

# Compliance Essentials: Internal Investigations & Self-Disclosures

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## Government Emphasis on Fraud

- Prosecuting “fraud” is good business
- HHS reported in FY 2019:
  - Federal government won or negotiated over \$2.6B in health care fraud judgments and settlements.
  - For every \$1 invested in OIG, DOJ and FBI investigations related to health care fraud in the past three years, \$4.00 was returned.

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# Agenda

- Enforcement Laws
- Internal Investigation Process & Considerations
- Self-Disclosure Options

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# Enforcement Laws

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# The Stark Law

Strict Liability: *not intent-based*

It is a civil offense for:

**1**  
A  
physician  
or  
immediate  
family  
member

to have  
financial  
relationship  
with an  
entity

and  
refer to  
that  
entity

for  
designated  
health  
services

*unless an exception applies*

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# 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 \$25,372 (in 2019) for each service
  - Up to \$169,153 for a circumvention scheme
  - Refund of actual damages
  - Possible imposition of CMPs/potential for exclusion
  - May be used as a predicate for a False Claims Act suit (i.e., bootstrapping)

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# The Anti-Kickback Statute

Intent-based Statute: *One Purpose Test*

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

**1**  
Knowingly  
and  
willfully

**2**  
*solicit,*  
*receive,*  
*offer or*  
*pay*

**3**  
remuneration,  
directly or  
indirectly,  
overtly or  
covertly, in  
cash or in kind

**4**  
for referring  
or arranging  
Medicare or  
Medicaid  
services

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# 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
  - Treble damages, plus up to \$102,522 (in 2019) per kickback
  - Up to 5 years imprisonment
  - Potential for exclusion
  - Both parties to a prohibited kickback are liable

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## False Claims Act

- A violation can occur if a person/entity:
  - Knowingly presents, or causes to be presented, a false or fraudulent claim for payment
  - Knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money to the government
- Severe criminal and civil penalties
  - Up to \$22,927 (in 2019) per claim + treble damages
- Whistleblowers can file qui tam actions on behalf of the government

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## Scienter Requirements

- Simply submitting an inaccurate 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

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# Falsity

- Factual Falsity: Incorrect statements 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 or regulatory requirement
  - Up-coding
  - Medically Unnecessary
  - Anti-Kickback or Stark violations

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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 lookback period for investigations

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## Internal Investigation Process & Considerations

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# 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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## Reasons to Conduct an Internal Investigation

- Learn facts relevant to a government investigation
- Demonstrate an effective compliance program
- Respond to an allegation (via hotline, in person, etc.)
- Understand internal controls and processes
- Follow up on an internal audit and expected remediation

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## Conducting an Internal Investigation

- Understand how the issue was raised (hotline, routine audit, external audit, etc.)
- Define scope of investigation/issue and refine as appropriate
- Determine whether legal (in-house or outside) needs to be involved
  - If yes, ensure investigation is under privilege
- Develop an investigative work plan involving materials and witnesses
- Conduct the investigation and document
- Implement corrective action
- If applicable, circle back with individual who reported issue
- Report to government if necessary

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## How Legal Counsel Can Help

- Serves as a key partner to Compliance on internal investigations
- 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 legal 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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## Responding to Identified Issues

- 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:
  - Rebilling claims
  - Correcting 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

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## 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 (and subsequently modified in 2018) highlights the DOJ's focus on individual accountability for senior officials involved in wrongdoing

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## Policy Rationale for Yates Memo

- The Yates Memo demonstrates the DOJ will closely scrutinize individuals who contribute to corporate misconduct and such individuals will not be released from liability via corporate settlements.
- The DOJ believes individual accountability is important to:
  - Deter future illegal activity;
  - Incentivize changes in corporate behavior;
  - Ensure that proper parties are held responsible for their actions; and
  - Promote the public's confidence in the federal justice system

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## After the Investigation

- Ensure investigative file is complete
- Reporting options
  - OIG Provider Self-Disclosure Protocol
  - CMS Voluntary Self-Referral Disclosure Protocol
  - DOJ Self-Disclosure Protocol
  - Attorney General's Office
  - Voluntary Refund
- Audit to ensure issue has been corrected
- Potentially add issue to work plan
- Assess effectiveness of compliance program
- WAIT on government's response if self-report is involved

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## Self-Disclosure Options

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## OIG Self-Disclosure

- Why Disclose?
- When Is It Time to Disclose?
- Where To Disclose?
- How to Disclose and What to Expect?

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## Deciding Where to Disclose

- If you decide there is an overpayment or potential liability, where to report and return:
  - Contractor Refund
  - CMS SRDP
  - OIG SDP
  - State Medicaid agencies
  - DOJ

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## OIG Self-Disclosure Protocol Basics

- Created in 1998 and updated in 2013
- Approximately 100 submissions per year
- Total Recoveries
  - FY 2019: about \$66 million for self-disclosure CMPs
- Time to Resolution
  - Self-disclosures typically settled within 11 months of acceptance

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## OIG Self-Disclosure Protocol

- What to Disclose
  - Potential violations of criminal, civil, or administrative law for which CMPLs are authorized
- What's Not Eligible
  - Errors or overpayments where no potential violation of CMPL
  - Requests for opinion on whether there is a potential violation
  - Stark-only conduct
  - Settlement less than \$10,000 (\$50,000 for AKS)

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## OIG SDP Resolutions

- Benchmark 1.5 multiplier
  - Claims Calculation
    - All claims or statistical sample of 100 claims minimum
    - Use point estimate (not lower bound)
  - Excluded persons – salary and benefits-based
  - AKS – remuneration-based
- Presumption of no CIA
- Six-year statute of limitations
- Tolling of the 60-day period after submission
- More predictable process, but DOJ may become involved

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## Common Mistakes Providers Make in the OIG Self-Disclosure Protocol

- States in the initial disclosure or at settlement that there is no fraud liability (No admission is required, but the expectation is that there is potential liability. If no potential liability, no release)
- Does not identify potential laws violated
- Discloses the conduct too early
- No plan to quantify damages
- Conduct only violates the Stark law
- Refuses to pay a multiplier
- Lack of cooperation
- Fails to follow SDP's damages calculation guidelines

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# Outcomes: OIG Disclosure Pros and Cons

## Pros

- Legal duty if received overpayment
- Start from positive place
  - Good corporate citizen
  - Effective compliance program
- Can be prepared
- Less disruptive
- Lower multiplier more likely
- Presume no CIA/exclusion
- Closure
- Less reputational effect possible

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# Outcomes: OIG Disclosure Pros and Cons

## Cons

- Some pathways are less predictable than others
- Payment usually necessary
- Not place to get agency's opinion
- Can be long process
- Referrals among agencies possible
- Follow on actions by private insurance or states
- Some publicity still happens

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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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## Critical Elements 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

*The most compelling case for mitigation occurs when the provider comes forward on its own and effectively self-reports*

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## Hypothetical: 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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## Hypothetical: 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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# Key Takeaways

1. Self-disclosure can be the best preventive medicine to minimize compliance exposure and keep the government off your doorstep
2. Instill and maintain a culture of compliance across the organization
3. Encourage communication and be proactive
4. Fix identified issues first!
5. Develop reasonable argument for starting the 60-day clock based on overpayment identification
6. Determine most appropriate self-disclosure avenue based on nature of perceived violation
7. Disclose all related and compromising facts for purposes of release
8. Try not to piece-meal self-disclosures
9. Importance of transparency and cooperation
10. Accuracy of underlying claims and other data
11. Self-promote and make sure government knows about the effectiveness of your Compliance Program

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