



U.S. Department of Health & Human Services Office of Inspector General



Fraud and Abuse Statutes, Administrative Authorities, and Self-Disclosures

1. The False Claims Act
2. Civil Monetary Penalties Law
3. The Anti-Kickback Statute
4. The Prohibition on Certain Physician Referrals (Stark Law)
5. The Inspector General's Exclusion Authority
6. The Self-Disclosure Process



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Presenter

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Office of Counsel to the Inspector General



Civil Cases

RELATIONSHIPS

- Anti-Kickback Statute
- Prohibition on Certain Physician Referrals (Stark)
- Civil Monetary Penalties Law
- Exclusion

BILLING

- False Claims Act
- Civil Monetary Penalties Law
- Exclusion



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The False Claims Act

31 U.S.C. Sections 3729-3733



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The Federal False Claims Act

- 31 U.S.C. Sections 3729 *et. seq.*
- Prohibitions on knowingly making--
 - False claim;
 - False record or statement;
 - Reverse false claim; or
 - Conspiracy.
- Treble damages.
- Per claim penalties.



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The False Claims Act



Common Issues:

- Medical necessity
- Arrangements
- Worthless services
- 60 day repayment
- Data-driven cases



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Civil Monetary Penalties Law

42 U.S.C. Section 1320a-7a



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Types of Civil Monetary Penalties (CMP) Cases

- Kickbacks
- Physician referral (Stark) violations
- False or Fraudulent Claims
- Billing while excluded
- Select Agents
- Patient dumping (EMTALA)
- About 40 other OIG CMPs





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Civil Monetary Penalties Law – Key Points

- Aside from 42 U.S.C. 1320a-7a, there are other CMPs are codified outside the CMPL, but incorporate the CMPL intent standards and procedures.
- CMPL is most often used by OIG as an alternative to civil action under the False Claims Act.
- DOJ authorization is required for a CMPL action, 42 U.S.C. § 1320a-7a(c)(1).
- OIG must prove the elements of a CMP action by preponderance of the evidence; Respondent has the burden to prove any mitigating factors and affirmative defenses.
- Six Year Statute of Limitations, 42 U.S.C. § 1320a-7a(c)(1).
- CMP, Assessments, and Exclusion available for most CMP cases.
- Administrative Law Judge Proceeding/Hearing, 42 U.S.C. § 1320a-7a(c)(2).



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The Anti-Kickback Statute

42 U.S.C. § 1320a-7b(b)



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The Anti-Kickback Statute

- Offer, Payment, Solicitation, or Receipt
- Remuneration
- Referrals
- Knowingly and Willfully
- Safe Harbors



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Violations of the Anti-Kickback Statute

- Criminal
- Civil Monetary Penalties
- Exclusion
- False Claims Act Liability
- Non-Payment
- Refunds to Beneficiaries



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Advisory Opinions (Ad Ops)

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Home > FAQs > Advisory Opinions FAQ

Advisory Opinions FAQ

- What is an advisory opinion?
- What law applies to the OIG advisory opinion process?
- Do I have to get an advisory opinion?
- What topics are NOT appropriate for the advisory opinion process?
- How do I request an advisory opinion?
- What information should an advisory opinion request include?
- What certifications are required?
- How long does it take to get an opinion?
- Can I withdraw my request after I've submitted it?
- How much does an advisory opinion cost? Can I set a cap?
- Can I get an estimate of the fee?
- Will my advisory opinion be released to the public?

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Choose your topic

- Office of Inspector General FAQ
- Advisory Opinions FAQ**
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- Student Diversity Volunteer Internship Program FAQ
- Provider Self-Disclosure Protocol FAQ

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The Prohibition on Certain Physician Referrals (Stark Law)

42 U.S.C. Section 1395nn



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Three Questions

- Is there a referral by a physician for a Medicare designated health service (DHS)?
- Does the physician have a financial relationship with the entity furnishing DHS?
- Does the financial relationship fit in an exception?
 - *If not, there's probably a violation*



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Violations of Stark Law

- Non-payment
- Refunds to beneficiaries
- Civil Monetary Penalties
- Exclusion
- False Claims Act Liability



Nutshell Stark

- Technical violations matter.
- Fair Market Value (FMV) matters even more.
- Evolving case law .

See CMS Advisory Opinions at:

[cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html](https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html)



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The Inspector General's Exclusion Authorities

Section 1128A of the Social Security Act
42 U.S.C. Section 1320a-7



Exclusion from Federal Health Care Programs Section 1128 of the Social Security Act

Mandatory – Section 1128(a)

- Conviction of “program related” crime;
- Conviction of patient abuse and neglect;
- Felony conviction of health care fraud; and
- Felony conviction relating to controlled substances.
- **Five year minimum.**

Permissive – Section 1128(b)

- 16 authorities, including:
 - Certain misdemeanor convictions;
 - Loss of state license to practice;
 - Failure to repay health education loans; and
 - Failure to provide quality care.



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Length of Exclusion

Generally defined period, but certain may be indefinite in length.

Must apply for and be granted Reinstatement.

Directions for application can be found at www.oig.hhs.gov.



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What can you do?

Contact the OIG.

Negotiate a voluntary exclusion.
Effective upon signing.



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Procedure for Exclusions

Derivative Exclusions – Implemented and then the excluded individual or entity has a right to a hearing.

Affirmative Exclusions – By agreement or hearing.

*See 42 C.F.R. sections 1001 et. seq. and
www.hhs.gov/dab*



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OIG Self- Disclosure



Self-Disclosure

- Should I disclose?
- Where should I disclose?
 - Contractor
 - OIG
 - DOJ
 - CMS
- Get some advice.





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Resolution

- **OIG - Civil Monetary Penalties Law settlement.**
- **DOJ - False Claims Act settlement.**
- **No Corporate Integrity Agreement (if cooperative).**





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Self-Disclosure Information

The screenshot shows a web browser window displaying the "Self-Disclosure Information" page on the OIG website. The browser's address bar shows the URL <https://oig.hhs.gov/compliance/self-disclosure-info/index.asp>. The page content includes a breadcrumb trail (Home > Compliance > Self-Disclosure Information), a search bar with the text "I'm looking for" and a dropdown menu set to "Select One", and a list of topics such as "Accountable Care Organizations", "Advisory Opinions", "Compliance 101 and Provider Education", "Compliance Guidance", "Corporate Integrity Agreements", "Open Letters", "RAT-STATS", "Safe Harbor Regulations", "Self-Disclosure Information", and "Special Fraud Alerts, Bulletins, and Other Guidance". The main content area provides an overview of the OIG's self-disclosure processes and lists three categories: Health Care Provider Self-Disclosures, HHS Contractor Self-Disclosures, and HHS Grantee Self-Disclosures, each with a brief description and a link to the relevant webpage.

Home > Compliance > Self-Disclosure Information

Self-Disclosure Information

The Office of Inspector General (OIG) has several self-disclosure processes that can be used to report potential fraud in Department of Health and Human Services (HHS) programs. Choose the one that applies to you from the following descriptions to learn more.

Self-disclosures should not be reported to the OIG Hotline.

Health Care Provider Self-Disclosures

- Health care providers, suppliers, or other individuals or entities subject to [Civil Monetary Penalties](#) can use the Provider Self-Disclosure Protocol, which was created in 1998, to voluntarily disclose self-discovered evidence of potential fraud. Self-disclosure gives providers the opportunity to avoid the costs and disruptions associated with a Government-directed investigation and civil or administrative litigation. Visit the [Provider Self-Disclosure Protocol](#) webpage for more information.

HHS Contractor Self-Disclosures

- Contractors are individuals, businesses, or other legal entities that are awarded Government contracts, or subcontracts, to provide services to the Department of Health and Human Services (HHS). OIG's contractor self-disclosure program enables contractors to self-disclose potential violations of the False Claims Act and various Federal criminal laws involving fraud, conflict of interest, bribery or gratuity. This self-disclosure process is available for those entities with a Federal Acquisition Regulation-based contract. Visit the [Contractor Self-Disclosure](#) webpage for more information.

HHS Grantee Self-Disclosures

- HHS grantees or subrecipients may voluntarily disclose evidence of potential violations of Federal criminal law involving fraud, bribery, or gratuity violations, potentially affecting the Federal award. 45 C.F.R. 75.113 notes mandatory disclosures of criminal offenses that non-Federal entities must make with respect to HHS grants. Recipients submitting disclosures in connection with this requirement should include the subject reference line "Mandatory Grant Disclosure." Recipients choosing to disclose conduct that may not fit squarely within the scope of offenses described in 45 C.F.R. 75.113, should include the following subject

I'm looking for

Let's start by choosing a topic

Select One

- Accountable Care Organizations
- Advisory Opinions
- Compliance 101 and Provider Education
- Compliance Guidance
- Corporate Integrity Agreements
- Open Letters
- RAT-STATS
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Self-Disclosure Protocol

The screenshot shows a web browser window displaying the Office of Inspector General website. The URL is <https://oig.hhs.gov/compliance/self-disclosure-info/protocol.asp>. The page features a dark blue header with the text "REPORT FRAUD" and navigation links for Home, FAQs, FOIA, Contact, HEAT, Download Reader, and social media icons. The main content area includes the Office of Inspector General logo and name, a search bar, and a navigation menu with links for About OIG, Reports & Publications, Fraud, Compliance, Exclusions, Newsroom, and Careers. The main heading is "Provider Self-Disclosure Protocol". Below the heading, there is introductory text: "Providers who wish to voluntarily disclose self-discovered evidence of potential fraud to OIG may do so under the Provider Self-Disclosure Protocol (SDP). Self-disclosure gives providers the opportunity to avoid the costs and disruptions associated with a Government-directed investigation and civil or administrative litigation." A red button labeled "Self-Disclosure Online Submission" is prominently displayed. On the right side, there is a section titled "I'm looking for" with a dropdown menu and a list of topics: Accountable Care Organizations, Advisory Opinions, Compliance 101 and Provider Education, Compliance Guidance, Corporate Integrity Agreements, and Open Letters.

[Home](#) > [Compliance](#) > [Self-Disclosure Information](#)

Provider Self-Disclosure Protocol

Providers who wish to voluntarily disclose self-discovered evidence of potential fraud to OIG may do so under the Provider Self-Disclosure Protocol (SDP). Self-disclosure gives providers the opportunity to avoid the costs and disruptions associated with a Government-directed investigation and civil or administrative litigation.

Have you or any of your affiliates submitted a self-disclosure to the OIG in the past or currently have one pending? If so, please identify the submission date of the self-disclosure and list the name of the entity and affiliates.

[Self-Disclosure Online Submission](#)

I'm looking for

Let's start by choosing a topic

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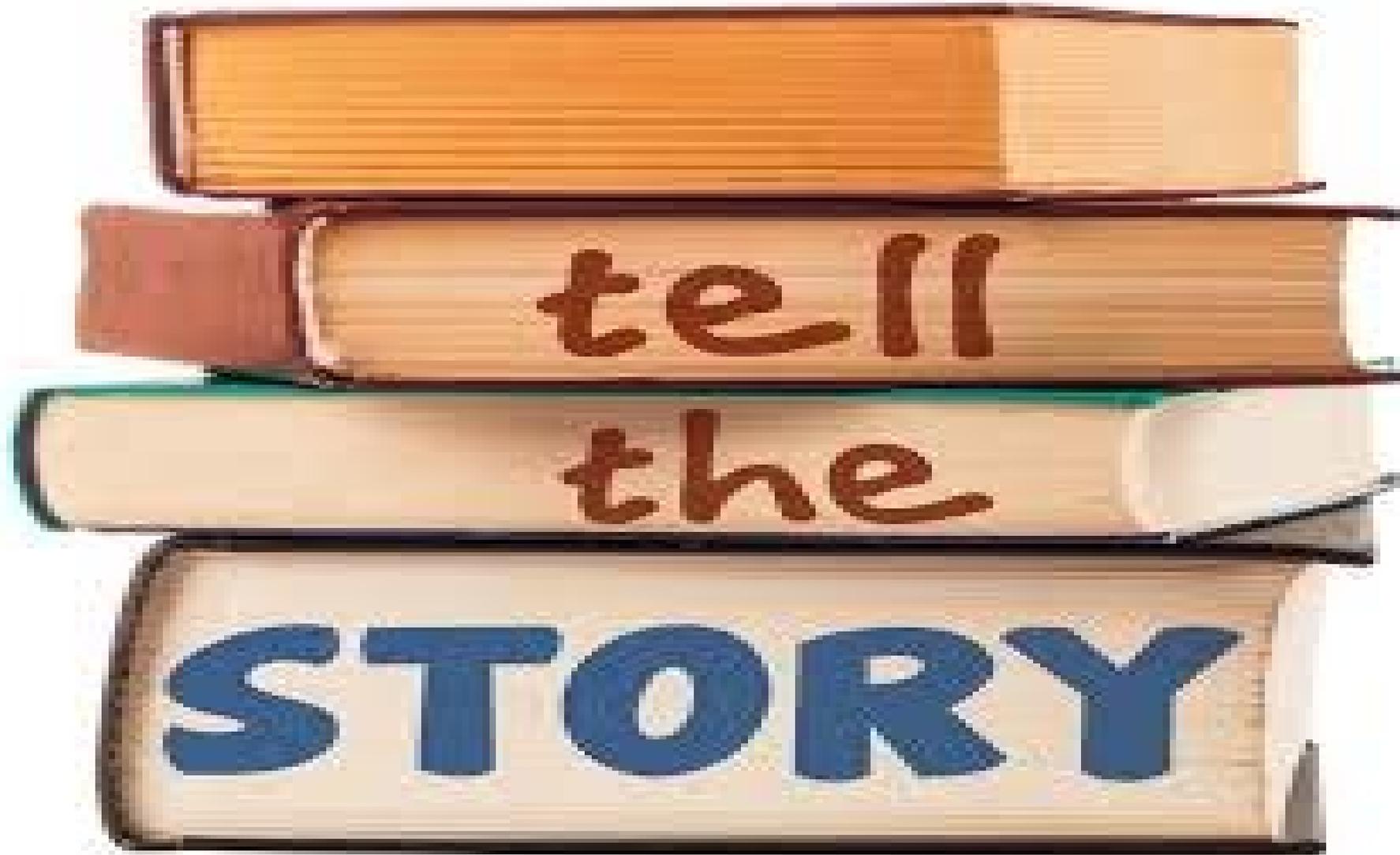


On-Line Submission

Self-Disclosure
Online Submission



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OIG Self-Disclosure Protocol

- Make sure the submission is complete.
- Consult OIG's website at:
oig.hhs.gov.





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Benefits of Self-Disclosure

- **Cooperative Process.**
- **Likely a smaller settlement amount.**
- **Usually no integrity obligations.**



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Questions?

