Federal Administrative Sanctions Healthcare Enforcement Compliance Conference

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Sponsored by the Health Care Compliance Association

Kristin Carter
Shareholder
Co-Chair Fraud and Abuse Subgroup
Baker, Donelson, Bearman, Caldwell &
Berkowitz, PC

Michael Torrisi Senior Counsel Office of HHS Inspector General

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Road Map

- OIG's Exclusion and Civil Monetary Penalty Authorities
- OIG Administrative Investigations
- Recent OIG Enforcement Actions
- CMS Administrative Sanctions
- Recent CMS Enforcement Actions

Criminal, Civil, and Administrative Enforcement

Criminal

Prosecutions

- Judge/Jury
- Guilt "beyond a reasonable doubt"

Civil

Lawsuits

- e.g. Federal
 False Claims
 Act
- Judge/Jury
- "Preponderance of Evidence"

Administrative

Administrative Actions

- Administrative Law Judge
- "Preponderance of Evidence"

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HHS-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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Goals of OIG-Initiated Litigation

- Use exclusion to protect Federal health care programs and beneficiaries
- Complement the work of other OIG components and government partners
- · Change industry behavior
- · Hold individuals accountable
- Amplify OIG priorities and support OIG guidance

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What is Exclusion?

- · Remedial measure designed to protect Federal health care programs
- No Federal health care program <u>payment</u> 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 prohibits participation in Federal health care programs
 - Includes Medicare, Medicaid, CHIP, VA, TriCare, Champus, Indian Health Services
- Exclusion applies to direct providers (e.g., doctors, nurses, hospitals) and indirect providers (e.g., drug manufacturers, device manufacturers)

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What is Exclusion?

- · Individual or entity remains excluded until affirmatively reinstated.
- Exclusion violations may lead to criminal prosecutions, civil actions, and civil monetary penalties (CMP).
- Civil Monetary Penalties Law (CMPL) liability for employing or contracting with an excluded person.
- OIG recommends monthly screening against List of Excluded Individuals and Entities (LEIE).
- OIG's Special Advisory Bulletin on the Effect of Exclusion for additional information: https://oig.hhs.gov/exclusions/files/sab-05092013.pdf.

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Types of Exclusions Mandatory vs. Permissive

- OIG Exclusion Statute and Regulations
 - 42 U.S.C. § 1320a-7, 42 C.F.R. § 1001.101 et seq.
- Mandatory: Section 1128(a) of the Social Security Act (SSA)
 - 4 authorities based on convictions for:
 - Medicare/Medicaid Fraud
 - Patient Abuse/Neglect
 - Felony Health Care Fraud
 - Felony Relating to Controlled Substances
 - Conviction is broadly defined in SSA Section 1128(i)
- Minimum exclusion term of 5 years
 - OIG may increase length of exclusion based on statutory and regulatory factors (aggravating and mitigating)

Types of Exclusions Mandatory vs. Permissive

- Permissive—SSA Section 1128(b)
 - 16 authorities in section 1128 (more elsewhere), 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 permissive exclusion varies based on the authority
 - Most authorities have a base period of 3 years
 - Adjustments to term based on aggravating and mitigating factors

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OIG Exclusions – Mandatory Authorities

Social Security Act	42 USC §	Amendment
1128(a)(1)	1320a-7(a)(1)	Conviction of program-related crimes. Minimum Period: 5 years
1128(a)(2)	1320a-7(a)(2)	Conviction relating to patient abuse or neglect. Minimum Period: 5 years
1128(a)(3)	1320a-7(a)(3)	Felony conviction relating to health care fraud. Minimum Period: 5 years
1128(a)(4)	1320a-7(a)(4)	Felony conviction relating to controlled substance. Minimum Period: syears
1128(c)(3)(G)(i)	1320a-7(c)(3)(G)(i)	Conviction of second mandatory exclusion offense. Minimum Period: 10 years
1128(c)(3)(G)(ii)	1320a-7(c)(3)(G)(ii)	Conviction of third or more mandatory exclusion offenses. Permanen Exclusion

Source: http://oig.hhs.gov/exclusions/authorities.asp

OIG Permissive Exclusion Authorities

Social Security Act	42 USC §	Amendment
1128(b)(1)(A)	1320a-7(b)(1)(A)	Misdemeanor conviction relating to health care fraud. Baseline Period: 3 years
1128(b)(1)(B)	1320a-7(b)(1)(B)	Conviction relating to fraud in non-health care programs. Baseline Period: 3 years
1128(b)(2)	1320a-7(b)(2)	Conviction relating to obstruction of an investigation or audit. Baseline Period: 3 years
1128(b)(3)	1320a-7(b)(3)	Misdemeanor conviction relating to controlled substance. Baseline Period: 3 years
1128(b)(4)	1320a-7(b)(4)	License revocation, suspension, or surrender. Minimum Period: Period imposed by the state licensing authority.
1128(b)(5)	1320a-7(b)(5)	Exclusion or suspension under federal or state health care program. Minimum Period: No less than the period imposed by federal or state health care program.
1128(b)(6)	1320a-7(b)(6)	Claims for excessive charges, unnecessary services or services which fail to meet professionally recognized standards of health care, or failure of an HMO to furnish medically necessary services. Minimum Period: 1 year

Source: http://oig.hhs.gov/exclusions/authorities.asp

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OIG Permissive Exclusion Authorities

Social Security Act	42 USC §	Amendment
1128(b)(7)	1320a-7(b)(7)	Fraud, kickbacks, and other prohibited activities. Minimum Period: None
1128(b)(8)	1320a-7(b)(8)	Entities controlled by a sanctioned individual. Minimum Period: Same as length of individual's exclusion.
1128(b)(8)(A)	1320a-7(b)(8)(A)	Entities controlled by a family or household member of an excluded individual and where there has been a transfer of ownership/control. Minimum Period: Same as length of individual's exclusion.
1128(b)(9), (10), and (11)	1320a-7(b)(9), (10), and (11)	Failure to disclose required information, supply requested information on subcontractors and suppliers; or supply payment information. Minimum Period: None
1128(b)(12)	1320a-7(b)(12)	Failure to grant immediate access. Minimum Period: None
1128(b)(13)	1320a-7(b)(13)	Failure to take corrective action. Minimum Period: None
1128(b)(14)	1320a-7(b)(14)	Default on health education loan or scholarship obligations. Minimum Period: Until default or obligation has been resolved.
1128(b)(15)	1320a-7(b)(15)	Individuals controlling a sanctioned entity. Minimum Period: Same as length of entity's exclusion.
1128(b)(16)	1320a-7(b)(16)	Making false statement or misrepresentations of material fact. Minimum period: None.
1156	1320c-5	Failure to meet statutory obligations of practitioners and providers to provide medically necessary services meeting professionally recognized standards of health care (Quality Improvement Organization (QIQ) findings). Minimum Period: 1 year

Source: http://oig.hhs.gov/exclusions/authorities.asp

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OIG's Revised Criteria for 1128(b)(7) Exclusions

- Fraud, kickbacks, and other prohibited activities
- 62 Fed. Reg. 67392 (Dec. 24, 1997), superseded and replaced by new Criteria for Implementing Section 1128(b)(7) Exclusion Authority, published on April 18, 2016: https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf
- · Updated criteria for:
 - evaluating risk to Federal health care programs
 - assessing whether to impose exclusion under section 1128(b)(7)
- · Begins with the presumption that exclusion should be imposed

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Provides a compliance "risk spectrum" from high to low risk based on: - (1) nature and circumstances of conduct; - (2) conduct during investigation; - (3) significant ameliorative efforts; and - (4) history of compliance. Exclusion Heightened Scrutiny Integrity Obligations No Further Action Release (Self-Disclosures)

Civil Monetary Penalties Law (CMPL)

- · Administrative fraud remedy
 - 42 U.S.C. § 1320a-7a, 42 C.F.R. § 1003 et seq.
 - Penalties updated annually for inflation, 45 CFR Part 102
- Affirmative case initiated by OIG
 - Alternative or companion case to a criminal or a civil health care fraud action
- Over 40 CMP authorities provide grounds for enforcement actions, including:
 - false or fraudulent claims
 - kickbacks and beneficiary inducement
 - employing 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
 - grant and contract fraud

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CMPL

- Remedies:
 - Penalties up to \$10,000 (subject to inflation adjustment) for each item or service or \$50,000 (subject to inflation adjustment) for each act of a kickback
 - Assessments of up to 3 times the amount improperly claimed (or for a kickback, up to 3 times the total amount of remuneration)
 - Exclusion from Federal health care programs
- Burden of proof: Preponderance of the evidence
- · Statute of limitations: 6 years
- Intent: generally "knows or should know"
 - Actual knowledge
 - Deliberate ignorance or reckless disregard

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Appeals of CMPs and Exclusions 42 C.F.R. Part 1005

- Appeal from OIG's Demand Letter, demanding CMP, assessment, and/or exclusion
- Hearing is before the HHS Departmental Appeals Board ALJ
- ALJ reviews for whether OIG had a legal basis for its actions and reasonableness of amount of CMP, assessment, and/or length of exclusion
- · Burden of proof: Preponderance of the evidence
- · Hearsay is admissible: FRE serve as a guideline

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Recent Developments – Grant and Contract CMP

21st Century Cures Act (Dec. 2016) expanded CMPL authority to include improper conduct involving HHS grants, contracts and other agreements. Among other things:

- · Presenting false claims
- Making false statements or omissions
- Making or using false records
- · Failing to grant access to OIG

42 U.S.C. §§ 1320a-7a(o)-(s)

Recent Developments – Grant and Contract CMP Recent Developments – Grant and Contract Fraud CMPL Authority

Penalties: between \$10,000 and \$50,000 per act

<u>Assessments</u>: recovery of up to 3 times the total amount of funds involved

Exclusion: bar from participation in all Federal health care programs

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OIG Administrative Investigations

- When do they start?
 - OCIG Only
 - Parallel Investigations with other Authorities
 - Criminal and Civil
- What are the OIG's Administrative Investigative Tools?
 - Document Subpoenas
 - Investigational Inquiries (Testimonial Subpoena)
 - Data Analytics

Data Analytics in CMP Cases

- · What is Data Analytics?
 - Process of analyzing large quantities of data and extracting previously unknown information to identify aberrant billing trends
- · It is a tool that:
 - identifies billing abnormalities;
 - identifies patterns and trends of abuse:
 - identifies cost-saving areas; and
 - allows for assessment of quality of care
- 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

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OIG CIA Enforcement Actions

- OIG integrity agreements provide for stipulated penalties and exclusion for breach and material breach.
- Multiple grounds:
 - Failure to timely submit Annual or Implementation report
 - Failure to provide training, screen employees, post OIG hotline number
 - Failure to repay IRO-identified overpayment
 - Failure to comply with Focus Arrangements Requirements
 - Failure to timely retain an Independent Quality Monitor
 - Failure to distribute new/revised policies and procedures
 - IRO Retention
 - Failure to designate compliance contact

Recent Affirmative Exclusion Actions

First Initiative, Shameika Amin, and Tymekka Greenough: Behavioral health company and owner excluded for 50 years for billing Nevada Medicaid for services not rendered as claimed. The in-house biller of the company, Greenough, was excluded for 25 years.

Anthony Vertino: Psychologist excluded for 20 years for billing for psychological services purportedly provided in his office or at a SNF when the patients were in fact hospitalized or when he was traveling out of state.

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Recent Affirmative Exclusion Actions

<u>Cindy Scott</u>: APRN excluded for 10 years for prescribing controlled substances that were medically unnecessary, substantially in excess of the needs of her patients, and below professionally recognized standards of care.

<u>Stephen Latman</u>: Physician excluded for 10 years for issuing prescriptions for opioids to patients that were substantially in excess of the needs of those patients.

Recent CMPL Actions

- Duplex ultrasound cases (3 settlements, \$1.9 million CMPs)
- Pelvic floor therapy cases (7 settlements, \$3 million CMPs, and 3 exclusions)
- Ambulance cases (23 settlements, \$4.4 million CMPs)

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Recent CMPL Actions

- Urine drug specimen cup cases (9 CMPL settlements and 1 FCA settlement, \$1.05 million)
- Specimen validity testing cases (3 settlements, \$430K CMPs)
- Grant fraud (3 NIH grantees and 3 HRSA grantees, \$486K CMPs)

CIA Enforcement Actions

- OIG integrity agreements provide for stipulated penalties and exclusion for breach and material breach.
- Multiple grounds, including:
 - Failure to timely submit Annual or Implementation report
 - Failure to provide training, screen employees, post OIG hotline number
 - Failure to repay IRO-identified overpayment
 - Failure to timely retain an Independent Quality Monitor
 - Failure to distribute new/revised policies and procedures

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Recent CIA Enforcement Actions

- · Exclusions for material breach of CIA
 - Tri-County Ambulance: 5-year exclusion
 - La Fuente Ocular Prosthetics: 5-year exclusion
- Stipulated Penalties
 - eClinical Works: \$132,500

Recent Excluded Persons Enforcement Actions

Liability under CMPL for employing excluded individual

Recent Examples:

- Texas SNF employed excluded vocational nurse (\$113K CMP)
- Oklahoma assisted living facility employed excluded admission specialist (\$96K CMP)
- Tennessee SNF employed excluded registered nurse (\$81K CMP)

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CMS Program Integrity Initiatives

- Move away from "pay and chase" to stopping payment before the money goes out.
- Tools:
 - Greater emphasis of safeguards in provider and supplier enrollment
 - Use of Enrollment/Revocation authorities to remove fraudulent providers from Medicare programs
 - Proactively identify "potentially fraudulent" billing through predictive modeling and other means
 - Healthcare Fraud Prevention Partnership (partnering with states and private sector)

CMS Program Integrity Functions

Pre- and Post-Payment medical review

Overpayment collections

Enrolls/Screens new providers

Supports OIG and DOJ in FCA, enforcement and criminal prosecutions

Coordinates investigative efforts with law enforcement Oversees CMS contractors (UPICs, MACs, RACs, MEDIC, ZPICs, MICs)

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CMS Program Integrity: By the Numbers

- CMS estimates Program Integrity activities saved Medicare approximately \$15.5 Billion in FY 2017
 - Return on investment \$10.8 to \$1

Activities to Prevent Improper Payments (\$13.2 Billion)

Automated Actions (\$4.0 B)

Prepayment Actions (\$8.3 B)

Provider Enrollment Revocations/Deactivations (\$701.1M)

Other Actions (e.g. payment suspensions) (\$262.8M)

Recovered Savings
(\$2.2 Billion)

Overpayments (\$1.6B)

Cost Report Payment Accuracy (\$499.5M)

Plan Penalties (\$27.4M)

Other Actions (28.3M)

Law Enforcement Referrals \$79.5M)

Source: Medicare & Medicaid Integrity Programs, FY 2017 Annual Report (10/1/2016-9/30/2017)

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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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Mechanisms to Verify Compliance

Screening based on Risk Category: 42 C.F.R. § 424.518

- CMS established three categories of providers and suppliers based on perceived risk (<u>limited, moderate, or high</u>) of fraud.
- More rigorous screening procedures as the perceived risk increases.
- All moderate risk providers must undergo site visit when newly enrolling, adding or changing practice location, undergoing a CHOW resulting in a new Tax ID, reactivating or revalidating

Enrollment Actions

- <u>Denial</u> denial of enrollment application if determined to not be in compliance with the enrollment requirements in 42 CFR 424, Part P or in the enrollment application.
- <u>Deactivation</u> temporary suspension of billing privileges without termination of the provider or supplier agreement. 42 C.F.R. § 424.540
- <u>Revocation</u> -- termination of the provider or supplier agreement. 42 C.F.R. § 424.535
 - Reportable event to Medicaid and other federal payers (mandated cross-termination), and other third party payers.

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Revocations

Bar to Re-Enrollment

- Bar itself is not discretionary.
- With some exceptions, length of bar is discretionary and is to be based on severity of the basis for revocation.
- Must reapply as a new provider/supplier

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Bases for Revocation

- · Currently 14 possible reasons
- New Rule Effective November 4th (tomorrow), 5 additional reasons

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Bases for Revocation (42 C.F.R. § 424.535)

- (1) **Non-compliance with enrollment regulations** or 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
- (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.

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Bases for Revocation (42 C.F.R. § 424.535)

- (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.
- (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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Bases for Revocation (42 C.F.R. § 424.535)

- (9) **Failure to report** certain adverse legal actions and changes in practice location by deadlines required under regulations
- (10) Failure to document or provide CMS access to documentation in certain circumstances
- (11) HHAs that don't meet initial reserve operating funds requirements
- (12) Medicaid billing privileges are terminated or revoked.
- (13) DEA or state prescribing privileges revoked or suspended for physicians and other eligible professionals
- (14) Improper Part D prescribing practices

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CMS Sanctions – Billing Privilege Revocation

- The letter revoking billing privileges must contain:
 - A legal basis of each reason for the 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 requirements were not satisfied;
 - The effective date of the revocation;
 - Procedures for submitted a Corrective Action Plan (CAP); and
 - Complete and accurate information about further appeal rights

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New Program Integrity Rule

CMS Announces New Enforcement Authorities to Reduce Criminal Behavior in Medicare, Medicaid, and CHIP

Sep 05, 2019 | Compliance, Fraud, waste, & abuse, Legislation

"For too many years, we have played an expensive and inefficient game of 'whack-a-mole' with criminals – going after them one at a time -- as they steal from our programs. These fraudsters temporarily disappear into complex, hard-to-track webs of criminal entities, and then re-emerge under different corporate names. These criminals engage in the same behaviors again and again," said CMS Administrator Seema Verma. "Now, for the first time, we have tools to stop criminals before they can steal from taxpayers. This is CMS hardening the target for criminals and locking the door to the vault. If you're a bad actor you can never get into the program, and you can't steal from it."

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New Program Integrity Rule

- Effective Tomorrow Nov. 4, 2019
- 84 Fed. Reg. 47,794 (Sept. 10, 2019)
- Updates/changes:
 - Disclosure of "Affiliations"
 - 5 new authorities for revocation/denial of enrollment
 - Extension of re-enrollment bar

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New PI Rule: Disclosure of Affiliations

General regulatory requirement:

"Upon a CMS request, an initially enrolling or revalidating provider or supplier must disclose any and all affiliations that it or any of its owning or managing employees or organizations (consistent with the terms "owner" and "managing employee" as defined in § 424.502) has or, within the previous 5 years, had with a currently or formerly enrolled Medicare, Medicaid, or CHIP provider or supplier that has a disclosable event (as defined in § 424.502). CMS will request such disclosures when it has determined that the initially enrolling or revalidating provider or supplier may have at least one such affiliation."

84 Fed. Reg. at 47,853 (to be codified at 42 C.F.R. § 424.519(b)

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New PI Rule: Disclosure of Affiliations

What is a "Disclosable Event"?

Provider/supplier <u>must disclose any "current or previous direct or indirect affiliation"</u> with a provider or supplier that

Has *Current* uncollected debt to Medicare, Medicaid, or CHIP (regardless of the amount or status of appeal or repayment terms)

Has been or is subject to a payment suspension under a federal health care program;

Has been or is excluded by the OIG from Medicare, Medicaid, or CHIP (including decisions under appeal)

Has had its Medicare, Medicaid or CHIP billing privileges denied or revoked (including decisions under appeal)*

*No look-back period established

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New PI Rule: Disclosure of Affiliations

· What is the definition of an "Affiliation"?

5% or greater direct or indirect ownership interest that an individual or entity has in another organization

General or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization

Managing control: conducting day-to-day operation of another organization under either contract or other arrangement, regardless of whether individual or entity is a W-2 employee

An interest in which an individual is acting as an officer or director of a corporation

Any reassignment relationship under § 424.80

*Five-Year Look-Back Period from the date on which the application is submitted

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New PI Rule: Disclosure of Affiliations

What must be disclosed?

- Any and all affiliations that it or any owning or managing employees or organizations has, or within the past 5 years, had with a current or formerly enrolled Medicare, Medicaid, or CHIP provider or supplier that has a disclosable event.
 - Applies regardless of (1) affiliation has ended; or (2) whether supplier/provider was enrolled in federal health care program at time of affiliation

"Phased In" Approach

- Will not apply until CMS updates enrollment forms (CMS-855) to accommodate required disclosures
 - Notice and comment rulemaking required
- Initially will apply to newly enrolling or revalidating providers/ suppliers specifically selected by CMS
 - Based on CMS determination of potential affiliation through PECOs, and other means

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New PI Rule: Disclosure of Affiliations

- If CMS determines particular affiliation poses "undue risk of fraud, waste or abuse" can deny application or revoke Medicare enrollment
- Factors considered:
 - The duration of the affiliation
 - Whether the affiliation still exists and, if not, how long ago the affiliation ended
 - The degree and extent of the affiliation
 - If applicable, the reason for the termination of the affiliation

New PI Rule: Disclosure of Affiliations

- CMS also has authority to deny or revoke enrollment for failure to disclose affiliations
- Reasonableness" Standard
 - CMS considers if the provider "knew or should have known" of information
 - CMS acknowledges that provider/supplier may not necessarily know whether a disclosable event occurred after an affiliation ceases
 - CMS intends to issue subregulatory guidance clarifying the level of effort it expects from the provider/supplier to secure the information

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New PI Rule: Additional Authorities

New Authorities for Revocation/Denial of Enrollment

- Allow for denial or revocation of enrollment/billing privileges if CMS determines that the provider or supplier:
 - 1. Bills for services/items from noncompliant locations;
 - 2. Exhibits a pattern or practice of abusive ordering or certifying of Medicare Part A or Part B items, services or drugs;
 - "Abusive" not defined
 - 3. Has an outstanding debt to CMS from an overpayment that was referred to the U.S. Department of the Treasury;
 - 4. Is currently revoked under a different name, numerical identifier or business identity, and the applicable reenrollment bar period has not expired; or
 - Bills for services performed at, or items furnished from, a location that it knew or should reasonably have known did not comply with Medicare enrollment requirements

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New PI Rule: Additional Authorities

- Increase to Re-Enrollment Bar
 - Prior reenrollment bar 1-3 years
 - Increases max. to 10 years, with option of adding 3 years
 - Max of 20 years if being revoked for second time
 - 3-year reapplication bar if provider/supplier submitted false or misleading information on application

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CY2020 Proposed PFS Rule

- Proposed New Revocation/Denial of Enrollment Authority
- Physicians/Eligible Professionals
- Subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm.

(84 Fed. Reg. at 40723)

CY2020 Proposed PFS Rule

- In considering whether an action constitutes patient harm, CMS will consider, inter alia:
 - License restriction(s) pertaining to certain procedures or practices;
 - Required compliance appearances before State oversight board members;
 - Required participation in rehabilitation or mental/behavioral health programs;
 - Required abstinence from drugs or alcohol and random drug testing;
 - Administrative/monetary penalties;
 - Formal reprimand(s);
 - If applicable, the nature of the IRO determination(s); or
 - Any other information that CMS deems relevant to its determination.

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Revocation: Abuse of Billing Privileges

- Monique Barbour, M.D. & Clear Vue Laser Eye Center, Inc. (DAB Case Nos. 2957 & 2958 (July 2019)): Revocation of physician for "abuse of billing privileges" (42 CFR 424.535(a)(8)) where data analysis indicated that physician was out-of-country on dates of service for three claims. Revocation, and 3-year bar to reenrollment.
- Arriva Medical, LLC (DAB Case No. 2934 (Mar. 2019): Revocation
 of DME supplier for submission of claims for diabetic supplies
 provided to 211 Medicare beneficiaries who, per SSA Death Master
 File, were deceased on date of service. DME supplier claimed it
 had valid requests for refills and wasn't aware of the death due to
 limited access to database. Represented only 0.003% error rate
 during 5-year period. Revocation, and 3-year bar to re-enrollment.

Revocation: Felonies

- <u>Dr. Robert Kanowitz (DAB Dec. No. 2942 (May 2019))</u>: DAB upheld denial of physician's 2017 enrollment application based on felony conviction from 2010. OIG had previously excluded physician for 5-years and reinstated in August 2017. DAB: "revocation under section 424.535 and exclusion under section 1128 are distinct remedial tools, each with its own set of prerequisites and consequences for the provider or supplier."
- Pennsylvania Physicians, P.C. (Dec. No. CR5297 (Apr. 2019)): ALJ determination upholding revocation of medical practice due to felony that CMS determined was detrimental to program. Physician had been subject to prior revocation action in 2009 because (1) his medical license as suspended; and (2) he didn't report the final adverse legal action. Physician was allowed to re-enroll in 2010, and physician disclosed felony in application. Following revalidation in 2016, CMS determined to revoke based on 2009 conviction.

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Revocation: Not "Operational"

- Wendell Foo, M.D. v. Azar, Civ. No. 18-00490-JAO-WRP (D. Haw. 2019):
 - Plaintiff anesthesiologist provides services to patients at several ambulatory surgery centers (ASCs). Receives correspondence at UPS store with private mailbox.
 - Enrollment form instructs that a supplier must list its "practice location" where the supplier renders services to Medicare beneficiaries. ALJ found that Physician listed the UPS store as his practice location. MAC (Noridian) conducted two on-site inspections, found the locations were not operational and revoked Medicare enrollment
 - Court affirmed DAB Decision upholding revocation of Medicare enrollment and billing privileges for 2-year period.

Questions or Comments?

Kristin Carter
Shareholder
Baker, Donelson, Bearman,
Caldwell & Berkowitz, PC
(410) 862-1109
kcarter@bakerdonelson.com

Michael Torrisi Senior Counsel U.S. Dept. of HHS/OIG (202) 401-2693 michael.torrisi@oig.hhs.gov

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