

Health Care Compliance Association
Clinical Practice Compliance Conference

Compliance Essentials: Internal Investigations and Self-Disclosures

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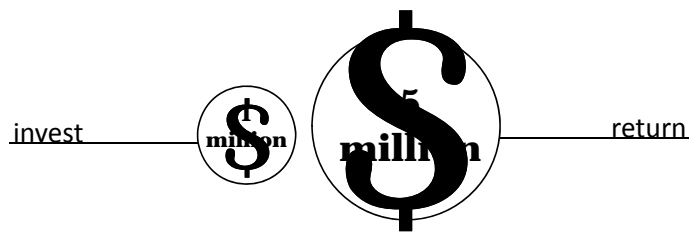
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Government Emphasis on Fraud

Prosecuting "fraud" is good business



In January 2017, an HHS report stated that for every \$1
invested in OIG, DOJ and FBI investigations related to health
care fraud in the past three years, \$5.00 was returned

The Stark Law

Strict Liability: *not-intent based*

It is a civil offense for:

1 A physician or immediate family member

2 to have a financial relationship with an entity

3 and refer to the entity

4 for designated health services

unless an exception applies

The Stark Law

- **The Stark Law is strict liability**
 - No intent required
 - Prohibited relationship is *per se* improper
 - There are exceptions based on the type of relationship
 - Must meet all of the elements of an exception
- **Significant Penalties**
 - Up to \$24,253 for each service
 - Up to \$161,691 for a circumvention scheme
 - Refund of actual damages
 - Possible imposition of CMPs/potential for exclusion
 - *Predicate for a False Claims Act suit*



Anti-Kickback Statute

Intent-based Statute: *One Purpose Test*

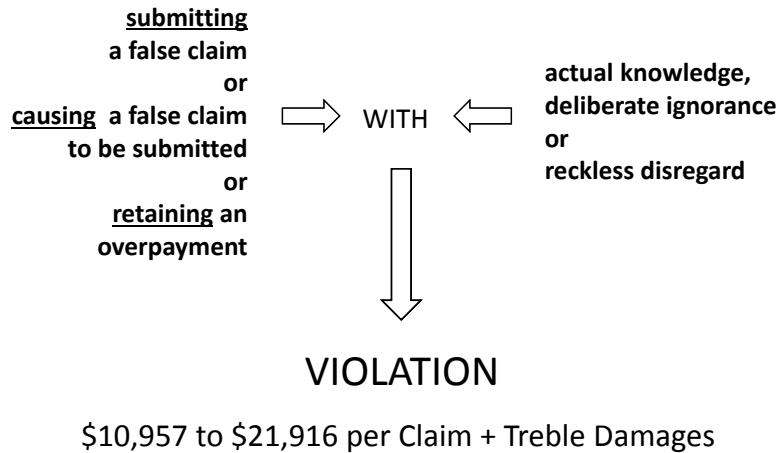
It is a civil or criminal offense for a provider to:

- | | | | |
|-------------------------------|---|--|--|
| 1 | 2 | 3 | 4 |
| Knowingly
and
willfully | solicit,
receive,
offer or
pay | remuneration,
directly or
indirectly,
overtly or
covertly, in
cash or in kind | for referring
or arranging
Medicare or
Medicaid
services |

Anti-Kickback Statute

- The AKS is intent-based – any “one purpose”
 - There are safe harbors that can protect some referral arrangements
 - Each element must be met for absolute protection
 - Compliance is not mandatory but best practice to avoid government scrutiny
 - Perfect compliance is often difficult
 - Penalties
 - Fines up to \$25,000
 - Up to 5 years imprisonment
 - Potential for exclusion
- Both parties to a prohibited kickback are liable

False Claims Act



Penalties and Extrapolation

- Up to treble (3x) damages
- For matters brought after August 1, 2016 for conduct after November 2, 2015
 - Per-claim penalties between \$10,957 and \$21,916
- DOJ uses statistical sampling to establish liability and damages
- Small, but statistically valid, sample sizes are becoming the norm

Scienter Requirements

- **Simply submitting a false claim is not enough**
- The FCA requires a false claim to be **knowingly** submitted (or overpayment retained)
- Knowledge can be shown by evidence of:
 - *Actual knowledge;*
 - *Deliberate ignorance of truth or falsity; or*
 - **Reckless disregard for truth or falsity**

Falsity

- **Factual Falsity:** Lies about goods or services rendered
 - Service billed for but never provided
 - Worthless Services
- **Legal Falsity:** Good or service provided but in violation of a statutory, regulatory or contractual requirement
 - Upcoding
 - Medically Unnecessary
 - Anti-Kickback or Stark violations

What Is a Compliance Program?

- A compliance program is a program of coordinated efforts designed to:
 - Establish a culture of proactive adherence to health care laws and regulations
 - **Promote prevention, detection and resolution of conduct that does not conform to federal and state law or federal and state payor health care program requirements**

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Anatomy of a Compliance Investigation/Audit

- Knowing When to Perform
- Goals of Review
- Conducting the Investigation/Audit
 - Gather information relevant to the problem
 - Obtain facts
 - Identify potential cause(s) and impact(s)
- Corrective Action
- Follow-up Audits

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Responding to Identified Issues

- Active auditing and monitoring is the sign of a healthy compliance program
- If issues are identified, it is important to ensure timely and effective remedial action
- Failing to timely implement remedial measures from review findings can create additional exposure for the organization (and individuals)

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Initial Corrective Actions

- First priority is to correct the issue going forward as soon as possible
- Initial corrective actions may include:
 - Implementation of bill hold
 - Prospective correction of inappropriate conduct
 - Modification of internal policies
 - Education and/or discipline of employees
 - Monitoring via periodic verification audits
- Continuing to engage in noncompliant activity raises the risks and potential liability
- Correction going forward is mandatory prior to self-reporting

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Additional Corrective Actions

- Once an issue is corrected going forward, then the focus shifts to correcting past issues
- Depending on the type of issue, corrective actions may include:
 - Rebilled claims
 - Corrected reports
 - Voluntary refunds
 - Self-disclosures
- The compliance officer should maintain a compliance log detailing all compliance reviews and corrective actions taken

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Support from Experts and Consultants

- Retain Experts and Consultants (e.g., internal audits)
 - Depending on the type of alleged misconduct or issue (e.g., coding, medical necessity, valuation, etc.), it may be necessary to engage outside experts
 - Consider having legal counsel engage a consultant under the attorney-client privilege and work product doctrine in order to protect communications and work product
 - Counsel should direct the engagement—i.e., a consultant must only act at the direction of counsel and submit conclusions directly to counsel

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Focus on Individuals: Practical Tips

- Ask the difficult questions during an internal investigation under privilege
 - Internal investigation should provide for fact-finding interviews/email review
 - Be sure to give all employees *Upjohn* warnings, clarifying that the company, not the employee, holds the privilege over employee-counsel communications
- Evaluate when disciplinary actions are appropriate
 - Want to balance between a desire to know all facts and potential for whistleblower and showing appropriate, quick action
- Recommend separate counsel for employees when interests diverge
 - Consider options of a joint defense agreement or indemnification for employee's separate counsel

Federal Guidelines Impacting Decisions to Voluntarily Self-Disclose

- The Department of Justice ("DOJ") and other federal agencies implemented initiatives to encourage corporate compliance and self-disclosure through incentive programs
- Federal guidance and initiatives governing self-disclosure continue to evolve
- Former Deputy Attorney General Yates' memorandum on Individual Accountability for Corporate Wrongdoing, issued in 2015, requires a company to provide all facts relevant to its employees' wrongdoing before it can receive cooperation credit

The Yates Memo – 6 Key Factors


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1 Companies will have to turn over information on involved individuals in order to get cooperation credit.
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2 All investigations—both criminal and civil—will start with a focus on individual actors within the company.
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3 Criminal and civil attorneys will work in lockstep on corporate cases, sharing information freely.
- 

4 Line prosecutors need written approval from a senior DOJ attorney before offering protection to individuals.
- 

5 Individual actions have to be resolved (or have a resolution plan) before corporate actions can be resolved.
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6 Civil actions will be pursued against culpable individuals, even if they can't pay a substantial fine.

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Impact of the 60-Day Refund Rule

- **FERA** imposed False Claims Act liability for knowingly concealing or knowingly and improperly avoiding or failing to return overpayments
- **ACA § 6402(a)**
 - Imposes a deadline for reporting and returning overpayments and notifying the persons to whom the overpayments were returned of the reason for the overpayments in writing
 - Deadline for reporting and returning overpayments is the later of: 60 days after the date the overpayments are identified; or, the date any corresponding cost reports are due, if applicable
- Taken together, FERA and ACA create False Claims Act liability for failing to report and return identified overpayments within 60 days of when the overpayments are identified

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Impact of the 60-Day Refund Rule

- An overpayment is "identified" when the person has, or should have: (1) through the exercise of reasonable diligence, determined that the person has received an overpayment; and (2) quantified the amount of the overpayment
 - Reasonable diligence includes both (1) proactive compliance activities and (2) reactive investigations conducted in a timely manner in response to credible information of a potential overpayment
- An investigation is considered "timely" if completed within 6 months from the date upon which credible information indicating there may be an overpayment was received (barring extraordinary circumstances)
- CMS now has 6-year look back period for investigations

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Key Benefits of Self-Disclosure

- Discharges the provider's legal obligation to refund overpayments
- Much more favorable results than if issue escalates into a governmental investigation
- Decreases risk of whistleblowers
- Impact on settlement damages and imposition of Corporate Integrity Agreements
- Depending on the self-disclosure approach, may preclude a later *qui tam* case
- Confirms the effectiveness of the Compliance Program if the provider commits to paying back overpayments

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Before Proceeding with Self-Disclosure...

- Remember, issue not ripe for self-disclosure until fixed going forward...
 - BUT, important to take a thoughtful, reasoned approach
 - Don't rush into it
- Important to manage expectations
 - Investigation and self-disclosure process takes time
 - Time for resolution varies by approach taken
 - Need to follow appropriate steps

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Four Self-Disclosure Strategies - #1

Voluntary Refund to Program Payer Representative

- Most common and low profile approach for simple billing/coding mistakes creating inadvertent overpayments
- May be an option to refund program overpayments from problematic physician referrals under Stark
- Refund by check/cover letter or through on-line process depending on age of claim
- Some submissions could be referred for enforcement
- No release from future enforcement related to the disclosed activity

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Four Self-Disclosure Strategies - #2

CMS Self-Referral Disclosure Protocol (SRDP)

- For perceived problematic financial relationships with referring physicians under Stark
- Suspends provider obligation to refund overpayments within 60 days
- Current SRDP requires 6-year lookback period
- Lengthy process
- As of June 1, 2017, must use the new SRDP form
 - Intended to “streamline and simplify” the SRDP process but has its own challenges
- CMS reserves right to refer matters to OIG or DOJ
- No real “negotiation” or explanation of amounts
- Includes a release of claims only from CMS authorities

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Four Self-Disclosure Strategies - #3

OIG Provider Self-Disclosure Protocol (SDP)

- For actual or potential violations of the Anti-Kickback Statute, the CMP law or the False Claims Act
- Releases under Stark and Anti-Kickback Statute may be important depending on arrangements in question
- Also suspends 60-day refund obligation
- Typically a faster and more predictable process
 - Reaffirms presumption against requiring a CIA
 - Recognizes standard 1.5 multiplier
 - Damages based on remuneration approach
- Includes a release of claims from appropriate authorities
- Publication

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Four Self-Disclosure Strategies - #4

Local United States Attorney's Office (USAO)

- On occasion, providers may self-disclose to USAO directly
- Differing local USAO positions on receipt and acceptance of self-disclosures
- USAO will normally seek input from OIG/CMS anyway
- May present opportunities to agree upon time frames for investigations, scope, etc.

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The Three “Cs” of Effective Self-Reporting

- Credibility of the provider
- Claims data: accurate and complete
- Corrective action: did the provider fix the problem and make timely and adequate restitution

To the government, the most compelling case for mitigation occurs when the provider comes forward on its own and effectively self-reports

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Case Study: Physician Overpayment

A routine compliance audit reveals numerous overpayments for Physician A. Compliance recommends repayment of the overpayments. The physician is compensated on a wRVUs basis. Legal is consulted to determine if the repayment will impact the wRVUs paid to Physician A's compensation. The repayment does impact Physician A's compensation. Management for the employed physician group has expressed reluctance in asking the physician to pay back the overpayment and/or reducing the physician's wRVU compensation.

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Case Study: Documentation Deficiencies

An anonymous complaint was received on skilled nursing facility's compliance hotline. The caller raised concerns about patients routinely not receiving the required hours of therapy. A compliance audit reveals numerous issues not only in terms of the hours of therapy, but also deficiencies in documentation. For example, charts lacked required physician certifications and recertifications for Medicare patients, as well as progress notes that were not properly authenticated by the treating physician. This is not the first time the facility has received a complaint about therapy hours.

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How Compliance Counsel Can Help

- Disclosure questions involve high potential risks
- Requires individual evaluation of the circumstances and issues involved
- No hard-and-fast rules regarding when and how to disclose
- Guidance from counsel, under the attorney-client privilege, can be vital in determining whether and how to disclose noncompliance with government rules and guidelines
- The attorney-client privilege can also be used to protect internal compliance reviews if they are done at the direction of counsel

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Key Takeaways

- Self-disclosure can be the best preventive medicine to minimize compliance exposure and keep the government off your doorstep
- Fix identified issues first!
- Develop reasonable argument for starting the 60-day clock based on overpayment identification
- Determine most appropriate self-disclosure avenue based on nature of perceived violation
- Disclose all related and compromising facts for purposes of release
- Try not to piece-meal self-disclosures
- Importance of transparency and cooperation
- Accuracy of underlying claims and other data
- Self-promote and make sure government knows about the effectiveness of your Compliance Program

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