Responding to Noncompliance

Curing, Reporting and Repaying Overpayments

Kim C. Stanger

(9.24)

Holland & Hart

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.

Caution

- This is a quick overview of relevant federal laws and regulations.
  - Beware other laws, including state laws.
- Application may depend on—
  - Circumstances of your particular case.
  - Payer involved (e.g., govt, insurer, patient).
  - Jurisdiction.
- Be sure to confirm applicable laws and requirements when applying law to your facts.

Non-Compliance

- If you want govt money, you must comply with govt conditions.
  - Billing rules
  - Conditions of payment or participation
  - Fraud and abuse laws
- Failure to comply with conditions may result in:
  - Repayment obligation.
  - Additional penalties.

Key Fraud and Abuse Laws

- False Claims Act
- Anti-Kickback Statute ("AKS")
- Eliminating Kickbacks in Referrals Statute ("EKRA")
- Ethics in Physician Referrals Act ("Stark")
- Civil Monetary Penalties Law ("CMPL")

False Claims Act

- Prohibits knowingly and improperly avoiding an obligation to pay or transmit money or property to the govt.

(31 USC 3729(a)(1)(G))

- "Obligation" = means a duty to repay the govt arising from statute or contract or "retention of any overpayment."

(31 USC 3729(b)(3))

- Statute of limitations:
  - 6 years from false claim or failure to pay, or
  - 3 years from the time the govt knew about it, but no more than 10 years from false claim.

(31 USC 3731)

Penalties

- Up to $24,947* per violation.
  - *Each overpayment constitutes a separate violation.*
- 3x damages incurred by govt.
- Costs of litigation.
- *Qui tam* lawsuit.

(31 USC 3729; 45 CFR 102.3*)

Civil Monetary Penalties Law

If a person has received an overpayment, must report and repay to relevant govt agency, intermediary or contractor within the later of:

- 60 days after the overpayment is identified; or
- Date corresponding cost report is due.

(42 USC 1320-7k(d))

- 6 –year lookback period.

(42 CFR 401.305)

Penalties

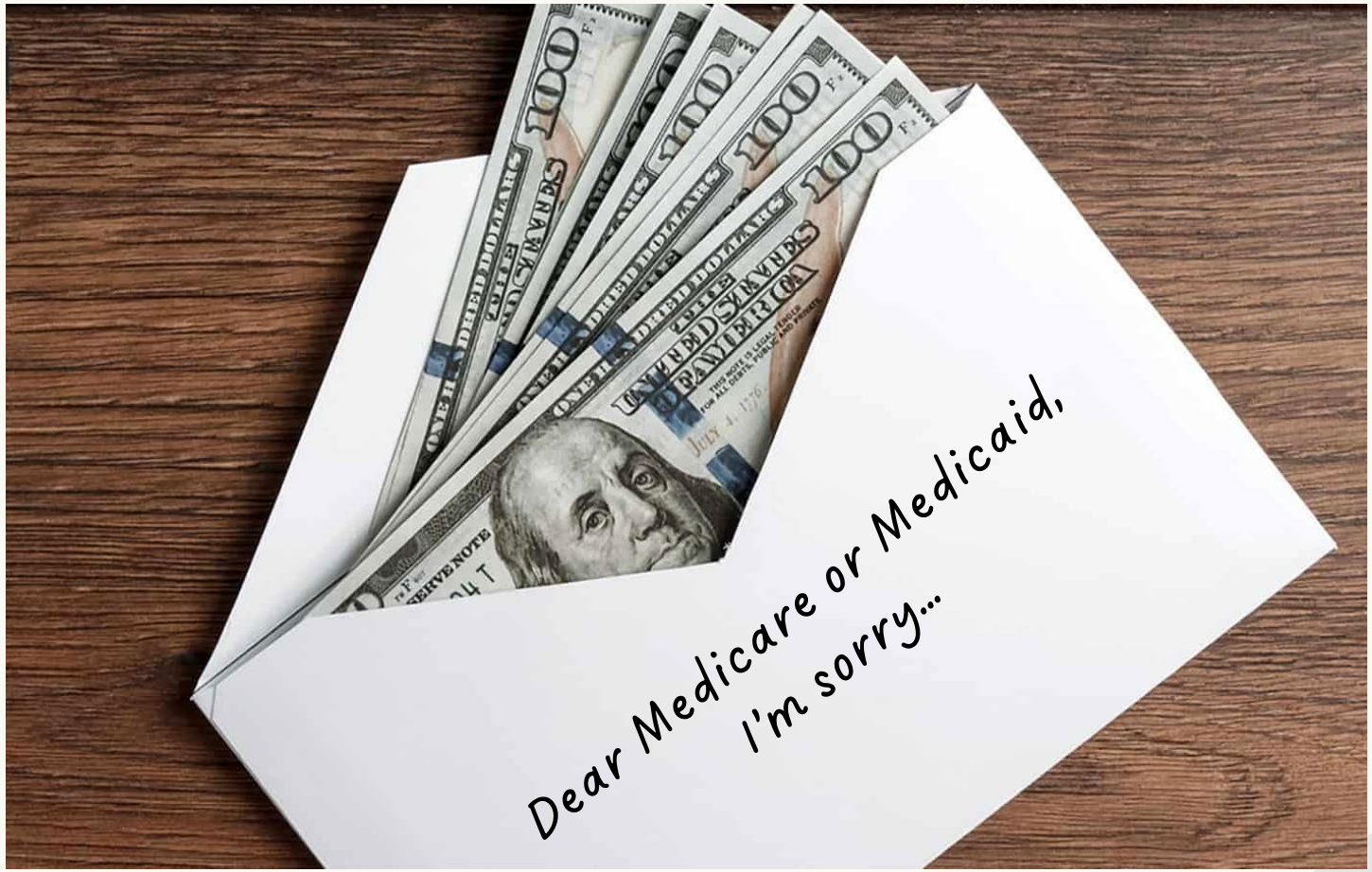
- $24,947* penalty
- 3x damages incurred by govt
- Exclusion from Medicare or Medicaid

(42 USC 1320a-7a(a)(10); 42 CFR 1003.210(a)(8); 45 CFR 102.3*)

Report and Repay Processes

- CMS Report and Repay Rule
  - Requirements
  - Repayment Rule
- Ethics in Patient Referrals Act ("Stark")
  - Requirements
  - Self-Referral Disclosure Protocol
- Anti-Kickback Statute
  - OIG Self-Disclosure Protocol
- Other?

CMS Report and Repay Rule



CMS Report and Repay Rule

Implements the Civil Monetary Penalties Law.

- "A person that has received an overpayment must report and return the overpayment in the form and manner set forth in this section.
- "A person who has received an overpayment must report and return the overpayment by the later of either of the following:
  - (i) The date which is 60 days after the date on which the overpayment was identified; or
  - (ii) The date any corresponding cost report is due, if applicable."

(42 CFR 401.305(1))

Report and Repay Rule: "Overpayment"

- "Overpayment" = "funds that a person receives or retains … to which the person, after applicable reconciliation, is not entitled…"

(42 USC 1320a-7k(d)(4); 42 CFR 1003.110)

- Examples:
  - Payments for non-covered services
  - Payments in excess of the allowable amount
  - Errors and non-reimbursable expenses in cost reports
  - Duplicate payments
  - Receipt of Medicare payment when another payor is primary
  - Payments received in violation of Stark, Anti-Kickback Statute, Exclusion Statute, etc.

Report and Repay Rule: Lookback Period

- "An overpayment must be reported and returned in accordance with this section if a person identifies the overpayment … within 6 years of the date the overpayment was received."

(42 CFR 401.305(f))

- Must look back to overpayments received within prior 6-year period.
- Beware waiting for 6-year lookback period to run…
  - Potential liability under other statutes, including fraud?
  - Potential *qui tam* action?

Report and Repay Rule: "Knowing"

- Person who "knowingly" fails to report an repay by the deadline is liable.

(31 USC 3729(a)(1)(G) and (b)(3); 42 USC 1320a-7a(a)(10); 42 CFR 1003.210(a)(8))

- Under the False Claims Act, "knowing" and "knowingly" =
  - Has actual knowledge of the information;
  - Acts in deliberate ignorance of the truth or falsity of the information; or
  - Acts in reckless disregard of the truth or falsity of the information; and
  - Does not require proof of specific intent to defraud.

(31 USC 3729(b)(1))

Report and Repay Rule: "Identified"

- Must report and repay within 60 days after the date on which the overpayment is "identified"
  - "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 CFR 401.305(a)(2), emphasis added)

Overpayments: "Identified"

- Under current rule, an overpayment is "identified" if have either:
  - Actual knowledge, or
  - Should have known through exercise of "reasonable diligence", including
    - Proactive monitoring.
    - Reactive investigations.
- Providers have duty to investigate if receive credible info re potential overpayment, e.g.,
  - Significant and unexplained increase in Medicare revenue.
  - Review of bills shows incorrect codes.
  - Discover services rendered by unlicensed provider.
  - Internal or external audit discloses overpayments.
  - Discover AKS, Stark or CMPL violation.

(81 FR 7659-61)

Report and Repay: "Identified" – 2022 Proposed Rule

- Replaces "reasonable diligence" standard with "acts in reckless disregard or deliberate ignorance of the overpayment."
  - Aligns with False Claims Act.
  - Responds to 2018 case in which court held "reasonable diligence" standard improperly made providers liable for negligent conduct contrary to False Claims Act standards.

(87 FR 79559)

- Under the 2022 proposed rule, "[a] person has identified an overpayment when the person knowingly receives or retains an overpayment," i.e.,
  - Has actual knowledge of the information;
  - Acts in deliberate ignorance of the truth or falsity of the information; or
  - Acts in reckless disregard of the truth or falsity of the information.

(87 FR 79560, 79708)

Overpayments: Time to Investigate

- Under current rule, have up to 6 months to investigate + 2 months to report and repay.
  - CMS concluded that provider must show "reasonable diligence", i.e., "timely, good faith investigation of credible information, which is at most 6 months from receipt of the credible information, except in extraordinary circumstances."
  - "Extraordinary circumstances" may include unusually complex investigations, natural disasters or state of emergency.
- Maintain documentation to show "reasonable diligence."

(81 FR 7662)

Report and Repay: Time to Investigate – 2024 Proposed Rule

- Suspends 60-day reporting period up to 180 days if need to timely investigate.
- "(i) The deadline for reporting and returning overpayments will be suspended when both of the following occurs:
  - (A) A person has identified an overpayment but has not yet completed a good-faith investigation to determine the existence of related overpayments that may arise from the same or similar cause …; and
  - (B) The person conducts a timely, good-faith investigation to determine whether related overpayments exist.
- "(ii) If the [foregoing] conditions … are satisfied, the deadline for reporting and returning the initially identified overpayment and related overpayments … will remain suspended until the earlier of:
  - (A) The date that the investigation of related overpayments has concluded and the aggregate amount of the initially identified overpayments and related overpayments is calculated; or
  - (B) The date that is 180 days after the date on which the initial identified overpayment was identified."

(89 FR 66208)

Report and Repay: Time to Investigate – 2024 Proposed Rule

- **Hypothetical:** "[O]n day 1, a person identifies an overpayment arising from a physician's failure to properly document the medical record to support the coding of a specific claim, and the person has reason to believe that this may be a common practice of the physician, so there could be more affected claims. At this point, the person has up to 180 days to conduct and conclude a good faith investigation to determine whether related overpayments that arise from the same or similar cause or reason as the initially identified overpayment exist.
  - If the person does NOT conduct an investigation, or the investigation is not timely or not conducted in good faith, the identified overpayment must be reported and returned by day 60.
  - If the person does conduct a timely, good faith investigation, suspension of the report and return obligation under § 401.305(b)(3) begins on day 1. The suspension ends when the investigation is concluded and the initially identified overpayment and related overpayments, if any, are calculated, or by day 180, whichever is earlier. The overpayment must be reported and returned within 60 days after either completion of the investigation or day 180, whichever is earlier."

(89 FR 62006)

Report and Repay: Suspension of Deadlines

- The deadline for returning overpayment is suspended while:
  - Submission per OIG Self-Disclosure Protocol is pending.
    - Continues while SDP is pending.
  - Submission per CMS Voluntary Self-Referral (Stark) Disclosure Protocol is pending.
    - Continues while SRDP is pending.
  - Obtain extended repayment schedule.
    - Continues until contractor rejects request or provider fails to comply.

(42 CFR 401.305(b)(2))

Report and Repay: Reporting

- Use the appliable claims adjustment, credit balance, self-reported refund or other reporting process set forth by applicable Medicare contractor.
  - Check Medicare contractor website.
  - If used statistical sampling, must describe the methodology in the report.
- If settlement reached through SDP or SRDP, comply with the reporting requirements per the settlement.

(42 CFR 401.305(d))

Report and Repay: Reporting

noridian Healthcare Solutions Medicare

Jurisdiction F - Medicare Part B

Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming

Contact Us | Help | Tools | Noridian Medicare Portal (NMP) Login

Search

Browse by Topic | Browse by Specialty | Fees and News | Policies | Medical Review | Education and Outreach | Provider Enrollment | Forms

JF Part B > Browse by Topic > Overpayment and Recoupment

Browse by Topic

- Advance Beneficiary Notice of Noncoverage (ABN)
- Appeals
- Claims
- Clinical Trials
- Compliance Program
- Documentation Requirements
- Drugs, Biologicals and Injections
- Durable Medical Equipment, Prosthetics, Orthotics and Supplies

Overpayment and Recoupment

An overpayment occurs when too much has been paid to a provider and refund to Medicare is necessary.

Overpayments are either communicated to a provider via a Noridian Demand Letter **or** self-reported by a provider. To be in compliance with Medicare policies for reporting and repaying overpayments, selecting the appropriate payment method for each situation is critical.

Is the overpayment Medicare Secondary Payer (MSP) | Non MSP related? Has a Demand Letter issued or is the overpayment is being voluntarily sent in to Noridian? The answer to these will determine which form, if necessary, should be completed and sent.

When determining a payment method, it is important to consider which form to use and the timeliness of when payment must be made.

Bankruptcy - Notify Noridian if you file bankruptcy. View details.

Extended Repayment Schedule (ERS) - Providers may need longer than 30 days to repay full amount of an overpayment. Providers have the option to submit a Request For Extended Repayment Schedule (ERS) Form. View details.

Overpayment: Reporting

- Repayment per Report and Repayment Rule does not resolve violations or penalties under other laws, e.g.,
  - Anti-Kickback Statute, Civil Monetary Penalties Law, or False Claims Act, which are resolved by OIG or DOJ.
  - Stark, which is resolved by CMS.
- If Medicare contractor believes repayment involves violation of federal law, contractor may report repayment to the OIG, CMS, or other federal agency.

Addressing Stark Problems

Stark

- No Medicare/Medicaid payment may be made for a designated health services ("DHS") furnished per referral prohibited by Stark.
- An entity that collects payment for a DHS that was performed pursuant to a prohibited referral must refund all amounts on a timely basis, i.e., within the 60-day period from the time the prohibited amounts are collected by the individual or the entity.

(42 CFR 411.353(c)-(d), referencing 42 CFR 1003.110)

- Stark is a strict liability statute; intent is irrelevant.

<u>Penalties</u>

- FCA penalties discussed above.
- CMPL penalties discussed above.
- $30,868* per violation.
- 3x amount claimed for each DS submitted.
- Exclusion from Medicare/Medicaid.

(42 CFR 1003.300 and -.310*)

- FCA penalties discussed above.
- CMPL penalties discussed above.

Stark

- Verify whether there was actually a violation.
  - Financial relationship between DHS provider and a physician or physician family member.
  - Physician referred DHS.
  - No safe harbor applies.
    - Only need one safe harbor.
    - May use multiple safe harbors to cover different aspects of situation.
  - Check definitions in 42 CFR 411.351.
  - Check special rules in 42 CFR 411.354, e.g., indirect compensation arrangements; grace period to obtain written agreement; agreement amendments; etc.
- Reconcile payments, if possible.

Stark:
90-day Reconciliation Rule

As amended, Stark allows parties to remedy an overpayment/underpayment situation if:

- "(1) No later than 90 consecutive calendar days following the expiration or termination of a compensation arrangement, the entity and the physician (or immediate family member of a physician) … reconcile all discrepancies in payments under the arrangement such that, following the reconciliation, the entire amount of remuneration for items or services has been paid as required under the terms and conditions of the arrangement; and
- "(2) Except for the discrepancies in payments described in paragraph (h)(1) of this section, the compensation arrangement fully complies with an applicable exception in this subpart."

(42 CFR 411.353(h))

Stark:
Claims for Hospital Services

- Stark only applies if there are "referrals" for "DHS":
  - *Was there a referral for DHS as defined in the statute?*

- "For services furnished to inpatients by a hospital, a service is not a designated health service payable, in whole or in part, by Medicare if the furnishing of the service does not increase the amount of Medicare's payment to the hospital under any of the following prospective payment systems (PPS):
  - (i) Acute Care Hospital Inpatient (IPPS);
  - (ii) Inpatient Rehabilitation Facility (IRF PPS);
  - (iii) Inpatient Psychiatric Facility (IPF PPS); or
  - (iv) Long-Term Care Hospital (LTCH PPS)."

(42 CFR 411.351, definition of "DHS")

CMS Voluntary Self-Referral Disclosure Protocol

https://www.cms.gov/medicare/regulations-guidance/physician-self-referral/self-referral-disclosure-protocol

Physician Self-Referral

Spotlight

Advisory Opinions (AOs)

Call Center

List of CPT/HCPCS Codes

CPI-U Updates

Self-Referral Disclosure Protocol

Patient Protection and Affordable Care Act:

Section 6409 of the Patient Protection and Affordable Care Act (ACA) was signed into law on March 23, 2010. Section 6409(a) of the ACA required the Secretary of the Department of Health and Human Services, in cooperation with the Inspector General of the Department of Health and Human Services, to establish a Medicare self-referral disclosure protocol that sets forth a process to enable providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute.

Health care providers of services and suppliers are required to submit all information necessary for CMS, on behalf of the Secretary, to analyze the actual or potential violation of Section 1877 of the Social Security Act (the Act). Providers of services and suppliers must use the forms included in the most recent OMB-approved collection instrument entitled CMS Voluntary Self-Referral Disclosure Protocol (SRDP) in order to utilize the SRDP. Earlier versions of these forms cannot be used.

SRDP

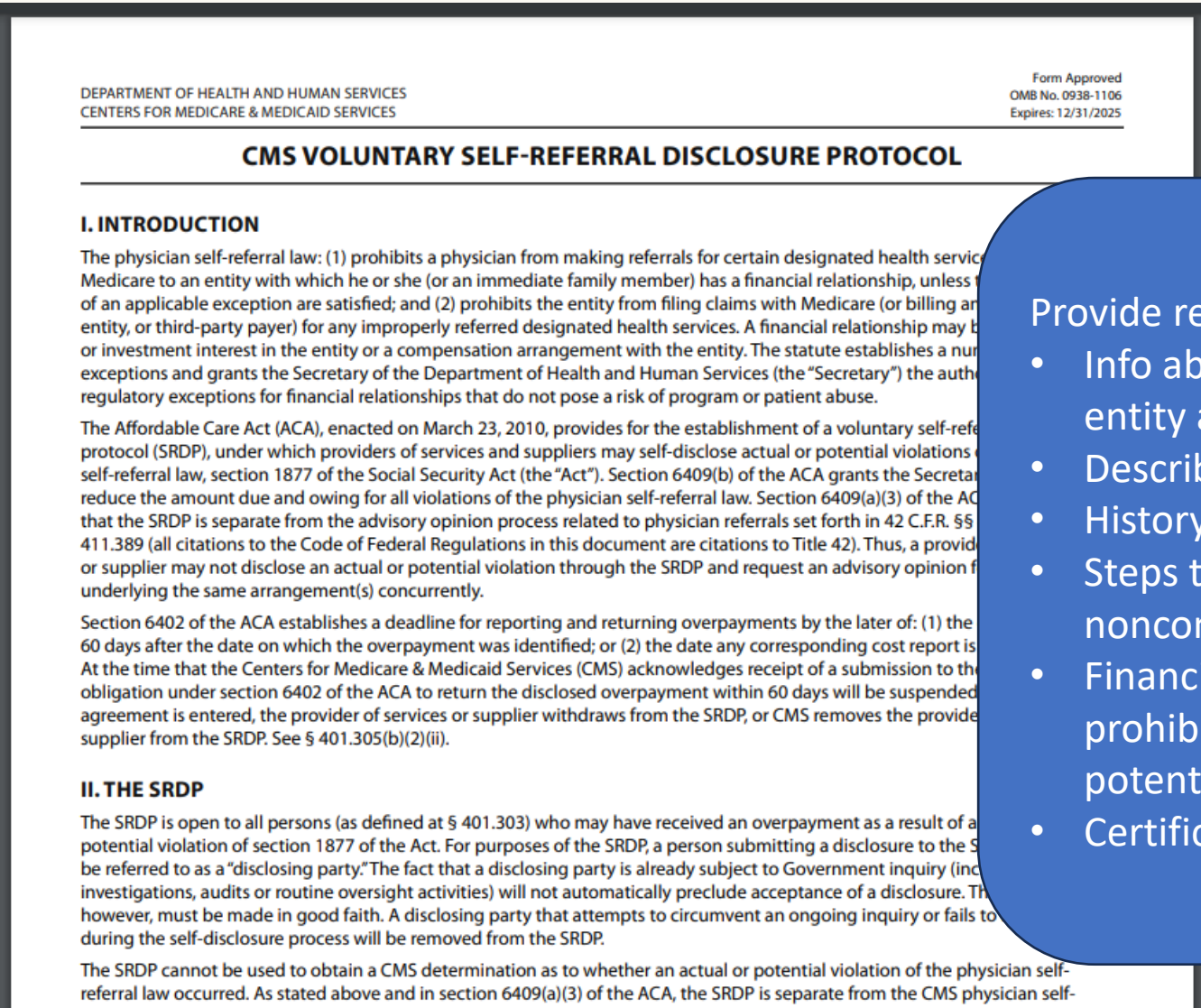
PROS

- Suspends 60-day Report and Repay Rule.
- CMS will likely reduce repayment significantly if fully cooperate in timely manner.
- May preclude *qui tam* lawsuit.
- Allows for finality.

CONS

- No guarantees of reduced penalty.
- May be subject to additional penalties if do not fully cooperate.
- CMS may broaden investigation.
- Disclosure may waive privileges.
- Likely admission of liability.
- May toll FCA statute of limitations.
- CMS may refer to DOJ or OIG.

SRDP



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-1106
Expires: 12/31/2025

CMS VOLUNTARY SELF-REFERRAL DISCLOSURE PROTOCOL

I. INTRODUCTION

The physician self-referral law: (1) prohibits a physician from making referrals for certain designated health servic
Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless
of an applicable exception are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing ar
entity, or third-party payer) for any improperly referred designated health services. A financial relationship may b
or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a nu
exceptions and grants the Secretary of the Department of Health and Human Services (the "Secretary") the auth
regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

The Affordable Care Act (ACA), enacted on March 23, 2010, provides for the establishment of a voluntary self-refe
protocol (SRDP), under which providers of services and suppliers may self-disclose actual or potential violations
self-referral law, section 1877 of the Social Security Act (the "Act"). Section 6409(b) of the ACA grants the Secreta
reduce the amount due and owing for all violations of the physician self-referral law. Section 6409(a)(3) of the AC
that the SRDP is separate from the advisory opinion process related to physician referrals set forth in 42 C.F.R. §§
411.389 (all citations to the Code of Federal Regulations in this document are citations to Title 42). Thus, a provid
or supplier may not disclose an actual or potential violation through the SRDP and request an advisory opinion f
underlying the same arrangement(s) concurrently.

Section 6402 of the ACA establishes a deadline for reporting and returning overpayments by the later of: (1) the
60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is
At the time that the Centers for Medicare & Medicaid Services (CMS) acknowledges receipt of a submission to th
obligation under section 6402 of the ACA to return the disclosed overpayment within 60 days will be suspended
agreement is entered, the provider of services or supplier withdraws from the SRDP, or CMS removes the provide
supplier from the SRDP. See § 401.305(b)(2)(ii).

II. THE SRDP

The SRDP is open to all persons (as defined at § 401.303) who may have received an overpayment as a result of a
potential violation of section 1877 of the Act. For purposes of the SRDP, a person submitting a disclosure to the S
be referred to as a "disclosing party." The fact that a disclosing party is already subject to Government inquiry (inc
investigations, audits or routine oversight activities) will not automatically preclude acceptance of a disclosure. Th
however, must be made in good faith. A disclosing party that attempts to circumvent an ongoing inquiry or fails to
during the self-disclosure process will be removed from the SRDP.

The SRDP cannot be used to obtain a CMS determination as to whether an actual or potential violation of the physician self-
referral law occurred. As stated above and in section 6409(a)(3) of the ACA, the SRDP is separate from the CMS physician self-

Provide requested info, including:

- Info about the disclosing entity and physician.
- Describe noncompliance.
- History of similar conduct.
- Steps taken to prevent future noncompliance.
- Financial analysis of prohibited referrals and potential repayment.
- Certification of accuracy.

SRDP

- Use when you know you have a Stark violation.
  - SRDP is effectively an admission of violation or that you lack facts to confirm compliance.
  - Cannot be used to determine if there was a violation.
    - Compare advisory opinion process.
- Do not make repayments pending SRDP process.
- Following submission, CMS will propose a settlement.
  - "Take it or leave it"; not a negotiation.
  - In past, CMS has been willing to settle for 1% - 3% of potential repayment exposure.
  - By settling, provider waives any appeal rights.
- If provider rejects offer, provider withdraws from the SRDP.

SRDP

- Factors considered by CMS when determining amount owed:
  - Nature and extent of the improper or illegal practice;
  - Timeliness of the self-disclosure;
  - Cooperation in providing additional information related to the disclosure.
- Although CMS may consider these factors in determining whether reduction in any amounts owed is appropriate, CMS is not obligated to reduce any amounts due and owing.

(SRDP at p.5, https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/downloads/cms-voluntary-self-referral-disclosure-protocol-original.pdf)

Self-Referral Disclosure Protocol Settlements

The CMS Voluntary Self-Referral Disclosure Protocol (SRDP) enables providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute. The following table displays settlements to date and will be updated on a yearly basis.

Calendar Year	Number of Disclosures Settled	Range of Amounts of Settlements	Aggregate Amount of Settlements
2011	3	$60 - $579,000	$709,060
2021	27	$631 - $1,110,148	$1,988,451
2022	103	$299 - $1,171,174	$9,287,866
2023	176	$26 - $548,302	$12,560,017
Totals	677	**$26 - $1,196,188**	**$60,004,717**

In 2022 and 2023, CMS worked to clear backlog and encouraged providers to review and, as appropriate, withdraw SRDP's based on new guidance, including the 2021 Stark Rules.

Notes:

As of December 31, 2023, an additional 267 disclosures to the SRDP were withdrawn, closed without settlement or settled by CMS' law enforcement partners.

Because disclosures of actual or potential violations of the physician self-referral law include proprietary, confidential, or otherwise nondisclosable information, we present settlement information on an aggregate basis.

OIG Self-Disclosure Protocol

Holland & Hart

OIG

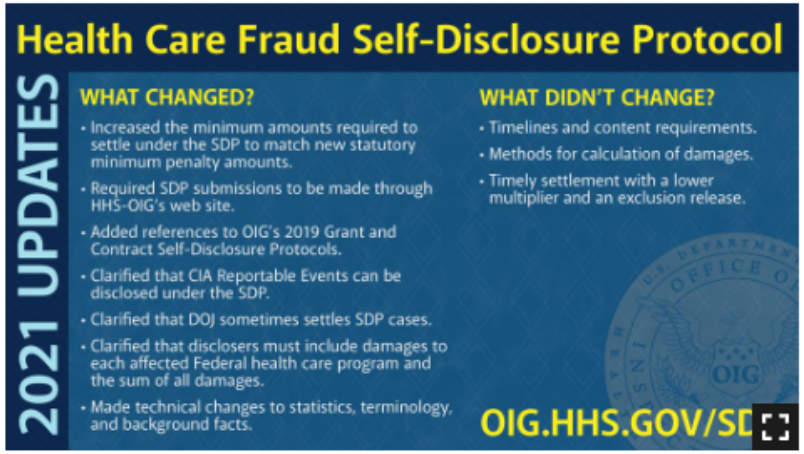
- Enforces various federal laws, e.g.,
  - Anti-Kickback Statute
  - Civil Monetary Penalties Law
  - Exclusion authorities
  - Healthcare Fraud
  - Information Blocking Rule
  - Others
  - Not Stark

- Most of these laws are intent-based, i.e., must have improper intent.
  - "Know or should have known" of facts resulting in violation, not that facts violated law.
  - "One purpose" test may apply.
- *Whether there was violation may turn on whether there was prohibited intent, but often difficult to defend against.*

OIG Self-Disclosure Protcol

https://oig.hhs.gov/compliance/self-disclosure-info/self-disclosure-protocol/

Health Care Fraud Self-Disclosure Protocol



Persons who wish to voluntarily disclose self-discovered evidence of potential fraud to OIG may do so

SDP

PROS

- Suspends 60-day Report and Repay Rule.
- OIG may reduce penalties if fully disclose and cooperate.
  - 1.5x damages
  - Minimum of $20,000
  - Minimum of $100,000 for AKS
- OIG may not require a corporate integrity agreement or exclusion.
- May preclude *qui tam* lawsuits.

CONS

- No guarantee OIG will reduce penalties.
- OIG may broaden investigation.
- Matters discovered by OIG are outside the SDP.
- Failure to fully disclose or cooperate may result in additional penalties.
- OIG may report to DOJ or other govt agencies.
- Participation is burdensome.
- Waive 6-year statute of limitations.
- May be subject to FOIA request.

SDP
Recent Settlements

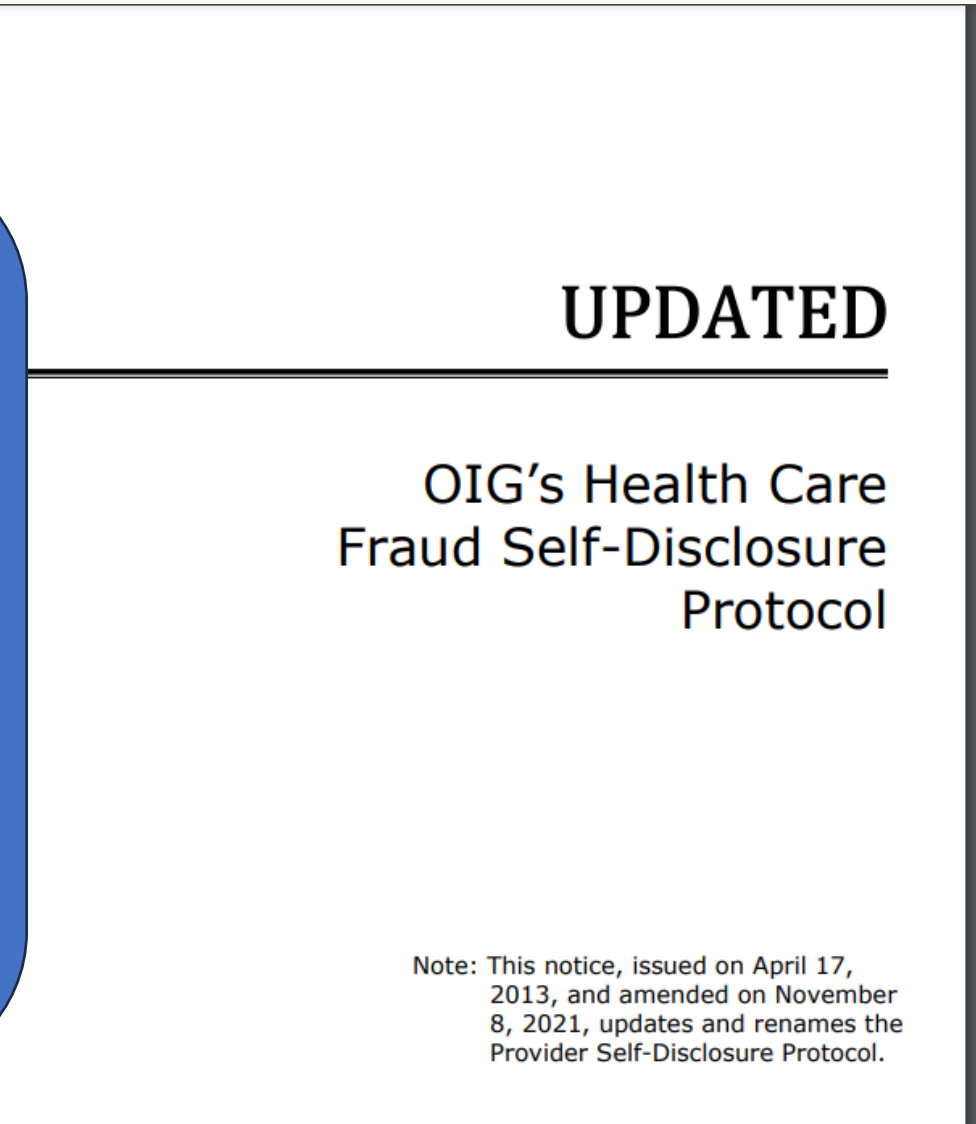
Date	Conduct	Settlement
6/25/24	Medical group submitted claims for services not provided as claimed.	$291,000
6/14/24	Ambulance company employed excluded individual.	$196,000
6/13/24	Group submitted claims for incident-to services without proper supervision.	$58,000
6/6/24	Hospital paid medical director services, management services, and provided free staff.	$10,700,000
6/6/24	EMS submitted claims for unlicensed individual.	$266,000
6/6/24	Facility paid above FMV for space, equipment and staff lease payments.	$609,000
6/4/24	Provider retained overpayments.	$55,000
5/31/24	Provider submitted claims for services not provided as claimed.	$426,000
5/19/24	Pharmacy paid inducements in form of reduced deductibles.	$180,000
5/10/24	Pharmacy chain submitted claims supported by false prior authorizations.	$23,500,000
5/8/24	Hospital paid above FMV for on-call services.	$556,000
3/12/24	Hospital paid improper inducements to physicians in infusion center.	$17,300,000

SDP

https://oig.hhs.gov/documents/self-disclosure-info/1006/Self-Disclosure-Protocol-2021.pdf

Includes:

- Info about disclosing party.
- Describe relevant facts, including time periods, persons involved, etc.
- Describe statutes violated.
- Damages or estimate of damages if uncertain.
- Describe corrective action.
- Name of person with authority to enter settlement agreement.
- Financial info if claim cannot pay.
- Certification.



UPDATED

OIG's Health Care Fraud Self-Disclosure Protocol

Note: This notice, issued on April 17, 2013, and amended on November 8, 2021, updates and renames the Provider Self-Disclosure Protocol.

SDP

- For violations of federal criminal, civil or admin laws for which civil monetary penalties are authorized.
  - Not to obtain opinions.
  - Not for Stark law violations.
- Ensure prohibited conduct has ended.
- Specific requirements depend on nature of violation, e.g.,
  - False billing.
  - Excluded individuals.
    - OIG has a formula for calculating settlement.
  - Anti-kickback violations.
    - Minimum of $100,000.

SDP

- "The benefits of self-disclosure, such as a speedy resolution, lower multiplier, and an exclusion release without integrity agreement obligations, depend on the disclosing party's willingness to work cooperatively with OIG throughout the process.
- "Cooperation includes, for example, conducting a thorough investigation, submitting all necessary information, communicating through a consistent point of contact, being responsive to OIG requests for additional information, and being willing to pay a penalty or multiplier of damages for self-disclosed conduct.
- "Disclosing parties who fail to cooperate with OIG in good faith will be removed from the SDP."

(SDP at p.12, https://oig.hhs.gov/documents/self-disclosure-info/1006/Self-Disclosure-Protocol-2021.pdf)

Report to Dept. of Justice ("DOJ")

Holland & Hart

Report to DOJ

Provider may disclose noncompliance to the DOJ or local US Attorney's Office.

PROS

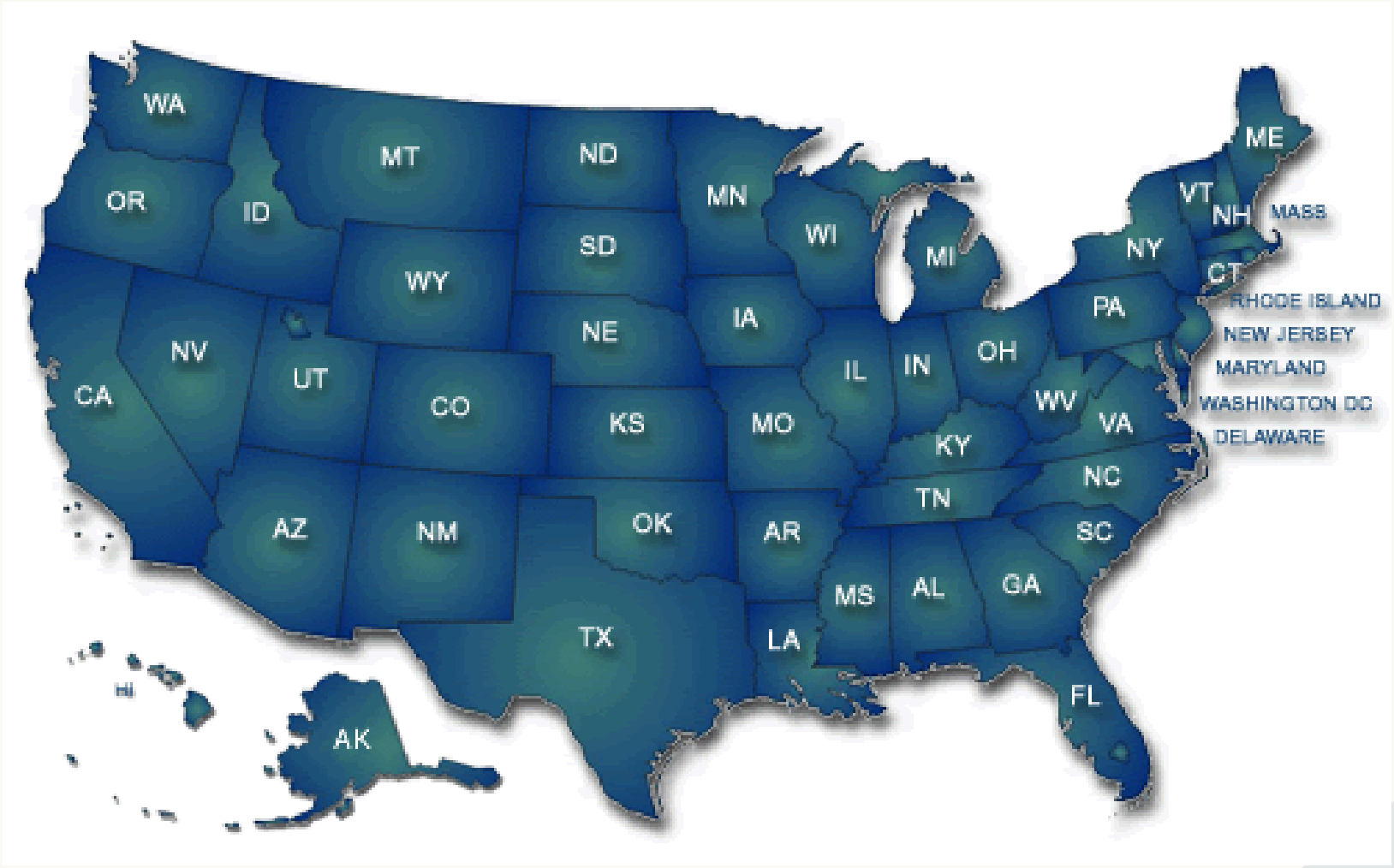
- DOJ has authority to settle most claims.
  - FCA, CMPL, and criminal statutes.
  - Common law claims for mistake or unjust enrichment.
- Local US Attorney may be more sympathetic.

(*See* SRDP Report to Congress (2012))

CONS

- DOJ is in the business of prosecuting.
- DOJ is unknown commodity.
- No defined process for resolving matters.

Remember State Laws



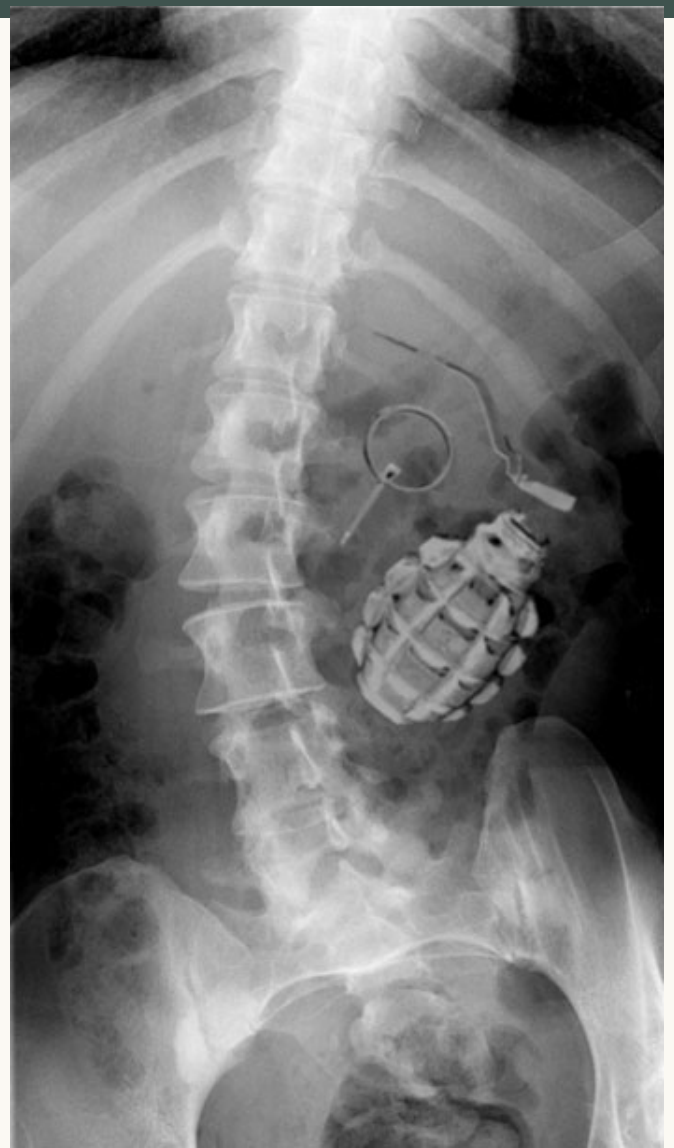
Holland & Hart

State Laws

- Most states have versions of federal fraud and abuse laws.
  - Anti-kickback laws
  - Self-referral laws ("mini-Stark")
  - Fee splitting statutes
- Many states have their own report and repay requirements under Medicaid or other state programs.
  - Medicaid or program statutes
  - Fraud recovery statutes
  - Provider agreement
- Federal and state criminal laws may apply to fraudulent retention of overpayments from private payors.

Action Items

Non-Compliance and Repayment



Holland & Hart

Preventive Medicine

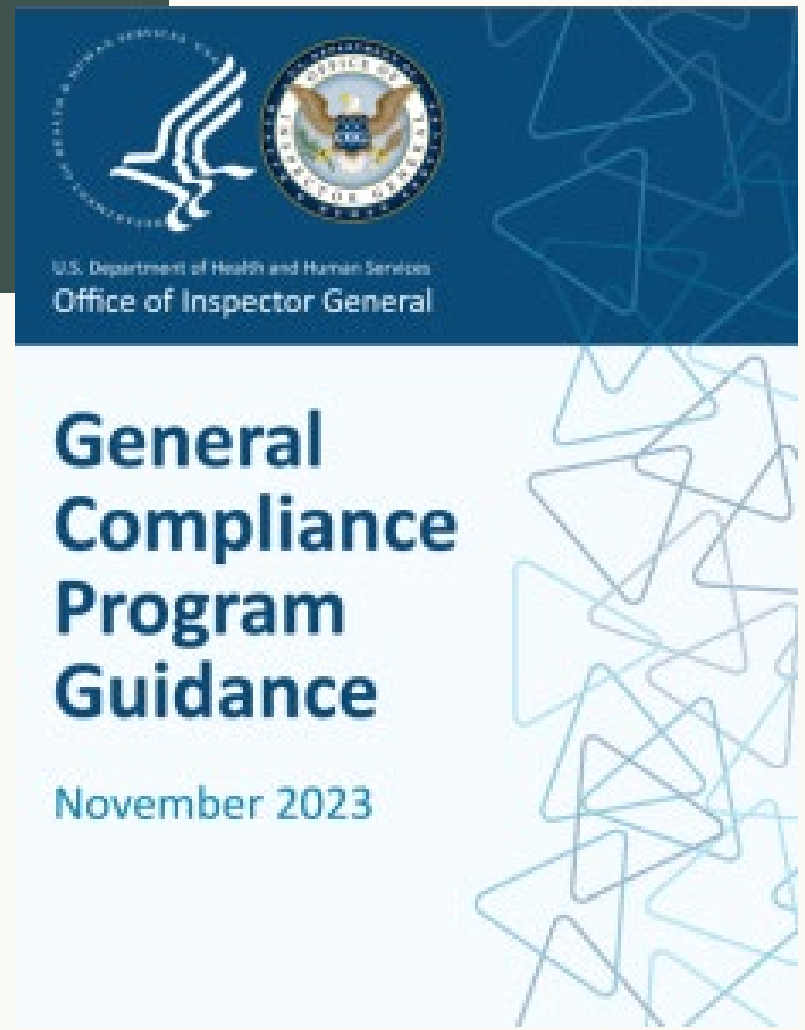
- Understand the relevant fraud and abuse statutes
  - "High risk" issues identified by OIG.
    - Coding and billing issues
    - Anti-Kickback Statute
    - Stark
    - Civil Monetary Penalties Law
      - Beneficiary inducements
      - Physician inducement
      - Program exclusion
  - State fraud and abuse laws

Resources:

- OIG, *General Compliance Program Guidance* (11/23) (https://oig.hhs.gov/compliance/general-compliance-program-guidance/)
- OIG, *Supplemental Compliance Program Guidance for Hospitals* (1/05) (https://oig.hhs.gov/documents/compliance-guidance/797/012705HospSupplementalGuidance.pdf)
- OIG, *Updated Adviory Bulletin on Effect of Exclusion* (5/13) (https://oig.hhs.gov/exclusions/files/sab-05092013.pdf)

Preventive Medicine

- Implement an effective compliance program
  - See OIG *General Compliance Program Guidance*
    1. Written Policies and Procedures
    2. Compliance Leadership and Oversight
    3. Training and Education
    4. Effective Lines of Communication
    5. Enforcing Standards
    6. Risk Assessment, Auditing and Monitoring
    7. Responding to Detected Offenses and Corrective Action Initiatives.
  - May help ensure compliance.
  - May mitigate exposure if fail to comply.



https://oig.hhs.gov/compliance/general-compliance-program-guidance/

Preventative Medicine

- Train key personnel, including:
  - Administration.
  - Compliance officers and committees.
  - Human resources.
  - Physician relations and medical staff officers.
  - Marketing / public relations.
  - Governing board members.
  - Purchasing.
  - Accounts payable.
- Document training.
- Review and repeat.

Preventive Medicine

- Check and periodically audit financial relations with physicians and other referral sources if referrals involve govt health care programs.
  - Employment and services contracts
  - Group compensation structure
  - Recruitment arrangements
  - Joint ventures or investments
  - Leases for space or equipment
  - Free items or services or perks
  - Discounted items or services
  - Loans
  - Other "remuneration"

Implicate
- Stark
- Anti-Kickback
- Civil Monetary Penalties Laws
- EKRA

- Report and Repay Obligations

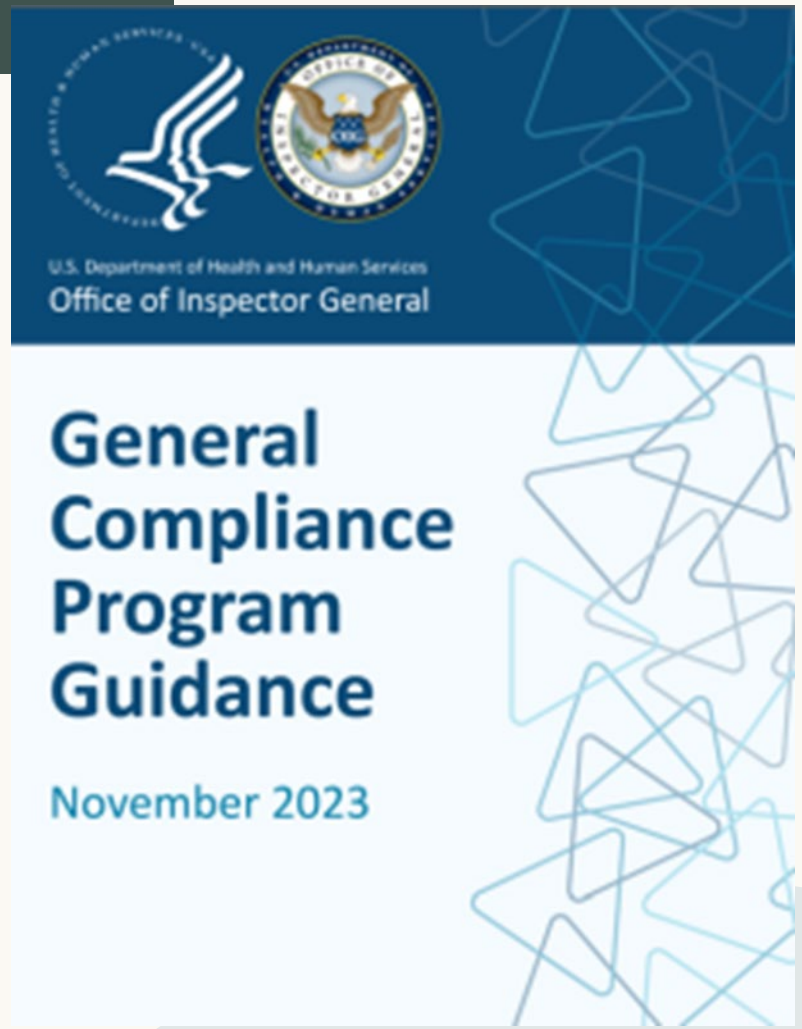
Preventive Medicine

- Consider and document:
  - Compliance with Stark and Anti-Kickback exceptions
  - Fair market value
  - Commercial reasonableness
  - Legitimate bases for action such as community need, patient care, etc.
  - Performance consistent with contract terms
- Beware:
  - Failure to satisfy all regulatory requirements
  - If "one purpose" is to generate referrals for items or services covered by federal programs
  - Changed circumstances

If there is a problem…

Responding to Non-Compliance

- Act promptly and appropriately.
  - "[I]t is important that the compliance officer act promptly to notify appropriate leaders and coordinate with entity counsel as needed upon receipt of reports or reasonable indications of suspected noncompliance to determine whether a material violation of applicable law has occurred." (OIG *General Compliance Program Guidance* at p.60)



Responding to Non-Compliance

- Know and comply with your compliance program.
  - "[C]ompliance programs should include processes and resources to thoroughly investigate compliance concerns, take the steps necessary to remediate any legal or policy violations that are found, including reporting to any Government program agencies or law enforcement where appropriate, and analyze the root cause(s) of any identified impropriety to prevent a recurrence." (OIG *General Compliance Program Guidance* at p.60)
  - How are you supposed to handle concerns?
  - To whom do you report?

Responding to Non-Compliance

- Don't panic or overreact.
  - It may be there is no violation; need the facts and analysis to confirm.
- Suspend relevant claims until situation resolved.
  - Submitting claim with knowledge of problem could violate False Claims Act or health care fraud statutes.
- Assess scope of problem.
  - Isolated event or extensive problem?
  - "Knowing" misconduct or innocent error?
- Consider involving appropriate attorney.
  - Expertise in evaluating relevant laws and regulations.
  - May provide some protection if act on advice of counsel.
  - May maximize attorney-client privilege.

Responding to Non-Compliance

- Immediately investigate.
  - May be directed by attorney to maintain privileges.
  - Remember 60-day deadline; must act with "reasonable diligence".
  - Immediately take steps to preserve relevant documents, including electronic files.
  - Gather and review relevant documents.
  - Interview relevant persons.
  - Document investigation.
  - Assume whatever you document will be discoverable.
- Never destroy relevant documents or falsify information.
  - Federal crime to destroy documents that are subject of existing or pending investigation. (18 USC 1519)
- Never retaliate against whistleblowers.

Responding to Non-Compliance

- Determine whether a violation actually occurred.
  - Involve qualified persons.
  - Review requirements of relevant regulations.
    - Definitions
    - Requirements or elements
    - Limitations and exceptions
    - Safe harbors
  - Did transaction involve federal program payments?
  - For AKS or CMPL situations, was there intent to induce referrals?
  - Other considerations?

Responding to Non-Compliance

- Ensure you are applying the appropriate version of the regulations.
  - Regulations have been amended at times.
  - Subsequent commentary or guidance may apply, e.g., Stark.
- Consider official commentary and decisions relevant to the compliance issue.
  - Advisory Opinions
  - Preamble to regs published in Federal Register ("FR")
  - Advisory Bulletins and Fraud Alerts
  - CMS and OIG Frequently Asked Questions
  - Local Coverage Determinations
  - Local guidance.

✓U.S. Supreme Court has recently limited agencies' ability to enforce subregulatory guidance or exceed scope of enabling statute.

Responding to Non-Compliance

Exception for providers "without fault"?

- A provider, physician, or other supplier is liable for overpayments it received unless it is found to be without fault. The contractor, as applicable, makes this determination. The contractor considers a provider, physician, or other supplier without fault, if it exercised reasonable care in billing for, and accepting, the payment; i.e.,
  - It made full disclosure of all material facts; and
  - On the basis of the information available to it, including, but not limited to, the Medicare instructions and regulations, it had a reasonable basis for assuming that the payment was correct, or, if it had reason to question the payment, it promptly brought the question to the contractor's attention."

(Medicare Fin. Mgmt Man. Ch. 3 § 90)

- Contractor generally may not adjust a claim against a provide who is not at fault after 5 years. (*See* 42 CFR 1395gg(b)-(c))

Responding to Non-Compliance

- If a problem exists, fix it.
  - Modify processes.
  - Discipline employees.
  - Execute, revise, or terminate improper referral arrangements as appropriate.
  - If there is Stark issue, require repayment to end period of non-compliance.

  * *Remember: fixing problem prospectively does not resolve past problem or end repayment obligation.*

  - Document remedial efforts.

Responding to Non-Compliance

- Implement and document voluntary corrective action plan to avoid similar problems in the future.
  - Update policies or processes.
  - Obtain additional guidance.
  - Conduct appropriate training.
  - Document remedial actions.
  - Include remedial efforts in any disclosure.

Responding to Non-Compliance

- If confirm repayment obligation, timely report and repay overpayments within 60 days.
  - Report and Repay Rule
    - Must repay in full at time of disclosure unless extension.
    - May limit further investigation, but no guarantees.
  - For significant Stark violations, use SRDP.
    - Suspends repayment obligation until settled.
    - May reduce Stark penalties.
    - Subject to further investigation.
  - For intentional or reckless violations of False Claims, Anti-Kickback, or Civil Monetary Penalties Laws, use SDP.
    - Suspends repayment obligation until settled.
    - May reduce penalties.
    - Subject to further investigation.

Responding to Non-Compliance

- When reporting to government:
  - Fully cooperate with investigation.
  - Do not misrepresent information.
  - Do not omit material information.
  - Do not provide more than is reasonably relevant.
  - Make your best case.
  - Discuss adverse financial impact on provider.
  - Assume the govt will check your facts and analysis.
  - Assume that govt investigation may go beyond your initial disclosure to consider other issues.

Responding to Non-Compliance

- When calculating exposure, verify actual payments received from federal programs during relevant period.
  - Did non-compliance materially affect whether govt would pay the claim?
  - Were payments received for DHS?
  - Were there cost report adjustments or write offs?
  - Were there copays from patients?
  - Was referring physician the admitting physician?
  - Did referrals affect the DRG payment?
- Limit analysis to relevant lookback or other period.

Responding to Non-Compliance

- When calculating repayment, use credible methodology.
  - No established or required methodology.
  - Must be reasonable under the circumstances.
  - Ensure personnel preparing the analysis are looking at the right issues, e.g., in Stark cases, Medicare/Medicaid payments for "referrals" for "designated health services".
  - See OIG SDP suggestions for methodology.
  - Government will evaluate appropriateness of methodology.

Responding to Non-Compliance

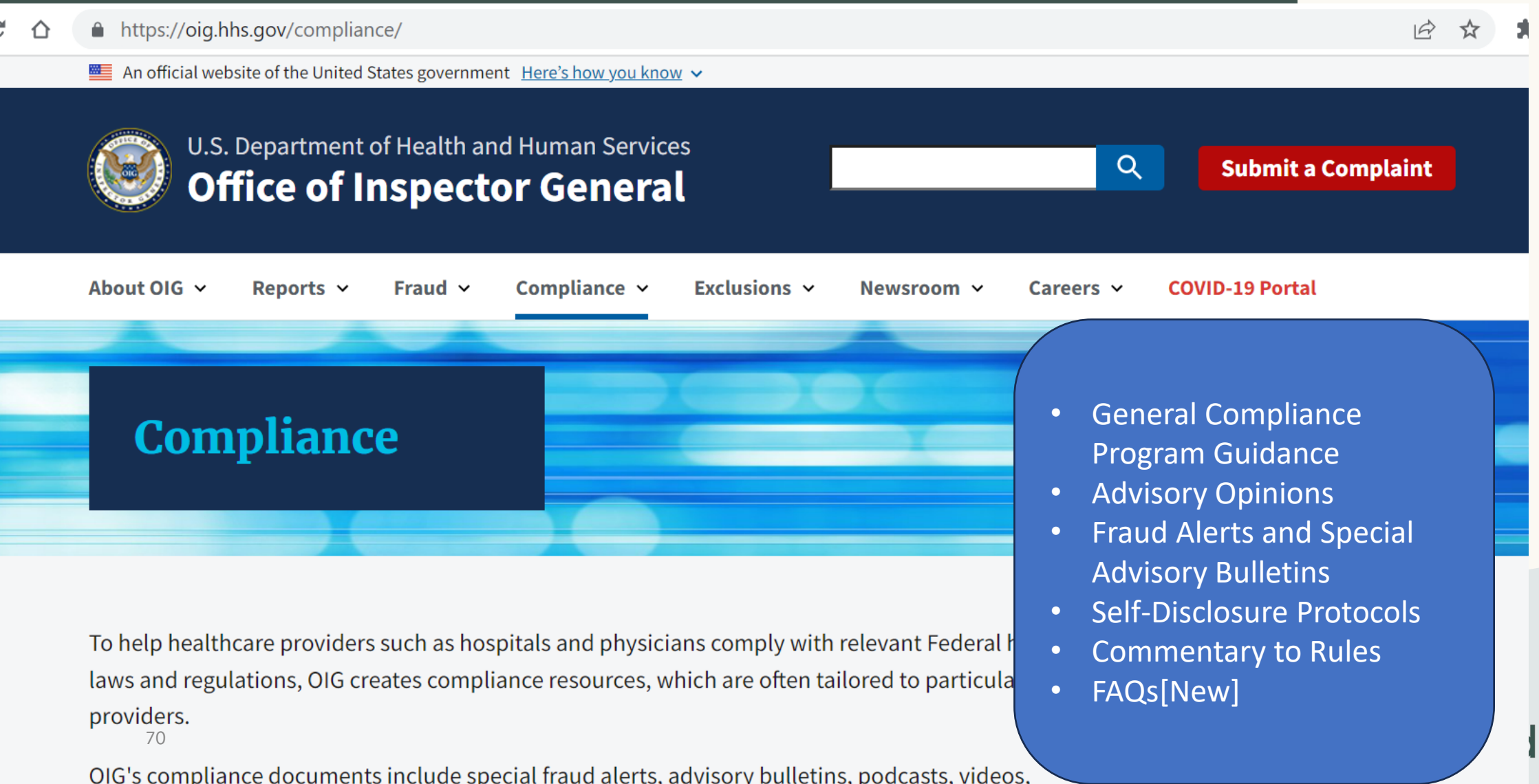
- Not obligated to accept govt's proposed settlement.
  - May withdraw from self-disclosure program.
  - Lose benefits of self-disclosure.
  - May reopen claims process.
- Document settlement in an agreement.
- Beware: settlement agreement with one agency does not bind other agencies who are not parties to agreement.
  - Unless released, may still be liable for additional suit or penalties, including:
    - Criminal penalties
    - Civil penalties
    - Administrative penalties

But these may be harder for govt to prove; less incentive to pursue additional claims.

Additional Resources

OIG Compliance Website

https://oig.hhs.gov/compliance/



- General Compliance Program Guidance
- Advisory Opinions
- Fraud Alerts and Special Advisory Bulletins
- Self-Disclosure Protocols
- Commentary to Rules
- FAQs[New]

https://oig.hhs.gov/compliance/compliance-guidance/

OIG is updating compliance guidance.

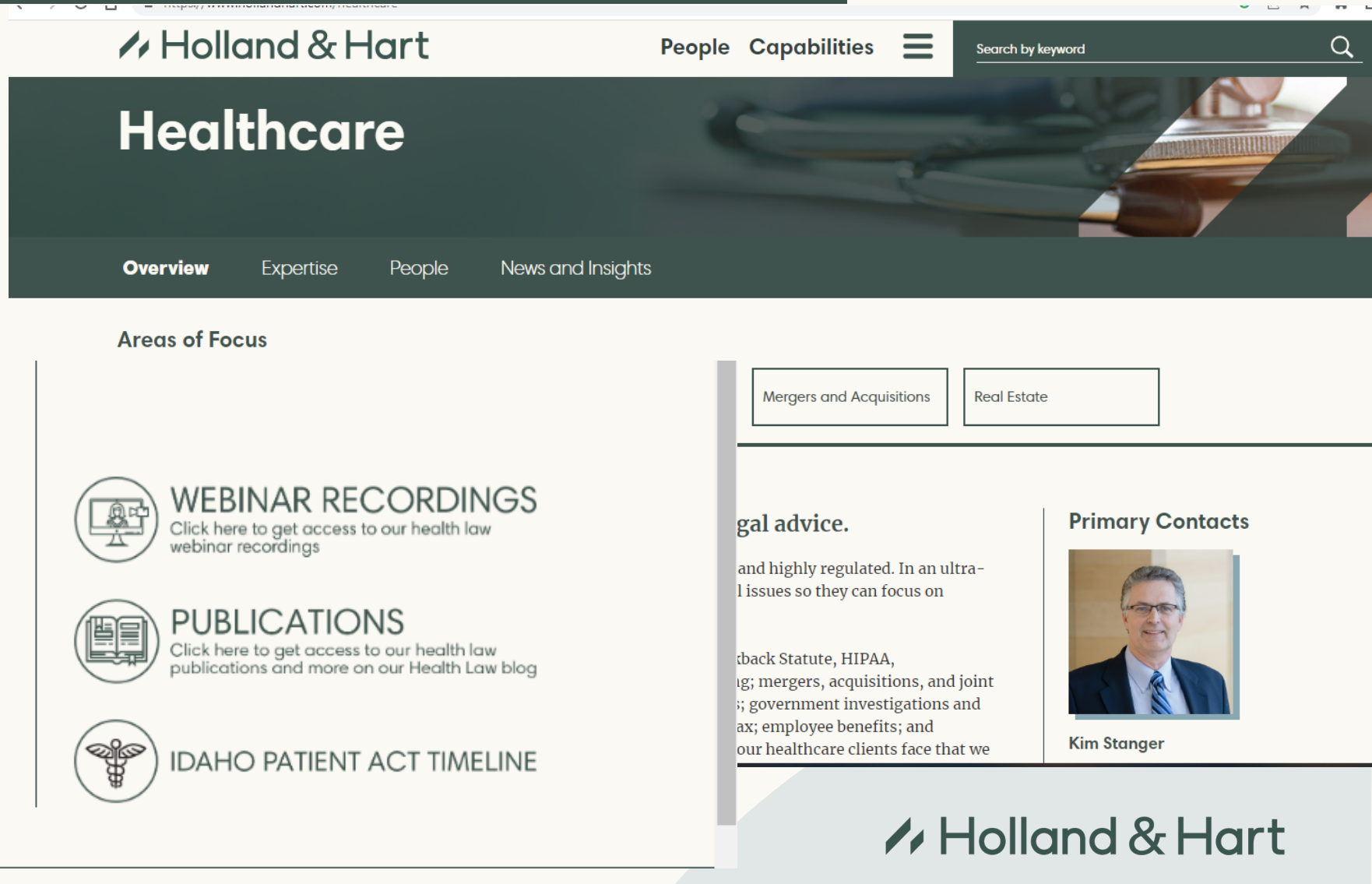
- General Compliance Guidance available.
  - Overview of fraud and abuse laws.
  - 7 Elements of Compliance Programs, including responding to violations:
    - ✓ Investigations
    - ✓ Reporting to govt
    - ✓ Implementing corrective action initiatives.
- Industry-Specific Guidance is expected shortly.

Holland & Hart

HTTPS://WWW.HOLLANDHART.COM/HEALTHCARE

Free content:

- Recorded webinars
- Client alerts
- White papers
- Other



Questions?

Kim C. Stanger

Office: (208) 383-3913

Cell: (208) 409-7907

kcstanger@hollandhart.com