

Self-Disclosures: Report, Repayment & the Options HCCA's 22nd Annual Compliance Institute

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Agenda

Panel format where we will discuss...

- **OIG's Provider Self-Disclosure Protocol**
- **CMS' Voluntary Self-Referral Disclosure Protocol**
- **State Self-Disclosure Protocols**
- **The 60-Day Overpayment Rule and Its Impact**
- **Scenarios Applying These Concepts**

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OIG's Provider Self-Disclosure Protocol

Background:

- Originally published through the Federal Register in 1998
- Revised through Open Letters to Health Care Providers in 2006, 2008, and 2009
- Current version, published in 2013, superseded Federal Register notice and Open Letters

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OIG's Provider Self-Disclosure Protocol (cont'd)

Purpose: To “establish a process for health care providers to voluntarily identify, disclose, and resolve instances of potential fraud”

- “Potential fraud” = “matters that, in the disclosing party’s reasonable assessment, potentially violate Federal criminal, civil, or administrative laws for which [Civil Monetary Penalties] are authorized”
- In the healthcare context, CMPs are authorized for:
 - Presenting a claim that you know/should know is fraudulent or for an item or service not provided as claimed
 - Presenting a claim that you know/should know is for an item or service Medicare will not cover
 - Violating the Anti-Kickback Statute

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OIG's Provider Self-Disclosure Protocol (cont'd)

3 types of conduct ineligible for self-disclosure under OIG protocol:

1. Overpayments/errors that do not involve “potential fraud”
 - i.e., “Honest billing mistakes or mere inadvertence”

Eric H. Holder, Jr. in remarks to the American Hospital Association (2/1/1999)

2. Prospective arrangements (appropriate for Advisory Opinion process only)
3. Violations of the Physician Self-Referral Law (a.k.a., the “Stark” law) only

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OIG's Provider Self-Disclosure Protocol (cont'd)

Steps:

1. **Internal Investigation and Corrective Action.** Prior to disclosure, conduct an internal investigation, ensure that the fraudulent conduct has ended, and take any necessary corrective action
 - Corrective action should be complete at the time of disclosure
 - If unable to complete internal investigation prior to submission, must certify that investigation will be completed within 90 days

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OIG's Provider Self-Disclosure Protocol (cont'd)

2. Submission to OIG. Disclosures may be submitted:

- Through OIG website; OR
- By mail
- Disclosures submitted by fax or other means **will not be accepted**

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OIG's Provider Self-Disclosure Protocol (cont'd)

Submission contents:

- Name, address, type of provider, provider ID number, and tax ID number of disclosing party and government payers affected
- Organizational chart diagramming pertinent relationships, if provider is part of a system or network
- Name and contact information of disclosing party's designated representative
- Concise description of conduct giving rise to the self-disclosure (types of claims, relevant period, names and roles of entities and individuals believed to be implicated)
- A statement of the Federal laws potentially violated
- Federal health care programs affected

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OIG's Provider Self-Disclosure Protocol (cont'd)

Submission contents, continued:

- Estimate (or actual amount, if determinable) of the damages to each Federal health care program
- Description of corrective action taken
- Statement indicating whether (to the disclosing party's knowledge) the matter is already under government investigation
- Name of an individual authorized to enter into a settlement
- Certification that the submission contains truthful information and is based on a good faith effort to resolve the matter
- Specific additional requirements where conduct involved false billing, excluded individuals, or violations of Stark/Anti-Kickback Statute

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OIG's Provider Self-Disclosure Protocol (cont'd)

- 3. Resolution.** Good faith cooperation is essential to obtaining beneficial settlement terms. At a ***minimum***, disclosing parties may expect:
- Multiplier of 1.5x the amount paid by the Federal health care programs
 - Mandatory False Claims Act multiplier = 3x
 - Kickback-related conduct: \$50,000 settlement
 - All other conduct: \$10,000 settlement
 - Use of the SDP is limited to settlements of these amounts or more

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Self-Disclosure Information



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 1996, 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 grants or subgrants 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 the "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
- RAAT-STATS
- Safe Harbor Regulations
- Self-Disclosure Information
- Special Fraud Alerts, Bulletins, and Other Guidance

EXCLUSIONS DATABASE

Self-Disclosure Protocol



REPORT FRAUD

Home > FAQs > FOIA > Contact > HEAT > Download Reader >

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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
Select One

- Accountable Care Organizations
- Advisory Opinions
- Compliance 101 and Provider Education
- Compliance Guidance
- Corporate Integrity Agreements
- Open Letters

On-Line Submission



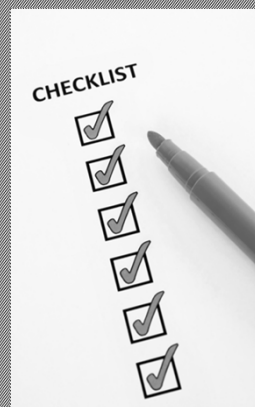
Self-Disclosure
Online Submission

OIG Self-Disclosure Protocol



- Make sure the submission is complete.
- Consult OIG's website:

OIG.HHS.GOV.



CMS' Voluntary Self-Referral Disclosure Protocol

Background: Published pursuant to Section 6409(b) of the Affordable Care Act, which grants the Secretary of HHS authority to reduce the amount due and owing for Stark violations

Conduct eligible for self-disclosure: Limited to actual or potential violations of Stark only

- **Where both Stark and AKS are implicated, use OIG's protocol**

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CMS' Voluntary Self-Referral Disclosure Protocol (cont'd)

Submission: Specific forms provided for disclosure (all required, plus optional cover letter)

1. **SRDP Disclosure Form**
 2. **Physician Information Form(s)**
 3. **Financial Analysis Worksheet** (Excel format)
 4. **Certification**
- Must submit electronic copy to 1877SRDP@cms.hhs.gov **and** hard copy to CMS

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CMS' Voluntary Self-Referral Disclosure Protocol (cont'd)

Update: Must inform CMS by email **within 30 days** if, after disclosure, disclosing party...

- Files for bankruptcy
- Undergoes a change of ownership
- Changes the designated representative

Factors considered by CMS in reducing the amount owed:

- Nature and extent of the improper or illegal practice
- Timeliness of self-disclosure
- Cooperation in providing any additional information needed

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State Self-Disclosure Protocols

- For Medicaid providers, the following states have established formal protocols to facilitate self-disclosure of Medicaid overpayments: AZ, AR, CT, GA, IL, IN, MS, MT, NE, NJ, NY, NC, OK, PA, TN, TX
- Of remaining states, approximately 15 indicate that the Medicaid program will accept and/or consider a provider's self-disclosure
 - No established processes to guide disclosures, but providers may be able to use federal protocols as models

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60-Day Overpayment Rule

- Provision of the Affordable Care Act, codified at 42 U.S.C. 1320a-7k(d)
- Requires providers to report overpayments within 60 days of identification
 - “Overpayment” = Any funds a person has received or retained to which that person is not entitled, **regardless of causation or fault**
 - “Identification” = Recipient has or should have, through reasonable diligence, discovered and quantified the overpayment

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60-Day Overpayment Rule (cont'd)

Applicability:

- By the terms of the ACA, 60-Day reporting period applies to both Medicare and Medicaid providers
- So far, CMS has issued implementing regulations applicable to:
 - Medicare Parts A and B (81 F.R. 7653)
 - Medicare Parts C and D (79 F.R. 29844)
- No published regulatory requirements applicable to Medicaid (yet)
 - This does not mean that 60-Day Rule does not apply to Medicaid

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60-Day Overpayment Rule (cont'd)

Consequences of failure to report: After 60 days, unreported overpayments become “obligations” that can trigger liability under the False Claims Act

- Although the term “overpayment” includes funds received by mistake, liability under the FCA requires at least “**reckless disregard**”
- Violations of the FCA expose providers to suit by the government and/or whistleblowers (“relators”)
- Penalties = Treble damages plus “per claim” penalties
 - Plaintiffs continue to challenge what constitutes a “claim,” especially where – as in the healthcare context – multiple types of requests are submitted for reimbursement

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60-Day Overpayment Rule (cont'd)

Consequences of failure to report, continued:

- Per 83 F.R. 2062, maximum amount of “per claim” penalty was set at \$11,181 for violations committed after 11/2/2015 and assessed CMPs after 1/15/2018
- Sec. 50412 of Bipartisan Budget Act (2/9/2018) doubled penalty amounts; no implementing regulations yet issued

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Panel Discussion: Introduction

Advantages of self-disclosure:

- Government more likely to perceive compliance program as effective and intentions as good
- Potential reduction in damages (OIG: 1.5x vs. 3x + per claim penalties)
- Whistleblower liability neutralized
- Quicker resolution/more control over publicity
- Presumption against requiring a Corporate Integrity Agreement (OIG)

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Panel Discussion: Introduction (cont'd)

Disadvantages of self-disclosure:

- Attracts scrutiny to a practice
- Government investigation may uncover additional violations (for which disclosing entity will not receive benefits of disclosure)
- No guaranteed reduction in damages/penalties
- Must acknowledge that a potential violation has occurred without benefit of seeking an advisory opinion (OIG)

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Panel Discussion: Recent Self-Disclosure Settlements

Tri-City Healthcare District

- 397 bed acute-care hospital in Oceanside, CA
- Self-disclosed conduct to OIG through a July 2011 letter and April 2012 report
- Conduct at issue:
 - 5 arrangements with former chief of staff (2008-2011) that, in the aggregate, were not commercially reasonable or fair market value
 - 92 financial arrangements with community-based physicians and practice groups that did not meet a Stark exception from 2009-2010 (written agreements expired, missing signatures, or lost)
- Settled: January 2016 for **\$3,278,464**

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Panel Discussion: Recent Self-Disclosure Settlements (cont'd)

21st Century Oncology

- Network of cancer care providers based out of Fort Myers, FL
- Self-disclosed conduct to OIG in 2016
- Conduct at issue:
 - Falsified reports demonstrating “meaningful use” of EHR
 - Employees, among other things, produced false reports with superimposed logos of EHR vendors
 - Also resolved qui tam allegations of Stark violations
- Settled: December 2017 for **\$26,000,000**

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Panel Discussion: Recent Self-Disclosure Settlements (cont'd)

Note: Because “meaningful use” attestations were required for providers to avoid “downward adjustments” in their general reimbursement rates for subsequent years, fraud in this area potentially affects **every claim** submitted by a healthcare provider during the year(s) the downward adjustment should have applied

- 2017 OIG report estimates that CMS spent \$729 million on improper meaningful use payments 2011-2014
- At least one other provider, Humana Inc., has self-disclosed and settled claims relating to false “meaningful use” attestations
 - Settlement: September 2017 for \$411,600

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Panel Discussion: Recent Self-Disclosure Settlements (cont'd)

DaVita Rx

- National pharmacy specializing in kidney disease, subsidiary of kidney dialysis firm DaVita Inc.
- Initial self-disclosure led to investigation of additional compliance problems by U.S. Attorney’s Office in 2016
- Conduct at issue:
 - Billed Medicare for prescription medications that were never shipped, were shipped but returned, or did not comply with documentation requirements
 - Accepted drugmaker copayment discount cards from Medicare beneficiaries in lieu of copays, wrote off beneficiary debt, and gave discounts for payment by credit card in violation of AKS
- Settled: December 2017 for **\$63,700,000** (\$22 million attributable to self-disclosure)

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Panel Discussion: Trends in 2017 Self-Disclosure Settlements

Largest settlements:

- Of the Self-Disclosure Settlements reported on OIG's website for 2017, 2 of the 3 largest resulted from services rendered that were not supported by the medical record
- Issues with billing or documentation protocols have the potential to affect a very large number of claims before they are identified – what strategies can/should a provider use to catch patterns of errors early on?

Most commonly reported violation:

- Employment of excluded providers
- Compared to others we have discussed, this seems like an easy violation to avoid – why is it such a prevalent issue?

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Scenario 1

- Pathways Counseling Center (PCC) is a Minnesota mental health agency providing services to children and adults. PCC is an enrolled provider in both Medicaid and Medicare.
- MN Medicaid restricts reimbursement to time spent providing face-to-face services with the patient and prohibits reimbursement for a therapist's time completing paperwork. In addition, patient care must be clinically supervised by a licensed therapist, like a social worker or psychologist, to ensure that the services being paid for by taxpayers are appropriate and medically necessary.
- Similarly, Medicare does not permit reimbursement for report preparation time and requires that services be provided directly or incident to the services of an appropriately licensed professional.

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Scenario 1 (cont'd)

- The majority of PCC's workforce consists of social work and psychology graduate students. The agency pays a local psychiatrist to serve as a part-time clinical director. However, the psychiatrist does not provide direct care to PCC clients. Instead, he will send any clients requiring ongoing medication management to his private practice for treatment.
- Further, the psychiatrist does not meet with the graduate students to provide clinical supervision. Instead, a PCC administrator signs the students' progress notes that serve as the basis for billing the Medicaid and Medicare Programs.
- PCC also has a practice of routinely adding an extra billable unit for paperwork time for each client visit and representing that the unit was spent in face-to-face therapy time with the client.

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Scenario 1 (cont'd)

- PCC's management is preparing the agency to be sold to a large, national provider of mental health services. The agency hires a new compliance manager to oversee the agency's day-to-day operations as well as the due diligence requests of potential buyers.
- While reviewing the client charts and billing records, the compliance officer discovers that the graduate students are largely unsupervised, that the contract between the agency and the psychiatrist expired two years ago, and that the agency has been billing clinical time for completion of paperwork. She conducts an internal investigation and reports her findings to the agency CEO, who contacts the agency's outside counsel.

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Questions for Discussion

- What are the issues?
- What are the key considerations for the in-house compliance officer in this scenario?
- What are the key considerations for outside counsel in this scenario?
- What options does PCC have to correct this matter?
- Is self-disclosure an option? If so, for what issues? To whom?
- If PCC discloses this matter to the OIG, how will the government analyze this scenario? Will there be any coordination with the MN Medicaid agency, should PCC disclose this situation?

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Scenario 2

- Mark is the compliance officer for a multi-hospital health system in New York. Two of the hospitals have skilled nursing units that serve patients who have been discharged from the hospital and need additional care before returning home. The SNF is an enrolled provider with both Medicare and Medicaid. Mark has included a project on his 2018 work plan to review payments for ambulance transports, as he knows this is an issue on the OIG Work Plan.
- As part of his review, Mark requests copies of the contracts with the ambulance providers that service the SNF, as well as a copy of payment records.

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Scenario 2 (cont'd)

- In reviewing the invoices and payment history for ambulance transports, Mark notices that some transports are charged at nominal amounts, while others cost significantly more.
- Mark schedules a meeting with the health system's finance department to review the invoices and different payment amounts. During that meeting, he learns that the health system has negotiated a fee structure requiring the two primary ambulance vendors to provide a 75% discount for patients with commercial insurance in exchange for a guarantee that the health system will refer all federal health care program patients to these transport companies.
- Mark reaches out to his colleague in the health system's legal department to discuss his findings and determine the next steps.

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Questions for Discussion

- What are the issues?
- What are the key considerations for the in-house compliance officer in this scenario?
- What are the key considerations for in-house legal counsel in this scenario?
- What options does the health system have to address this matter?
- Is self-disclosure an option? If so, to whom?
- If the health system discloses the matter to the OIG, how will the government analyze this scenario? Will there be any coordination with the NY Office of the Medicaid Inspector General, should the health system choose to self-disclose?

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Questions?



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