable to locate supplier in facility or signage.
 - Surveyor left message for owner; owner returned message that day and stated moved location.
 - MAC revoked billing privileges and terminated provider agreement on ground that IDTF was “no longer operational.”

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Revocation – No Longer Operational

- *AR Testing Corp. v. CMS* (cont'd)
 - Petitioner unsuccessfully argued it was operational because its mobile-unit and off-site locations were in compliance.
 - CMS guidance states IDTF performance standards, including accessibility requirement, apply to home location (e.g., maintenance of patient records, primary business phone). Petitioner's home location was not staffed and open to beneficiaries, and signage at location provided no clear guidance as to how services could be accessed.
 - ALJ upheld revocation

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Revocation - Adverse Final Action

- *Brown and Obeng v. CMS, HHS DAB*, Docket Nos. C-10-443 and C-10-481 (Jun. 9, 2010).
 - DC DOH summarily suspended Petitioners' licenses to practice medicine effective 4/17/09.
 - Petitioners entered into settlement agreements and license suspensions were lifted effective 5/6/09.
 - MAC revoked billing privileges with a one-year bar to reenrollment under 42 C.F.R. § 424.535(a)(9).

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Revocation - Adverse Final Action

- *Brown and Obeng v. CMS* (Cont.)
 - Petitioners unsuccessfully argued that suspension did not need to be reported since the licenses were reinstated within the 30-day reporting period.
 - Petitioners incorrectly interpreted the regulation as requiring reporting within 30 days, only if the adverse event continues, or will continue, beyond 30 days.

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Revocation – Failed Site Visit

- *Healthy Point Medical Care, PC v. CMS*, HHS DAB, Docket No. C-15-1614 (Sept. 29, 2015).
 - 9/23/14 site verification visit to practice location -- no longer operational.
 - Revocation under 42 C.F.R. § 424.516(d)(1)(iii) for failure to report a change in practice location within 30 days, with required two-year reenrollment bar for failed site visit.
 - Practice submitted a Corrective Action Plan enclosing CMS 855B to delete practice location effective 7/1/14 and affidavit from office manager accepting responsibility for reporting failure.
 - CMS prevailed on summary judgment motion.

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Revocation – Ordering and Referring

- *George M. Young, M.D. v. CMS*, HHS DAB, Docket No. C-15-3553 (Mar. 1, 2016).
 - 1/6/15 letter requesting medical records (orders, progress notes, patient information sheets) for 14 Medicare beneficiaries for whom ordered DME.
 - Physician unable to produce records since facility where he was employed, which had possession of the records, could not locate records.
 - Revocation under 42 C.F.R. § 424.535(a)(10), with one-year reenrollment bar, for failure to provide access to documentation.
 - Revocation upheld.

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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
- Burden of Proof: preponderance of the evidence (same as civil)
- Statute of Limitations: 6 years (same as civil)
- 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

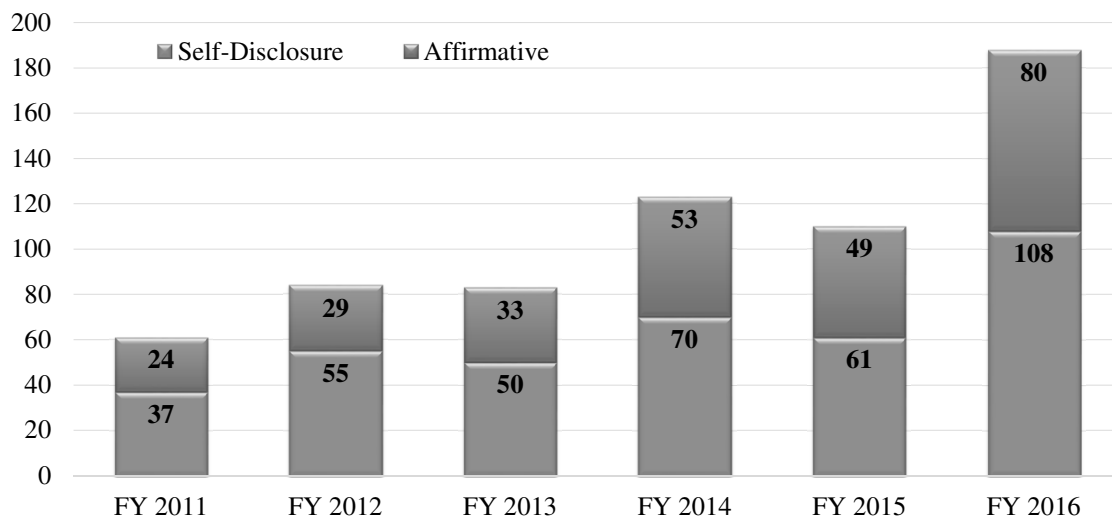
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How does the CMPL fit in the government's enforcement toolbox?

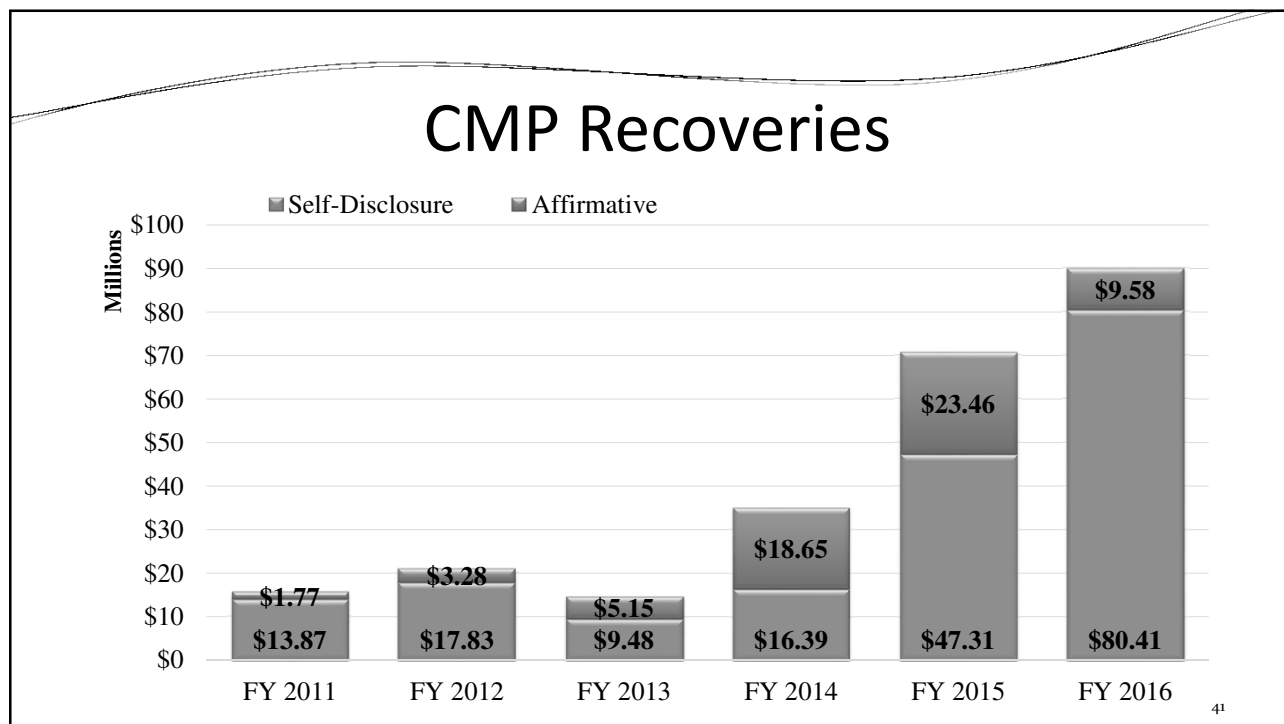
- Specialized areas of enforcement
 - Beneficiary inducement
 - Billing, ordering, prescribing while excluded
 - Knowing retention of an overpayment
 - Failure to properly report required drug pricing information
- Opportunity to complement criminal or civil cases
- Cases where exclusion is important remedy

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Number of CMP Settlements



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Fraud by Excluded Individuals

Roben Brookhim

- **Conduct:** Brookhim, an unlicensed dentist, was excluded in 2000; he subsequently owned and controlled a NJ dental practice using the identity of a licensed dentist to submit claims (even after the licensed dentist died).
- **Result:** \$1.1 million CMPL and 50-year exclusion



Kickback Cases

Orange Community MRI

- Criminal spin-off
- Conduct: Referring physicians received cash kickbacks for referrals; amount of remuneration per referral was based on the procedure ordered
- Result: Settlements with Dr. Sharif for \$52,280; Dr. Shah for \$104,950; Dr. Collin for \$111,415



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Kickback Cases

OneStep Diagnostic, Inc.

- Civil FCA spin-off
- Conduct: Physicians received remuneration from OneStep Diagnostic, Inc. in the form of Medical Directorship agreements.
- Result: Settlements with 8 physicians for a total of \$735k



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Kickback Cases

Jack Baker Fairmont Diagnostic Center and Open MRI, Inc.

- Civil FCA spin-off
- 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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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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Services Not Rendered or Supervised

Dr. Labib Riachi



- Conduct: Dr. Riachi failed to personally perform or supervise pelvic floor therapy services, physical therapy services, and other services provided by unqualified and unlicensed individuals.
- Result: 20 year exclusion (previous \$5.25m FCA settlement)

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Services Not Rendered or Supervised

Mississippi PT Doctors

- Criminal spin-off
- 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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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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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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Data Mining - *Ambulance Cases*

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

Result: Over \$3.4 million under the CMPL.



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Data Mining – *Molecular Pathology Procedures*

Conduct: Billing for physician interpretation and report on molecular pathology procedure where no consultation request had been made, no written report had been written, or exercise of medical judgment by a consulting physician was not required.

Result: Over \$650k under the CMPL.



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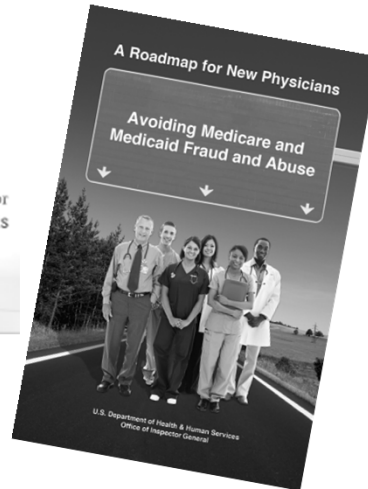
OIG Compliance Resources <http://oig.hhs.gov/compliance/>



Special Fraud Alert

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

GUIDANCE for Health Care Boards



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QUESTIONS?



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