



# Healthcare Fraud and Abuse: Responding to Noncompliance

J. Malcolm DeVoy  
Holland & Hart LLP  
(3/30/2023)

This presentation is similar to any other legal education materials designed to provide general information on pertinent legal topics. The statements made as part of the presentation are provided for educational purposes only. They do not constitute legal advice nor do they necessarily reflect the views of Holland & Hart LLP or any of its attorneys other than the speaker. This presentation is not intended to create an attorney-client relationship between you and Holland & Hart LLP. If you have specific questions as to the application of law to your activities, you should seek the advice of your legal counsel.

# Health Law Webinar Series

| Date           | Webinar   |
|----------------|---|
| 3/2/23         | Fraud and Abuse I: The Laws                             |
| 3/16/23        | Fraud and Abuse II: Applying the Laws                   |
| <b>3/30/23</b> | <b>Fraud and Abuse III: Responding to Noncompliance</b> |
| 4/13/23        | Telehealth  |
| 4/27/23        | EMTALA  |
| 5/11/23        | Reproductive Rights                                     |
| 5/25/23        | Nondiscrimination Rules                                 |
| 6/1/23         | HIPAA and Patient Privacy                               |

<https://www.hollandhart.com/events>

# Supplemental Resources

- .PPT slides
- OIG, *Health Care Fraud Self-Disclosure Protocol*:  
<https://oig.hhs.gov/documents/self-disclosure-info/1006/Self-Disclosure-Protocol-2021.pdf>
- CMS, *Voluntary Self-Referral Disclosure Protocol*:  
<https://www.cms.gov/medicare/fraud-and-abuse/physiciansselfreferral/downloads/cms-voluntary-self-referral-disclosure-protocol-original.pdf>

# Limitations

- This is a quick overview of the most relevant federal laws and regulations applied to common scenarios. Your state's laws may impose other or different additional requirements.
- No two scenarios are exactly alike: course of action depends on facts and circumstances, payor involved (federal program versus commercial insurance versus self-pay), and the applicable laws.
- Be sure to confirm which laws apply when evaluating your particular situation.
- Questions?
  - Use webinar chat feature, or
  - Email me: [jmdevoy@hollandhart.com](mailto:jmdevoy@hollandhart.com)

# Key Fraud and Abuse Laws

- Healthcare fraud and abuse laws can trigger a wide range of liability, civil penalties, and even criminal consequences.
- Anti-Kickback Statute
  - 42 U.S.C. § 1320a-7b; safe harbors: 42 C.F.R. § 1001.952
- Eliminating Kickbacks in Recovery Act
  - 18 U.S.C. § 220
- Ethics in Physician Referrals Act (“Stark Law”)
  - 42 U.S.C. § 1395nn; exceptions: 42 C.F.R. §411.350 – §411-389
- Civil Monetary Penalties Law
  - 42 U.S.C. § 1320a-7a
- State Law Analogues

# Fraud and Abuse Penalties

- Organizational consequences are significant, up to Medicare exclusion and forcing business or facility closure or sale.
- Civil fines/penalties for Stark Law violations:
  - \$26,000+ *per claim*.
  - Circumvention scheme: \$170,000+
  - Can quickly become millions.
- Anti-Kickback Statute:
  - Criminal fines of \$100,000 per violation.
  - Civil penalties of \$104,000 or more per violation.
  - Jail terms of up to 10 years (increased from 5).
  - Penalties increased as result of 2018 bipartisan budget act.
- CMPL:
  - Civil liability for kickbacks or improper payments.
  - Treble (3x) damages for improper payments.

# Common State Laws and Regulations

- False claims acts
- Anti-kickback statutes
- Self-referral prohibitions
- Fee splitting prohibition
- Disclosure of financial interests
- Insurance statutes
- Medicaid conditions of participation
- Fraud or misrepresentation
- Consumer protection laws
- Laws regarding billing
- Bribery
- Others?

## Penalties

- Civil penalties
- Criminal penalties
- Adverse licensure action
- Other

## Beware:

- May apply to private payers in addition to govt programs.
- May not contain the same exceptions or safe harbors as federal statutes



# How Noncompliance Happens

- Inadequate training or training that is incomplete or not up-to-date.
- Employee error, inattention, or overwhelm.
- Oversight – harmed by what one does not know.
- Vendor conduct.
- Employee misconduct.

# Examples of Noncompliance

- Employee fails to disclose, or is not asked, about a family member with a referral relationship for designated health services under the Stark Law.
- Employee paying for referrals, in cash or in kind (e.g., meals, gift cards), to generate more business.
- Employee covertly receives cash payments for referral of patients.
- Provider or biller up-coding charges or adding charges for ancillary services not performed (or mischaracterizing services performed).

# Discovering Noncompliance

- Confirming employee or vendor credentials.
- Background checks / credit checks (state and federal laws add steps to this process and may vary from state to state).
- Audit and audit-like safeguards:
  - Make employees take vacation!
  - Look for unexplained transactions and lack of internal controls: why are certain things done the way they are?
- Using information lawfully received:
  - Request for information regarding mortgage financing
  - Legal process received (e.g., service of lawsuits, notices, wage garnishments, etc.)
- Utilization reviews, claims reviews, and internal review organizations are helpful if financially feasible.

# Compliance: A Moving Target

- Standards for compliance frequently changing.
- Changes to coding, billing (including modifiers), bundling, and the fee scale.
- Proposed rulemaking important to follow, but final rule can vary drastically – often with time to prepare for and implement needed changes.

# Example of Recent Rule Change: Overpayment Rule

- CMS's 60-day overpayment rule
  - 60-day overpayment rule based in statute: an overpayment must be reported and returned within 60 days after “the date on which the overpayment was identified[.]” 42 U.S.C. § 1320a-7k(d)(2).
  - The lawyers ask: “when and how is an overpayment identified?”
  - CMS responds with rulemaking:

A person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment.

42 C.F.R. § 401.305(a)(2).

# Example of Recent Rule Change: Overpayment Rule

- CMS's 60-day overpayment rule
  - The rule to identify overpayments leads to more confusion and uncertainty about identifying overpayments – and that failing to identify an overpayment can be evidence that the person “knew” of an overpayment.
  - Proposed new rule is more favorable:
    - Still requires repayment of overpayments within 60 days of discovery, but
    - The standard for identifying an overpayment is higher and requires “knowingly” receiving or retaining an overpayment, as that term is defined in the False Claims Act, 31 U.S.C. § 3729(b)(1)(A).
  - If adopted, new rule gives providers flexibility and replaces diligence standard with more established standard of “knowledge” under the False Claims Act.

# Self-Disclosure

- HHS, through OIG, and CMS have self-disclosure protocols (“SDPs”) for violations of health care fraud laws.
- The OIG and CMS SDPs have undergone revisions within the last 2 years, but both programs have been along much longer.
- SDPs have certain similarities with HIPAA disclosure requirements to HHS Office for Civil Rights (“OCR”), but also share similarities with the DOJ’s established self-disclosure tools for the Foreign Corrupt Practices Act (“FCPA”).
  - While FCPA is different from AKS, CMPL, and Stark, data show that self-reporting can significantly reduce penalties where material noncompliance occurred.
  - <https://fcpa.stanford.edu/sullcrom-research-and-reports.html>

# OIG Self-Disclosure

- OIG Self Disclosure
  - Disclosure for violations of AKS and CMPL, as a violation of the AKS is itself a violation of the CMPL
  - HHS SDP is periodically updated and last updated in November 2021; previously, the SDP was updated in 2013.
  - Not all incidents or non-compliance is reportable to OIG. Stark Law violations are reported to CMS, which are covered separately.
  - SDP documents are submitted online for use by OIG.



# OIG Self-Disclosure

- **OIG SDP Considerations**
  - **OIG reports settlement data that can be used to determine how a claim may be evaluated and treated:**  
<https://oig.hhs.gov/Fraud/enforcement/cmp/psds.asp>
  - **Benefits include:**
    - Avoids qui tam actions
    - May reduce penalties and avoid possible criminal liability.
  - **Risks include:**
    - **OIG may conduct an investigation anyway.**
    - **Failure to cooperate or fully disclose may result in worse penalties than those originally reported.**
    - **Fulsome disclosure is burdensome and may become public, in whole or in part.**
    - **Penalties, while potentially reduced, are determined by OIG and may include exclusion.**

# CMS Self-Disclosure

- Overpayments, including Stark Law violations, are reported to CMS through its SDP.
- CMS self-disclosure is similar to but distinct from OIG, as it affects civil conduct only—not the criminal acts implicated by AKS—and Stark is fundamentally a payment statute.
- Based on the overpayment rule, CMS's SDP submission must be made within 60 days of discovering the overpayment(s) to be disclosed.
- Slightly different procedures for group practices (as defined by Stark), individual physicians, and physician-owned hospitals.
- Risks and benefits comparable to OIG self-disclosure.

# CMS Self-Disclosure

- Stark Law SDP settlements: last five years for which data is available.

| Calendar Year | Number of Disclosures Settled | Range of Amounts of Settlements | Aggregate Amount of Settlements |
|---------------|-------------------------------|---------------------------------|---------------------------------|
| 2016          | 103                           | \$80-\$1,195,763                | \$6,962,988                     |
| 2017          | 48                            | \$83-\$575,680                  | \$3,876,588                     |
| 2018          | 36                            | \$600-\$1,196,188               | \$3,663,100                     |
| 2019          | 17                            | \$269-\$280,068                 | \$1,025,507                     |
| 2020          | 34                            | \$33-\$191,755                  | \$4,303,980                     |
| <b>Totals</b> | <b>369</b>                    | <b>\$33 - \$1,196,188</b>       | <b>\$36,127,397</b>             |

# What To Know When Self-Disclosing

- Self-Disclosure may lead to government investigation similar to any other inquiry, and comparable to an investigation the government would conduct if it identified the noncompliance on its own.
- This may result in subpoenas, including to third parties such as vendors, contractors, banks, and other service providers.
- Demands may include interviews of personnel, documents, and other information the government would use to review its claims and evaluate the completeness—and potential response—to self-disclosure.

# What To Know When Self-Disclosing

- Participation in SDP, and particularly with OIG, as it may make referrals to DOJ and other components based on what it finds, should be viewed like a government investigation. Steps and considerations include:
  - Recommend aggressive compliance to show absence of wrongdoing and willingness to comply with government demands.
  - Retain and prevent from destruction relevant documents.
  - Never retaliate against whistleblowers.
  - Assume anything in writing—past documents, financial records, e-mails, and text messages—will be discovered.
  - This list is not exhaustive.

# Compliance Programming

- Trite, but true: the best defense is a good offense.
- Training on compliance updates and issues at least annually.
  - Those responsible for claims or billing at any phase should be aware of changes to the fee schedule, modifiers, and codes – chasing rejected claims can lead to noncompliance.
  - Employees involved in revenue cycle should also be aware of overpayment return requirements and any changes.
  - Proposed rule changing the standard for knowing of an overpayment is promising, but not final.

# Compliance Programming

- Indicia of an effective compliance program; elements should be tailored to suit your organization.
  - Chief compliance officer / compliance committee
  - Written and regularly updated policies and procedures
  - Open lines of communication and lines of reporting (e.g., compliance personnel should report to the executive or operations officer, not necessarily the financial officer)
  - Training, education, auditing and monitoring
  - Responding to non-compliance with corrective actions
  - Discipline for employees, up to and including termination
- OIG resources: <https://oig.hhs.gov/compliance/compliance-guidance/index.asp>

# Health Law Webinar Series

| Date           | Webinar  |
|----------------|--|
| 3/2/23         | Fraud and Abuse I: The Laws                      |
| 3/16/23        | Fraud and Abuse II: Applying the Laws            |
| 3/30/23        | Fraud and Abuse III: Responding to Noncompliance |
| <b>4/13/23</b> | <b>Telehealth</b>                                |
| 4/27/23        | EMTALA   |
| 5/11/23        | Reproductive Rights                              |
| 5/25/23        | Nondiscrimination Rules                          |
| 6/1/23         | HIPAA and Patient Privacy                        |

<https://www.hollandhart.com/events>



# Questions?

J. Malcolm DeVoy

(Las Vegas)

Holland & Hart LLP

Office: (702) 669-4636

[jmdevoy@hollandhart.com](mailto:jmdevoy@hollandhart.com)