


**HCCA Regional Compliance Conference
(San Francisco)**
The Enforcement Risks of Everyday Issues of Non-Compliance

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Road Map




- Administrative Enforcement Compared to DOJ cases
- OIG Exclusions and CMPs
- Provider Enrollment – Revocations as an enforcement tool
- Payment Suspensions Based on Credible Allegations of Fraud
- Data-driven Efforts, and Shared Data

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How is Administrative Enforcement Different From an Investigation?



- Quicker but still deadly for the provider/supplier.
- Equities may rest with the agency (protect the trust fund or Medicare beneficiaries), and adjudicators may be more familiar with the applicable rules and less sympathetic.
- More discretion for the agency (it's "their call" on many issues).
- Agency writes most of the rules (some of it is subregulatory).
- Rules of evidence may not apply in an administrative hearing proceeding.
- Lesser burden of persuasion for the government to "prove" its case.

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EXCLUSIONS AND CIVIL MONETARY PENALTIES

OIG AUTHORITIES

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What is Exclusion?

- 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 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 money penalties (CMP).
- CMP liability for employing or contracting with an excluded person.
- OIG recommends monthly screening against List of Excluded Individuals and Entities (LEIE).
 - CMS also recommended to State Medicaid Directors, and many States require monthly check.
- See 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 v. Permissive

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

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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: 5 years
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. Permanent Exclusion

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

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Types of Exclusions Mandatory v. Permissive

- **Permissive - § 1128(b) of the Social Security Act**
 - 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 – Permissive 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 Exclusions – Permissive (cont.)

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 (QIO) findings). Minimum Period: 1 year

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Revised Exclusion Regulations

82 Fed. Reg. 4,100 (Jan. 12, 2017)

■ Final Rules implement ACA authorities (and others)

- Expands permissive exclusion authority for convictions related to obstruction of an investigation to include audits.
- Adds permissive exclusion authority for making false statements, omissions or misrepresentations in enrollment or similar applications for participation.
- Adds permissive authority for failing to supply or allow the examination of payment information.

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Section 1128(b)(8) Exclusions

- Entities controlled by a sanctioned individual.
- **OIG may exclude the provider if certain circumstances regarding the ownership are present:**
 - Applies to any provider owned or controlled in part (5 percent or more) by an excluded person is potentially subject to exclusion.
 - Applies to any provider that has an excluded person in the role of an officer, director, agent, or managing employee (including a general manager, business manager, administrator, and director, who exercises operational or managerial control, or who directly or indirectly conducts the day-to-day operations).
 - Applies to any provider that was owned or controlled in part (5 percent or more) by an excluded person, but is no longer because of a transfer of ownership or control interest in anticipation of or following a conviction, assessment, or exclusion, to an immediate family member or a member of the household of the person.

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Section 1128(b)(15) Exclusions

- Individuals controlling a sanctioned entity.
- Applies to owner, officer, or managing employee of an entity that has been excluded or has been convicted of certain offenses if the individual with ownership or control knew or should have known of the conduct.
- Individual officer or managing employee can be excluded based solely on his or her position.
- Factors include circumstances of the misconduct and seriousness of the offense; individual's role in the sanctioned entity; individual's actions in response to the misconduct; and information about the entity.
- **Guidance:**
https://oig.hhs.gov/fraud/exclusions/files/permisive_excl_und_er_1128b15_10192010.pdf.

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OIG's Revised Criteria for 1128(b)(7) Exclusions (updated April 2016)

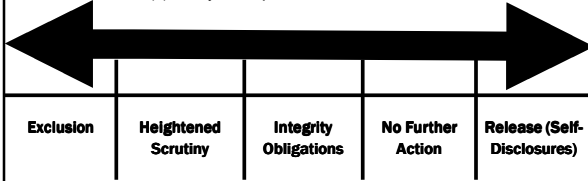
- Fraud, kickbacks, and other prohibited activities.
- 62 Fed. Reg. 67392 (Dec. 24, 1997), superseded and replaced by new Criteria for Implementing Section 1128(b)(7) Exclusion Authority, published April 18, 2016:
<https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf>.
- **OIG updated criteria on:**
 - (1) How it evaluates risk to Federal health care programs; and
 - (2) The non-binding criteria it uses to assess whether to impose exclusion under Section 1128(b)(7) of the Social Security Act.
- **Begins with the presumption that exclusion should be imposed.**

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Exclusion Criteria – Risk Spectrum

- Provides a compliance “risk spectrum” from high to low risk based on:
 - (1) Nature and circumstances of conduct;
 - (2) Conduct during Government’s investigation;
 - (3) Significant ameliorative efforts; and
 - (4) History of compliance.



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Notable Affirmative Exclusions

- **Cindy Scott:** APRN excluded for 10 years for prescribing controlled substances that were medically unnecessary, substantially in excess of the needs of her patients, and below the professionally recognized standards of care.
- **Anthony Vertino:** Physician excluded for 20 years for billing for psychological services provided in his office when the patients were hospitalized or when he was travelling out of state.
- **First Initiative and Shameika Amin:** Behavioral health service provider and owner excluded for 50 years for billing for individual therapy when group was provided, billing for services not rendered and billing under the names and NPI numbers of individuals who did not provide the services.
- **Stephen Latman:** Physician excluded for 10 years for issuing prescriptions for opioids to patients that were substantially in excess of the needs of those patients.

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Notable Affirmative Exclusions

- **Labib Riachi:** Physician excluded for 20 years for billing for pelvic floor therapy services that he failed to personally perform or directly supervise because he was traveling out of state or using unlicensed and unqualified individuals.

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OIG Civil Monetary Penalties (CMP)

- **OIG CMP is an administrative fraud remedy**
 - 42 U.S.C. § 1320a-7a, 42 C.F.R. § 1003.100 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.
- **42 CMP Authorities provide for enforcement actions on many grounds, including:**
 - False or fraudulent claims.
 - Kickbacks 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, 42 U.S.C. § 1396r-8(b)(3)(C).

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OIG CMPs (cont.)

- **Remedies:**
 - Monetary penalties up to \$10,000 (plus adjustment for inflation) for each item or service (or \$50,000 plus 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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Factors Favoring CMP Cases & Goals of OIG-Initiated Litigation

- **No explicit civil remedy**
 - Kickbacks
 - Billing while excluded
 - Violation of an assignment agreement
 - Failure to properly report required drug pricing information
 - EMTALA violations
- **Opportunity to hold individuals accountable**
- **Change industry behavior**
- **Amplify OIG priorities, support OIG guidance, or complement the work of other OIG components**
- **Exclusion sought**
- **Jury appeal issue**
- **Good evidence of fraud, but U.S. Attorney's Office declined**

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OIG CMP- Case Examples

- **OIG enforcement actions**
 (<https://oig.hhs.gov/fraud/enforcement/cmp/cmp-ae.asp>)
 - Kickbacks (ex. Open MRI doctors, 11 settlements for a total of \$1.4m and one exclusion).
 - Services not provided as billed (ex. Raia \$1.5m, 15 year exclusion; Fennell \$120k, 12 year exclusion).
 - Quality of care (ex. Merkle MD, 3 year exclusion; Hackley DDS, 3 year exclusion).
 - Drug price reporting CMP cases (ex. Sandoz, \$12.64m).
 - Non-emergency ambulance transport billed at emergency rate (CY 2016, \$2.18m, 10 agreements).

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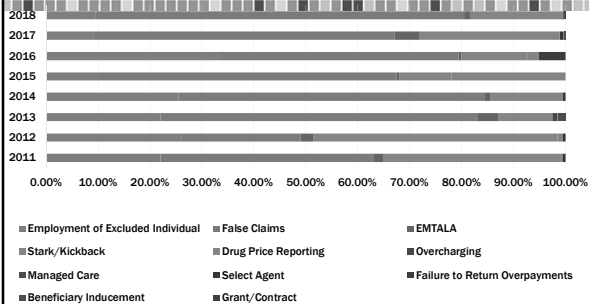
Data Analytics in CMP Cases

- **What is Data Analytics?**
 - Process of analyzing large quantities of data and extracting previously unknown information to identify aberrant billing trends that would otherwise remain hidden.
- **Purpose:**
 - 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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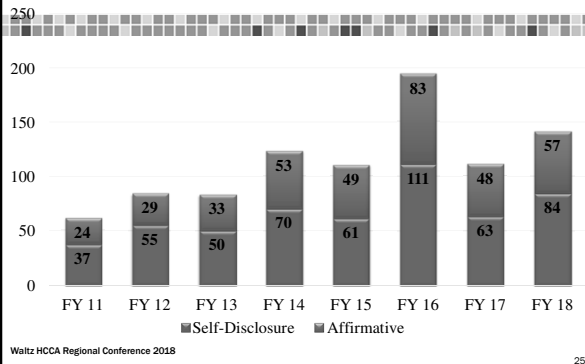
Percentage of CMP Monetary Recoveries by Allegation



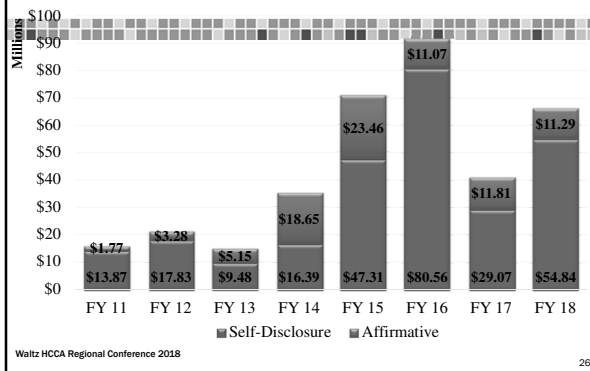
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Number of CMP Settlements



CMP Financial Recoveries



OIG CMPs – Final Rule

81 Fed. Reg. 88,334 (Dec.7, 2016).

- Reflects implementation of new ACA authorities:
 - 60 day refund rule – up to \$10,000/item or services, or \$11,052 after inflation.
 - Failure to grant timely access – up to \$15,000/day, \$16,579 after inflation.
 - False statements, omissions, or misrepresentations in enrollment or similar documents – up to \$50,000/false statement, \$55,262 after inflation.
 - Use of false record or statement that is material to a false or fraudulent claim – up to \$50,000/false statement, or \$55,262 after inflation.
- Inflation adjustments effective Feb. 3, 2017 are at 45 C.F.R. § 102.3; 82 Fed. Reg. 9,174 (Feb. 3, 2017).

2018 Balanced Budget Act CMP Updates

- The 2018 Balanced Budget Act doubled many CMP penalties
 - Doubled civil monetary penalties under 42 U.S.C. 1320a-7a from \$10,000 to \$20,000, \$15,000 to \$30,000 and \$50,000 to \$100,000 respectively.
 - Increased criminal fines under 42 U.S.C. 1320a-7b (\$25,000 to \$100,000).
 - Increased sentences for felonies involving fraud and abuse
 - Penalties for false statements and excess charges under 42 U.S.C. 1320a-7b(a) &(d) increasing from "not more than five years" to "not more than ten years."

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OIG Appeals (Exclusions and CMPs)

- ALJ does not have the authority to review the exercise of discretion by OIG to exclude an individual or entity, or to determine the scope and effect of the exclusion, or to set a period of exclusion at zero (42 C.F.R. § 1005.4).
- ALJ does not have the authority to review the exercise of discretion by the OIG to impose a CMP (42 C.F.R. § 1005.4).

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CMS ANTI-FRAUD EFFORTS

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CMS Fraud Prevention Themes

- Get away from the “pay-and-chase” to preventing fraudulent payments.
- Data-driven (predictive analytics).
- Reliance on administrative actions (denial of enrollment; revocation of billing privileges).
- Partnerships with the private sector (Healthcare Fraud Prevention Partnership – law enforcement, private plans, healthcare anti-fraud associations – 70 members in 2016).

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Provider Enrollment Appeals Data (provided by DAB Sept. 2018)

	CY2018 (through 9/18/2018)	CY2017 (through 9/18/2017)	CY2016 (through 9/18/2016)	CY2017 total	CY2016 total
PE	2	10	1	11	1
SE	17	17	17	31	21
PR	6	8	11	9	21
SR	87	132	114	177	169
PED	4	2	2	3	4
SED	385	310	171	502	210
Total	501	479	316	733	426
PE	Provider enrollment denial				
SE	Supplier Enrollment denial				
PR	Provider revocation				
SR	Supplier Revocation				
PED	Provider enrollment date appeal				
SED	Supplier enrollment date appeal				

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Enrollment Enforcement Actions - Stats

- From ACA implementation to August 2016
 - CMS enrolled or revalidated 1.9M providers and suppliers under the enhanced screening provisions.
 - CMS deactivated 730,000 providers and suppliers.
 - CMS revoked 47,000 providers and suppliers.
 - HCFAC CY 2016 Report says that 652,000 enrollment records have been deactivated or revoked since ACA, due to site visits, revalidation, and other initiatives.
 - According to Modern Healthcare’s analysis (2/22/2017), 65,000 Medicaid providers have been terminated as part of ACA implementation.

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Preclusion List

- Replaces requirement for Medicare enrollment of Part C and D providers/prescribers; individuals or entities who are not in good standing with Medicare will be placed on the list
- Final Rule – 83 Fed. Reg. 16440, 16639 (Apr. 16, 2018)
- List will be available beginning Jan. 1, 2019, must be applied beginning Apr. 1, 2019
- Part D sponsors required to reject pharmacy claims for Part D drugs prescribed by individuals on the list
- Medicare Advantage plans required to deny payment for an item or service furnished by an individual or entity on the preclusion list

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Medicaid Managed Care Network Providers Must Enroll in Medicaid

- 42 C.F.R. § 438.602(b) Screening and enrollment and revalidation of providers. (1) The State must screen and enroll, and periodically revalidate, all network providers of MCOs, PIHPs, and PAHPs, in accordance with the requirements of part 455, subparts B and E of this chapter. This requirement extends to PCCMs and PCCM entities to the extent the primary care case manager is not otherwise enrolled with the State to provide services to FFS beneficiaries. This provision does not require the network provider to render services to FFS beneficiaries.
- Contracts beginning after 1/1/2018 (effective date changed by 21st Century Cures Act).

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Revocation of Enrollment and Billing Privileges (42 C.F.R. § 424.535)

- Some overlap with OIG exclusion bases.
- Former opportunity to submit corrective action plan now only for very limited circumstances (per regulations effective 2/2015); appealable.
- 1-3 year re-enrollment bar [to be extended to 10 years under Proposed Rule, 81 Fed. Reg. 10720 (Mar. 1, 2016), but that rule has not been finalized]
- Program Integrity Manual Chap. 15, Sect. 15.27.2 – only limited determinations are delegated to the contractors without CMS approval – most require CMS review/approval.

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**Revocation of Enrollment –
Non-exclusive list of bases**

- Noncompliance with the enrollment requirements or has failed to pay any user fees.
- Provider or supplier conduct. (i) Excluded from the Medicare, Medicaid, and any other Federal health care program, (ii) is debarred, suspended, or otherwise excluded from participation.
- Felonies: Within the 10 years preceding enrollment or revalidation of enrollment, provider, supplier or any owner or managing employee (regulations effective 2/2015).

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**Revocation of Enrollment – Bases
(cont.)**

- False or misleading information on the enrollment application.
- On-site review - no longer operational, or is not meeting Medicare enrollment requirements to supervise treatment of, or to provide Medicare covered items or services for, Medicare patients.
- Misuse of billing number – provider/supplier knowingly sells to or allows another individual or entity to use its billing number.

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**Revocation of Enrollment – Bases
(cont.)**

- Abuse of billing privileges. Claim(s) for services that could not have been furnished to a specific individual on the date of service (e.g., beneficiary is deceased, the directing physician or beneficiary is not in the State or country when services were furnished, or when the equipment necessary for testing is not present where the testing is said to have occurred, medical necessity (new regulations effective 2/2015 discussed below).

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**Suspension/Revocation of Prescribing Authorities =
Denial/Revocation of Billing Privileges**

- Denial of Medicare enrollment: (424.530(a)(11)) , and Revocation of Medicare enrollment (424.535(a)(13)) if:
 - (i) A physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked; or
 - (ii) The applicable licensing or administrative body for any State in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs, and such suspension or revocation is in effect on the date the physician or eligible professional submits his or her enrollment application to the Medicare contractor.

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Adverse Action Reporting

- Revisions to Program Integrity Manual, Chap. 15, Sec. 15.5.3 *et seq.*
- Includes new “decision tree” (chart) for the Medicare Contractor to use as a guide to necessary actions.

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**CMS Form 855 Reports –
Reportable Adverse Events**

- Exclusions, Revocations, or Suspensions
- Any revocation or suspension of a license to provide health care by any State licensing authority. This includes the surrender of such a license while a formal disciplinary proceeding was pending before a State licensing authority.
- Any revocation or suspension of accreditation.
- Any suspension or exclusion from participation in, or any sanction imposed by, a Federal or State health care program, or any debarment from participation in any Federal Executive Branch procurement or non-procurement program.
- Any current Medicare payment suspension under any Medicare billing number.
- Any Medicare revocation of any Medicare billing number.

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Revocation Examples (From DAB Decisions)

- Misuse of locum tenens modifier – used for new physicians who didn't yet have their billing numbers (CR 3891 (5/22/2015)).
- Abuse of Billing Privileges – physician billing for more services than could be provided in given time period (CR 2592 (9/15/2014)).
- Home Health Certifications – physician was unable to submit complete medical records and documents had been created which made it falsely appear that beneficiaries were entitled (CR 3294 (7/11/2014)).

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Revocation Examples (From DAB Decisions) (cont.)

- Provider responsible for claims submitted by billing company even if provider has no knowledge of the error (CR 3373 (9/11/2014)).
- Reassignment – clinic billed for physician's services without a valid reassignment (CR 3124 (2/20/2014)).
- Home Health – not complying with laws relating to physician certifications (CR 3125 (2/20/2014)).
- IDTF – proficiency of interpreting and supervising physicians, and timely notifying CMS of employment of supervising physician (CR 3136 (2/18/2014)).

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Significant Risk Areas: 79 Fed. Reg. 72500 (12/5/2014)

- Denial of new enrollment if provider has Medicare debt (outstanding overpayment) from a prior terminated or revoked enrollment - (42 C.F.R. 424.530(a)(6)).
- Allows CMS to revoke billing privileges if there is a pattern or practice of submitting claims that do not meet Medicare requirements (example given is claims which do not meet medical necessity standards) - 42 C.F.R. 424.535(a)(8).
- Felony convictions (denied or revoked enrollments) –includes managing employees as well as owners.

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Medicaid Reciprocal Terminations

- ACA Section 6501 amended section 1902(a)(39) [T]he State agency shall...terminate the participation of any individual or entity in such program if ...participation of such individual or entity is terminated under title XVIII [Medicare] or any other State plan ...and provide that no payment may be made under the plan with respect to any item or service furnished by such individual or entity during such period...
- See also: 42 C.F.R. 445.416: "Must deny enrollment or terminate the enrollment".

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Medicaid Reciprocal Terminations (cont.)

- CPI-CMCS Informational Bulletin (May 31, 2011) (CPI-B 11-05) - includes FAQs.
- Defines "termination" - action to revoke provider billing privileges and appeals exhausted.
- A secure web-based portal allows States to share information regarding terminated providers - State is able to download information regarding terminated providers in other States and Medicare and to upload information regarding its own terminations.

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Differences Between Exclusion and Termination

- *Desfosses v. Noridian Healthcare Solutions, LLC*, D. Idaho, 2015 WL 1196018 (3/16/2015)
 - Denial of reenrollment for felony conviction and program revocation.
 - OIG said it would not pursue exclusion after billing privileges were revoked.
 - Court notes (and explains) difference between exclusion and termination.

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"Providers Terminated From One State Medicaid Program Continued Participating in Other States"

- OEI-06-12-00030 (Aug. 2015); see also OIG OEI-06-12-00031 (March 2014).
- 12% of providers (295 of 2,539) terminated for cause in 2011 were still participating in other states as of January 2014, paying \$7.4M to 94 providers.
- OIG identified challenges in implementation: no comprehensive data source for identifying terminations for cause and distinguishing them from other actions; 25 states did not require providers under managed care to be directly enrolled by state Medicaid agency (now required); differing terminology; misunderstanding of states that if license is active, they should not terminate the provider for cause.

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**Differing Reasons for "Termination"
OEI-06-12-00030, Table No. 1 (p. 9)**

- | | |
|------------------------------|-----------------------------|
| ■ Banned | ■ Exclusion |
| ■ Canceled | ■ Indictment |
| ■ Conviction | ■ Licensure
Modification |
| ■ Credentialing
violation | ■ Revocation |
| ■ Debarment | ■ Sanction |
| ■ Disciplinary Action | ■ Suspension |
| | ■ Termination |

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SUSPENSION OF PAYMENT

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What is a Payment Suspension?

- It's a "Time-Out."
- The withholding of an approved Medicare or Medicaid payment amount while a CMS contractor reviews previously paid claims to determine the existence and amount of an overpayment.
 - Many reasons for suspensions; this discussion is limited to those imposed for investigations of credible allegations of fraud.



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Credible Allegation Suspensions (ACA)

- "Credible allegation" includes:
 - Fraud hotline complaints.
 - Claims data mining (not recent "real time" abilities to identify claims abnormalities).
 - Patterns identified through audits, FCA cases, investigations.
- Medicaid suspensions shall be imposed if there is a pending investigation of credible allegation of fraud, except if good cause exists, such as...
 - Investigation would be compromised.
 - Access to care problem.
 - Not in best interests of the program.

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Credible Allegation Suspension - How Long Will it Last?

- Medicare - 18 months maximum; may be extended if case has been referred to, and is being considered by, OIG; or DOJ submits a written request to continue the suspension. CMS must evaluate whether there is good cause to not continue a suspension every 180 days after the initiation of a suspension.
- Medicaid - Presumptive limit for Medicare suspensions not adopted.

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Statistics on Payment Suspensions (Medicare)

- FY 2013 HCFA Report, as of Sept. 2013, there were 297 providers under active suspension, with 105 suspensions approved in FY 2013.
- FY 2014 – 507 suspensions
 - 207 new payment suspension in FY 2014.
 - 191 payment suspensions terminated.
- FY 2015 – 420 active suspensions
 - 105 new (imposed during FY 2015).
- FY 2016 – 508 active suspensions
 - 291 new (imposed during FY 2016).
- FY 2017 – 551 active suspensions
 - 252 new (imposed during FY 2017).

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Suspensions: Collateral to Large Investigations

- 295 providers (doctors, nurses, pharmacists) suspended, DOJ Justice News, “National Health Care Fraud Takedown Results in Charges against Over 412 Individuals Responsible for \$1.3 Billion in Fraud Losses” (July 13, 2017).
- Unspecified number of suspensions, DOJ, Justice News, “National Health Care Fraud Takedown Results in Charges against 301 Individuals for Approximately \$900 Million in False Billing” (June 22, 2016).
- 78 home health agencies in the Dallas area. HHS News Release, “HHS, Department of Justice Highlight Obama Administration Efforts, Health Reform Tools to Combat Medicare Fraud” (April 4, 2012).
- 52 providers suspended, DOJ Justice News, “Medicare Fraud Strike Force Charges 107 Individuals for Approximately \$452 Million in False Billing” (May 2, 2012).

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Suspensions: Medicaid Investigations

- June 2013 – 15 “major” Medicaid behavioral health provider organizations suspended in New Mexico for credible allegations of fraud. April 5, 2016: AP reports that “New Mexico AG clears last 2 mental health providers of fraud”; several non-profits filed suit against the state department, alleging their due-process rights were violated because they were denied hearings.
- March 2014 - District of Columbia suspended 52% of the providers of home health care aides for credible allegations of fraud – litigation and settlement, ABA, Inc., et al. v. District of Columbia, Civ. No. 14-550 (RMC).

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Federal Investigation Leads to Medicaid Suspension

- MaineCare payments to mental health agencies suspended by state after notified that HHS-OIG was investigating a credible allegation of fraud.
 - Both companies “shuttered”.
 - Payments restored after USAO declined to prosecute.
- Kennebec Journal, “MaineCare payments restored to mental health agencies accused of fraud” (9/02/2014).

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Suspension Despite Ongoing Negotiations with DOJ (Dr. Asad Qamar, Florida cardiologist)

- Letter from Dr. Qamar’s attorney (as quoted in Ocala.com, article dated 6/12/2015) “CMS’ imposition of 100 percent payment suspension threatens to overwhelm the pending discussions, hamper the ability of the parties to reach a settlement, and perhaps prevent the Medicare program from fully collecting any amount which may be determined or agreed to be owed to the program.”
- CMS response - short version: “Not Persuaded.”
- Litigation follows: Defendant alleges bad faith retaliatory response to exercise of 5th amendment right to defend against the claim of fraud, United States of America, et al. v. Institute of Cardiovascular Excellence, Case No. 5:11-CV-406 (M.D. FL)
- Dr. Qamar filed for bankruptcy 4/20/2016; practice for sale; Dow Jones Newswire story of 9/7/2016 says that Dr. Qamar came to national attention in April 2015 when the government released payment data for physicians, showing Dr. Qamar was paid second among all doctors in 2012, and 4X the next highest-paid cardiologist. Settlement discussions ongoing, with proposal to keep the amounts recovered in suspension.

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ADDITIONAL CMS ENFORCEMENT EFFORTS

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Additional CMS Fraud Efforts

- One Program Integrity (PI) Data Analysis - web-based portal with centralized access to multiple analytical tools and data sources.
 - Single access point with analytic tools.
 - Available to CMS contractors and law enforcement – one PI users can access IDR.
- Integrated Data Repository – provider, beneficiary, and claims data from Medicare Parts A, B, and D back to January 2006.
 - Data from three points in the claim life cycle: enumeration, adjudication, and payment data.
 - Allows pre-payment analytics to be done on historical data and development of models for predictive analytics.
 - ZPICs use to develop analytics for post-payment detection.
- Matching Medicaid data to Medicare claims and provider enrollment data.

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CMS' Data Driven Efforts: Targeted Probe and Educate

- Builds on 2014 program of "Probe and Educate" – but more targeted.
- Contractor reviews 20-40 claims per provider, per item or service, per round, for up to 3 rounds of review (each round is a probe).
- After each round, provider is offered individualized education.
- Claims will be those items/services that pose the greatest financial risk to the Medicare trust fund and/or those that have a high national error rate. MACs will focus on providers/suppliers that have the highest claim error rates or billing practices that vary significantly from peers, as identified by data analysis. (In other words, receipt of the targeted probe indicates that the provider/supplier has already been identified as potentially problematic.)
- GAO - "Medicare Provider Education: Oversight of Efforts to Reduce Improper Billing Needs Improvement" (GAO-17-290, March 2017)
- <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Targeted-Probe-and-EducateTPE.html>.

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January 23, 2018: CMS will share data with VA

- The VA and HHS announced a partnership to strengthen prevention of fraud, waste and abuse efforts
- This partnership will involve sharing data, analytics tools and best practices to identify and prevent fraud, waste and abuse
- "The VA-HHS alliance represents the latest example of VA's commitment to find partners to assist with identifying new and innovative ways to seek out fraud, waste and abuse and ensure every tax dollar given to VA supports Veterans," said VA Secretary Dr. David J. Shulkin. "This effort marks another step toward achieving President Trump's 10-point plan to reform the VA by collaborating with our federal partners to improve VA's ability to investigate fraud and wrongdoing in VA programs."

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Healthcare Fraud Prevention Partnership (HFPP)

HFPP Report, "Examining Clinical Laboratory Services" (May 2013), <https://hfpp.cms.gov/Hfpp-White-Papers/HFPP-Clinical-Lab-Services-White-Paper.pdf>, describes HFPP as follows:

The HFPP is a voluntary, public-private partnership between the Federal Government, state and local government agencies, law enforcement, private health insurance plans, employer organizations, and healthcare anti-fraud associations that seeks to identify and reduce fraud, waste, and abuse across the healthcare sector.[1] To advance this effort, entities that participate in the HFPP, known as Partners, regularly collaborate, share information and data, and conduct studies using a unique cross-payer data set. Additionally, the HFPP's broad membership provides a platform to address healthcare issues. This paper examines the challenges associated with the prevention and identification of fraud and abuse in the area of clinical laboratory services, a problem that can negatively impact the financial health of organizations and physical health of patients.

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Healthcare Fraud Prevention Partnership (HFPP) (cont.)

- *Strengthening the Health Care Fraud Prevention Task Force Act of 2018*, H.R. 6753 – would codify HFPP and authorize CMS to study a potential expansion of the program to allow use of real time data analytics
- Estimated savings of \$329M since 2012 (per AHIP)
- HFPP includes 23 state agencies, as well as federal departments (DOJ, DOD, VA, DOL, and HHS), plus 57 private payers, including Aetna, United Healthcare, Cigna, and Kaiser Permanente

Data Driven Anti-Fraud Effort by Aetna, Insurers Gathers Steam, BNA, James Swann (Sept. 12, 2018)

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Questions?

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