The State of Exclusions and OIG Enforcement Actions

A 360° LOOK AT OIG EXCLUSIONS, ENFORCEMENT, AND PREVENTION

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What is A Program Exclusion?

- Remedial
- Protects federal health care programs and beneficiaries 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
  - 1999
  - 2013

What is a Mandatory Exclusion?

- Mandatory – § 1128(a) of the SSA
  - Conviction Relating to Federal Heath Care Program
  - Conviction Relating to Abuse or Neglect (Only State or Federal)
  - Felony Conviction Relating to Fraud, Theft, Embezzlement, Breach of Fiduciary Duty, or other Financial Misconduct
    - In Connection With the Delivery of a HealthCare Item or Service
    - Or Act or Omission Involving a Federal Health Care Program (That is not covered by (a)(1)).
  - Felony Conviction Relating to a Controlled substance.
- Minimum Period: 5 Years
  - Aggravating and Mitigating Factors
- Reinstatement is **NOT** automatic.

What is a Permissive Exclusion?

- Permissive – § 1128(b) of the SSA
  - 16 Authorities
- Is Permissive really Permissive?
- How does OIG impose exclusions beyond the minimum term?
  - Aggravating Factors
  - Mitigating Factors

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. Minimum Period: 3 years
1128(b)(1)(B)†	1320a-7(b)(1)(B)	Conviction relating to fraud in non- health care programs. Minimum Period: 3
1128(b)(2)	1320a-7(b)(2)	Conviction relating to obstruction of an investigation. Minimum Period: 3 years
1128(b)(3)†	1320a-7(b)(3)	Misdemeanor conviction relating to controlled substance. Minimum Period: 3 years
1128(b)(4)	1320a-7(b)(4)	License revocation or suspension. Minimum Period: No less than the 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

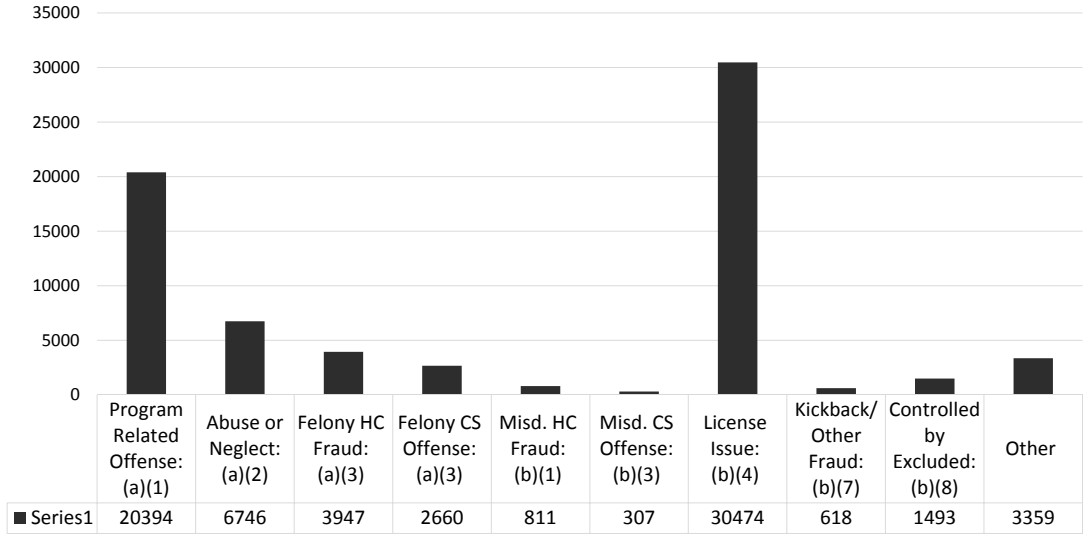
Permissive Exclusion Authorities

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 has been cured or obligations have been resolved to Public Health Service's (PHS) satisfaction.
1128(b)(15)‡	1320a-7(b)(15)	Individuals controlling a sanctioned entity. Minimum Period: Same period as entity.
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 (Peer Review Organization (PRO) findings). Minimum Period: 1 year

Interesting Facts about the OIG Exclusions

- Total OIG Exclusions as of 12-31-18 = 70,809
  - 53% of exclusions are for permissive purposes
  - 45+% of exclusions are due to license revocation, suspension or surrender
- Exclusions added in 2018 = 2,712
- 2,283 are excluded due to default on federal student loan
- 56% of State exclusions are not on OIG list*
  - * Top 5 states with State Medicaid Exclusions not on OIG list
    - California
    - Florida
    - Michigan
    - Maryland

Historical Exclusion Numbers by Authority



	Program Related Offense: (a)(1)	Abuse or Neglect: (a)(2)	Felony HC Fraud: (a)(3)	Felony CS Offense: (a)(3)	Misd. HC Fraud: (b)(1)	Misd. CS Offense: (b)(3)	License Issue: (b)(4)	Kickback/ Other Fraud: (b)(7)	Controlled by Excluded: (b)(8)	Other
Series1	20394	6746	3947	2660	811	307	30474	618	1493	3359

Basis for Exclusion	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Crimes related to Medicare/Medicaid	1,310	1,329	1,362	1,281	1,081
Crimes related to other health care programs	432	424	262	309	235
Patient abuse or neglect	189	302	299	266	200
Licensing actions	1,744	1,743	1,448	973	1,046
Other exclusion authorities	342	314	264	415	277
TOTAL Individuals and Entities Excluded	**4,017**	**4,112**	**3,635**	**3,244**	**2,839**

8

FY 2019 : October 2018-to-Date Exclusion Stats

Authority	Count	Individual	Businesses
1128(a)(1)	372	370	2
1128(a)(2)	86	85	1
1128(a)(3)	79	79	
1128(a)(4)	51	51	
1128(b)(1)	1	1	
1128(b)(2)	0		
1128(b)(3)	2	2	
1128(b)(4)	293	293	
1128(b)(5)	6	5	1
1128(b)(6)	0		
1128(b)(7)	16	6	10
1128(b)(8)	6		6
1128(b)(14)	19	19	
Settlement Agreement Breech/Default	1		1
Total	942	921	21

10

Total World of Exclusions

- 42 state Medicaid exclusion authorities* 68,973 (as of 2018)
- OIG.gov
- SAM.gov

- Total of State and Federal Exclusions exceeds 200,000

- Top 5 states with Most excluded providers:
  - California
  - Texas
  - New York
  - Pennsylvania
  - New Jersey
    - * Avg days from state Medicaid exclusion to OIG site is 169

Key Cases of Exclusion Enforcement

Two Home Health Agency Owners and Two Employees Convicted for Roles in $3.7 Million Home Health Fraud Scheme

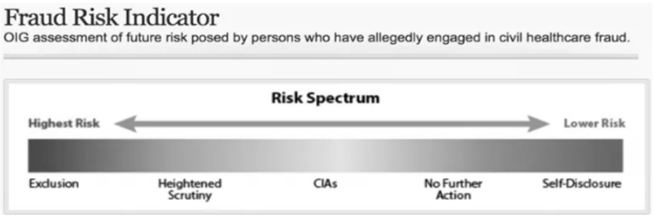
A Texas federal jury found two home health owners and two employees guilty today for their roles in a scheme to bill Medicare and Medicaid for over $3.7 million in charges when the owners had previously been excluded from participating in federal health care benefit programs.

California Health System Settles Case Involving Excluded Individual

On May 4, 2018, Alameda Health System (AHS), California, entered into a $257,874 settlement agreement with OIG. The settlement agreement resolves allegations that AHS employed an individual who was excluded from participating in any Federal health care program. OIG's investigation revealed that the excluded individual, an eligibility clerk, provided items or services to AHS's patients that were paid for by Federal health care programs

OIG Risk Factor Indicator

False Claims Act Settlements on the Risk Spectrum FY 2019 Q1



Excluded Person Appeal

- Initial hearing before an ALJ
  - Limited Discovery: Documents Only
  - Typically on the written record
- Issues:
  1. Is there a basis to exclude?
  2. Is the length of exclusion reasonable?
- Standard of proof: Preponderance of Evidence
- Burden:
  - IG: Elements of Exclusion Offense/Aggravating Factors
  - Petitioner: Mitigation Factors
- No Collateral Attacks

Decision and Appeal Options

- ALJ:
  - Makes an initial decision including findings of facts and conclusions of law.
  - The ALJ may affirm, increase, or reduce I.G. determination.
  - Party can file appeal to DAB with 30 days (possibility of extension).
- DAB Appeal (Board Review)
  - 3 Member Panel
  - Standard of Review: Is initial decision supported by substantial evidence and free of legal errors.
  - Written Submissions with possibility of oral arguments
  - DAB can affirm, increase, reduce, reverse or remand.
- Federal Court
  - CMPL – Circuit Court
  - Program Exclusion – District Court

15

Program Readmission/Reinstatement

- **Withdrawal/Rescission**
- FY 2014: 18 (4 during appeals)
- FY 2015: 17 (2 during appeals)
- FY 2016: 14 (4 during appeals)
- FY 2017: 26 (5 during appeals)
- FY 2018: 13 (2 during appeals)

- **Program Reinstatement**
- FY 2014: 534
- FY 2015: 520
- FY 2016: 571
- FY 2017: 564
- FY 2018: 614

Exclusion Waivers

- Mandatory exclusions -- sole community physician or sole source of essential specialized services in a community.
  - Not available for individuals excluded for abuse or neglect.
- Request must be initiated by a federal or State health care program.
- Limited in Scope – Typically by Geographical Area.
- Waiver would be rescinded if basis for waiver no longer exists.
  - Individual is no longer the sole source of services.

Primary Enforcement Authorities

- **False Claims Act (31 U.S.C. § 3729 - 3733)**
- Elements
  - (1) a false statement or fraudulent course of conduct;
  - (2) made or carried out with knowledge (actual knowledge of falsity, deliberate ignorance of the truth or falsity of the information, or reckless disregard of the truth or falsity of the information);
  - (3) that was material; and
  - (4) that involved a claim (i.e., a request or demand for money or property from the United States).

- **Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a)**
- Elements differ depending on authority;
- Elements very similar to the FCA for cases regarding the submission of false or fraudulent claims;
- CMPL incorporates the elements of the anti-kickback statute for case involving kickbacks;
- *Scienter* standard varies according to authority: most sections use "knowingly," which is defined in a similar manner to the FCA, while others appear to use actual knowledge standards or adopt scienter standards from other statutes by reference.

18

FCA vs. CMPL Remedies

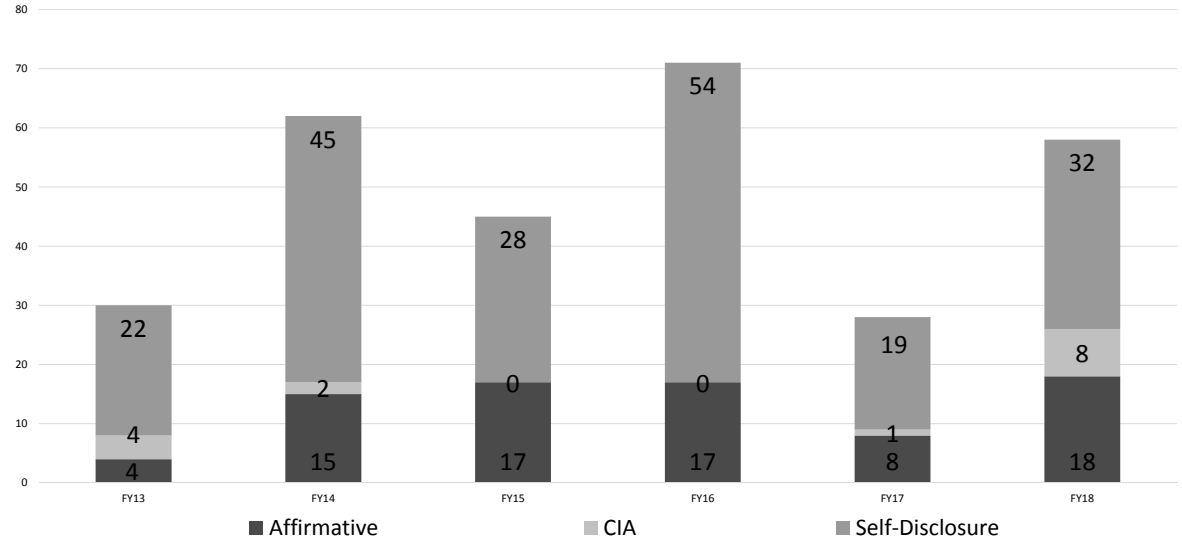
False Claims Act

- Civil Penalty of no less than $5,500 and not more than $11,000
  - Inflation Adjusted: $11,181 - $22,363 (CY 2018)
- 3 times damages sustained by the U.S.
- No Exclusion
- Statute of Limitations can be up to 10 years
- Trial by jury available
  - Federal Rules of Evidence
- Informal Self-Disclosure Process

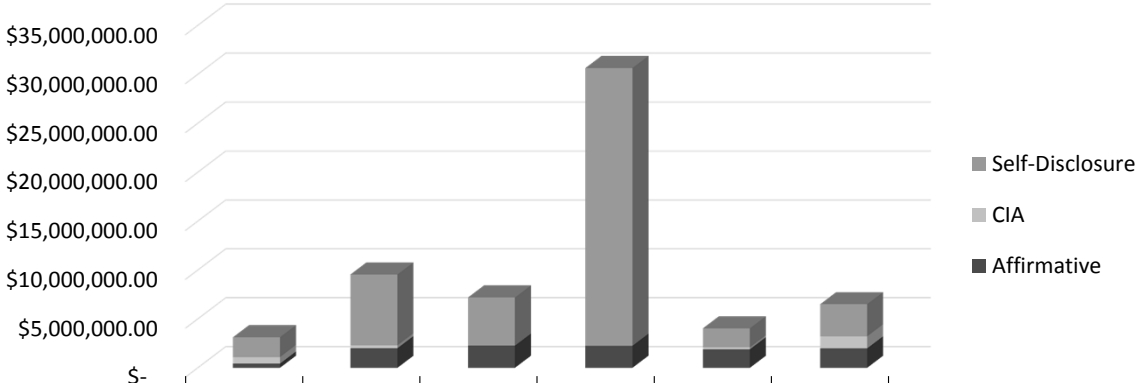
Civil Monetary Penalties Law

- Monetary Penalty up to $10,000 for each item or service improperly claimed
  - Inflation Adjusted: $20,000 (statutory change 2018)
  - Violation occurred AFTER 11/2/15
- Up to 3 times the amount improperly claimed
- Exclusion
- Statute of Limitations 6 years
- ALJ Proceeding
  - Hearsay Admissible
- Formal Self-Disclosure Process

Total Number of BWE Settlements



Total Monetary Recovery in BWE Settlements



	FY13	FY14	FY15	FY16	FY17	FY18
Self-Disclosure	$2,033,269.	$7,248,857.	$4,922,637.	$28,396,186	$1,948,334.	$3,296,620.
CIA	$661,109.00	$291,073.00	$-	$-	$197,556.00	$1,224,056.
Affirmative	$432,971.00	$2,010,299.	$2,269,888.	$2,255,061.	$1,896,953.	$1,990,893.

CMS Preclusion List

What is it?

- CMS list of providers and prescribers precluded from receiving payment for Medicare Advantage or Part D drugs for Medicare beneficiaries.
- 1/1/19 replaces Medicare Advantage and prescriber enrollment requirements and ensures patient protections and safety and protect Trust Funds from prescribers and providers identified as bad actors.
- CMS-4182 Final Rule

CMS Preclusion List

- Who is on the Preclusion list?

A list of prescribers and individuals or entities who fall within any of the following categories:

(1) Are currently *revoked* from Medicare, are under an *active re-enrollment bar*, and *CMS has determined* that the underlying conduct that led to the revocation is *detrimental to the best interests of the Medicare program;* or

(2) Have *engaged in behavior for which CMS could have revoked the prescriber*, individual or entity to the extent applicable ***if*** *they had been enrolled in Medicare*, **and** *CMS determines* that the *underlying conduct that would have led to the revocation is detrimental* to the best interests of the Medicare program.

(3) Such conduct includes, but are not limited to, *felony convictions and OIG exclusions*.

CMS Preclusion List

How long is a Provider is on the Preclusion list:

- A provider will be precluded for the length of their re-enrollment bar if they are currently revoked **or** would have been revoked had they enrolled in the Medicare program.
- The re-enrollment bar is a minimum of 1 year, but not greater than 3 years depending on the severity of the basis for revocation.
- The Preclusion List timeframe will be specified in the notification letter.

Screening Best Practices

- OIG-LEIE each month (search at least after 10th)
- Add State Medicaid Exclusion searches (42)
- SAM.gov
- Search names provided on application (maiden, former, hyphenated...)
- Don't forget vendors
- *Remember*: Disciplinary action on individual with a license is good precurser for possible future exclusion
- OIG LEIE does not contain ALL exclusions
- Exclusions are not automatically reinstated upon conclusion of term
- Starting in 2019 (April): CMS Preclusion list monitoring

The Affirmative Investigation

- OIG will issue a "Pre-Demand Letter"
  - Identity of Excluded Person
  - Effective Date of Exclusion
  - How OIG learned of Employment: Reinstatement Application
- Request for Information
  1. Facts and Circumstance of Employment
  2. Basic Evidence:
     - Application/Background Check Information
     - Resume/Job Description
     - Salary/Benefit Information
  3. Federal Payor Mix
  4. Any Other Information Provider Wants Considered

Best Practices For Response

- Treat the Pre-Demand Letter like a Subpoena
- Conduct Internal Inquiry Before Responding:
  1. Contact OIG Representative
  2. Check the LEIE
     - If excluded: place employee of administrative leave
     - Interview Employee?
  3. Gather the Requested/Relevant Information
  4. Confirm Liability
     - Was LEIE Correct
     - Was Exclusion Lawful
       - FOIA is your friend
     - Identify Statute of Limitations
  5. Calculate Likely Damages
- Draft Response

Questions or Comments or "Hypotheticals"

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