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# Responding to Non-Compliance: Self-Reporting and Repaying

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# Roadmap for Today's Webinar

- Compliance issues that may result in repayment obligation
- Affordable Care Act repayment requirements
- Self-disclosure process
  - Proposed Report and Repay Rule
  - OIG Self-Disclosure Protocol
  - CMS Self-Referral Disclosure Protocol
- Practical suggestions for avoiding or responding to potential repayment issue

# Written Materials

- Copy of slides
- CMS Proposed Repayment Rule
- OIG's Self-Disclosure Protocol ("SDP")
- Open Letters modifying SDP – 2006, 2008, 2009
- CMS Stark Self-Referral Disclosure Protocol ("SRDP")
- OIG's *Roadmap for New Physician: Avoiding Medicare and Medicaid Fraud and Abuse*

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# Preliminary Matters

- Presentation will be recorded and available for download at www.hhhealthlawblog.com
- If you have questions, please feel free to contact me at pdean@hollandhart.com
- If you experience technical problems during the webinar, please contact Luke Kelly at lskelly@hollandhart.com

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# Preliminary Matters

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# Non-Compliance Issues

- If you want government money, you must comply with government conditions.
- Failure to comply with conditions may result in:
  - Repayment obligation.
  - Additional penalties.



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# Failure to comply with conditions for payment

- Examples of billing practices that may result in overpayment:
  - Services not medically necessary
  - Services not covered by federal program
  - Services not provided as claimed
  - Services not provided by licensed provider
  - Substandard care
  - Double billing or duplicate payments
  - Unbundling
  - Upcoding
  - And many, many more . . .

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# Anti-Kickback Statute ("AKS") (42 USC 1320a-7b)

- Cannot knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals for items or services covered by federal health care programs unless structure transaction to fit within a regulatory exception in 42 CFR 1001.952.
- AKS is very broad; potentially applies to any transaction between referral sources or program beneficiaries.
- Criminal statute – intent based.
- But "intent" has been interpreted broadly - applies if "one purpose" of the transaction is to induce referrals for items covered by federal programs. (*U.S. v. Greber*, 760 F.2d 68 (3d Cir. 1985))

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# Anti-Kickback Statute

- Penalties
  - Felony
    - $25,000 fine
    - 5 years in prison
  - $50,000 administrative penalty
  - Exclusion from Medicare and Medicaid
- Anti-Kickback violations are also False Claims Act ("FCA") violations, which separately include potential penalties of
  - $5,500 to $11,000 per false claim submitted
  - 3 times damages; 2 times damages if disclose in 30 days
  - *Qui tam* ("whistleblower") lawsuits



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# Anti-Kickback Statute

- *Facts.* Hospital pays referring physician $75,000 per year to serve as medical director, but failed to document that physicians performed services.
- *Law.* Anti-Kickback exception requires written agreement at fair market value for services provided.
- *Penalties.*
  - Physician and hospital administrator sentenced to prison and $250,000+ fines.
  - Repay all amounts that hospital received from federal programs based on referrals from the physicians during the period that they were in violation of Anti-Kickback Statute.

(*See U.S. v. Anderson* (10th Cir. 2005))



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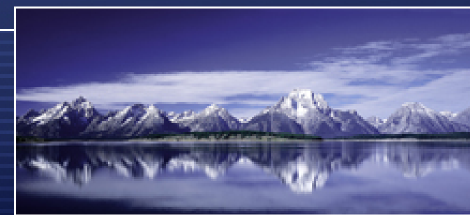
# Ethics in Patient Referrals Act ("Stark") (42 USC 1395nn)



- Applies to physician (or physician family member) specific referrals.
- If physician or physician's family member has a financial relationship with an entity,
  - physician cannot refer patients to the entity for designated health services ("DHS") payable by Medicare, and
  - entity cannot bill Medicare for DHS improperly referred,

  unless transaction fits within a regulatory exception in 42 CFR 411.350 *et seq*.
- Civil statute – intent is irrelevant.
- No "good faith" compliance.



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# Stark

- Designated health services ("DHS") payable by Medicare
  - Inpatient and outpatient hospital services
  - Outpatient prescription drugs
  - Clinical laboratory services
  - Physical, occupational and speech therapy
  - Radiology services, including ultrasound, MRI and CT scans
  - Radiation therapy services
  - Durable medical equipment
  - Parenteral and enteral nutrients, equipment and supplies
  - Prosthetics, orthotics and prosthetic devices and supplies
  - Home health services
- CMS maintains a list of CPT codes (updated annually) on its website.



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# Stark

- Penalties
  - No payment for DHS during period of disallowance
  - Repay amounts received per improper referrals within 60 days
  - $15,000 per claim submitted per improper referral
  - $100,000 per improper scheme
- Stark violation may be FCA violation
  - $5,500 to $11,000 per false claim submitted
  - 3 times damages; 2 times damages if disclose within 30 days
  - *Qui tam* lawsuit
  - Exclusion from federal programs

# Stark

- *Facts.* Hospital contracts with anesthesiologists to provide services at hospital and provides free space, equipment and support. Services expanded to include hospital's new pain management clinic, but contract not amended to cover new services.
- *Law.* Applicable Stark exceptions require written contract covering services.
- *Penalty.* Repayment of all amounts received by Medicare based on Hospital inpatient or outpatient services ordered by anesthesiologists during the period of non-compliance. Also possible AKS and FCA violations.

(*See Kosenske v. Carlisle HMA, Inc.* (3d Cir. 2009))



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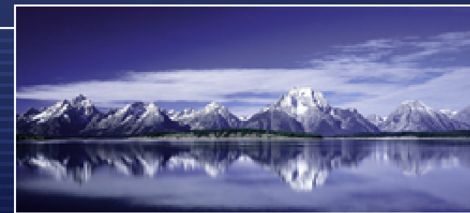
# Civil Monetary Penalties Law (42 USC 1320a-7a)



- Prohibits various actions, including:
  - Submitting claims if services were provided by excluded provider, employee or contractor.
  - Inducements to federal program beneficiaries to receive reimbursable services (e.g., discounts or waiver of co-pays).
  - Inducements to limit services by hospitals (e.g., “gainsharing”).
  - Failing to repay amounts when due.

# Civil Monetary Penalties (CMP) Law

- Penalties
  - $10,000 to $50,000 depending on conduct involved
  - 3 times damages
  - Exclusion from federal programs
- CMP violation may be FCA violation
  - $5,500 to $11,000 per false claim submitted
  - 3 times damages; 2 times damages if disclose within 30 days
  - *Qui tam* lawsuit
  - Exclusion from federal programs



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# Civil Monetary Penalties Law

- *Facts.* Physician practice employs excluded individual in non-clinical position for four years. No evidence of any impropriety or adverse effect on Medicare payments.
- *Law.* CMP law prohibits contracting with excluded individual or submitting claims for services performed by excluded provider.
- *Penalty.* OIG required repayment of over $100,000 based on employee's annual salary and percentage of Medicare/Medicaid revenues received by practice during that time.



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# Routes to Repayment

- ACA (Section 6402) disclosure
  - May be less invasive
  - Cannot resolve civil or administrative liability for conduct that led to overpayment (and, accordingly, not as final)
  - Will require repayment but may not involve a penalty
- Self-Referral Disclosure Protocol (SRDP)
  - Can resolve liability for overpayment and underlying Stark Law violations
  - Provides more certainty and provider involvement in resolution
  - Will involve penalty
- OIG Self Disclosure Protocol (SDP)
  - Can result in release of CMP and permissive exclusion authority
  - Provides more certainty and provider involvement in resolution
  - Will involve penalty



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# ACA Repayment Law (42 USC 1320a-7k(d))

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# ACA Repayment Law

- If provider has received an "overpayment", provider must:
  - Return the overpayment to federal agency, state, intermediary, or carrier, and
  - Notify the entity of the reason for the overpayment.
- Must report and repay within the later of:
  - 60 days after overpayment is identified, or
  - Date corresponding cost report is due.
    - Note that only items that can be reconciled on cost report are subject to these time deadlines.



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# ACA Repayment Law

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



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# Repayment Law

**Condition of payment from government program**

- Requires repayment, e.g.,
  - Billing or claim requirements
  - Anti-Kickback Statute
  - Stark Law
  - Civil Monetary Penalties re excluded individuals

**Condition of participation or other regulation**

- Does not necessarily require repayment, e.g.,
  - Conditions of Participation
  - Conditions of Coverage
  - Licensure requirements
  - HIPAA
  - EMTALA
  - OSHA

# ACA Repayment Law

- "Knowing" failure to report and repay by deadline also implicates:
  - False Claims Act violation
    - $5,500 to $11,000 per violation
    - 3 times damages
    - *Qui tam* lawsuit

      (31 USC 3729)
  - Civil Monetary Penalty Law violation
    - $10,000 penalty
    - 3 times damages
    - Exclusion from Medicare or Medicaid

      (42 USC 1320a-7a(a)(10))

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# ACA Repayment Law

- "Knowing" =
  - Has actual knowledge of overpayment
  - Acts in deliberate ignorance of overpayment
  - Acts with reckless disregard of overpayment
  - Does not require specific intent to defraud

  (31 USC 3729(b)(1))
- Original conduct giving rise to overpayment may not violate FCA or CMP.
- But, failing to timely repay overpayment may violate FCA or CMP.



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# Proposed Repayment Rule (Proposed 42 CFR 401.301)

- Issued 2/14/12 (77 FR 9179 (2/16/12)).
- Comments accepted through 4/16/12.
  - Final rule has not been issued but proposed rule is in effect
- Applies to Medicare parts A and B
  - Other stakeholders still subject to statute

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# Proposed Repayment Rule

- "The provider's initial decision of where to refer a matter involving non-compliance with program requirements should be made carefully."
  - 77 Fed Reg 9179, 9183, February 16, 2012
  - Multiple factors need to be considered in determining which disclosure protocol is best for the situation involved.
- In addition to the benefits and limitation involved with each disclosure protocol, some hard rules apply:
  - Stark Law-only violations must be disclosed to CMS through SRDP
    - But, if both AKS and Stark Law, must use SDP.
  - SDP should not be used for matters involving potential violations of federal criminal, civil, or administrative law for which CMPs are authorized.
    - (e.g., matters exclusively involving overpayments or errors).

# Proposed Repayment Rule

- To report and repay overpayments, use existing voluntary refund process ("self-reported overpayment refund process")
  - Medicare Financial Management Manual, Pub. 100-06, Chapter 4
- Use the form that contractors (fiscal intermediary) maintain on their website
  - Noridian, Palmetto, GBA, etc.

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# Proposed Repayment Rule

- Report must include:
  - Provider's name, NPI, and Tax ID
  - How error was discovered
  - Claim number
  - Corrective action plan to avoid repeat
  - Whether the provider is currently under a CIA or the OIG SDP
  - Reason for overpayment
    - e.g., incorrect service date, insufficient documentation, wrong CPT code, lack of medical necessity, duplicate payment, etc.
  - Total amount
  - If statistical sample used, method of calculation
- Include refund amount

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# Proposed Repayment Rule

- Must report and return payment within later of:
  - 60 days after overpayment identified, or
  - if overpayment related to issue in cost report, date corresponding cost report is due.
- Overpayment "identified" if person:
  - Has actual knowledge of existence of overpayment, or
  - Provider acts in reckless disregard or deliberate ignorance.

  Not necessarily amount of repayment.
- If have notice of potential overpayment, must make "reasonable inquiry" with "all deliberate speed" to determine whether overpayment exists.

# Proposed Repayment Rule

- Examples of "identified" overpayment
  - Upon reviewing records, discover erroneous codes used.
  - Discover services were rendered by unlicensed or excluded provider.
  - Internal audit reveals overpayment.
  - Compliance hotline tip notifies provider of possible overpayment but provider fails to make reasonable inquiry.
- Apparently, overpayment is "identified" when:
  - Existence of an overpayment is confirmed, or
  - Put on notice and failed to make reasonable inquiry.
- Final rule may clarified when an overpayment is identified.



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# Proposed Repayment Rule

- No minimum threshold for Repayment Rule.
- Not clear how the Proposed Repayment Rule works with existing processes, e.g.,
  - Submit adjustment request or "rebill".
  - Address in credit balance.

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# Proposed Repayment Rule

- Not clear how far back provider must look when evaluating repayment.
  - CMS may reopen claims:
    - Within 1 year for any reason.
    - Within 4 years for good cause.
    - Anytime due to fraud or fault.

      (*See* 42 CFR 405.980)
  - False Claims Act statute of limitations is 6 to 10 years.
  - Proposed Repayment Rule would extend look-back and reopening period to 10 years.
    - Expands potential repayment obligation but may be modified in final rule
    - Provides some certainty

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# Proposed Repayment Rule

- If need more time to repay, use existing Extended Repayment Schedule ("ERS") process.
  - Extension for repayment is not automatically granted.
  - Must submit significant documentation to demonstrate financial hardship as part of ERS process.
  - Must still report overpayment within 60 days.

  (*See* CMS Financial Management Manual Ch. 4)

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# Proposed Repayment Rule

- Repayment per Repayment Law 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.
  - Be careful how and what you disclose.
- May want to consider other disclosure protocols.
  - OIG Self-Disclosure Protocol (SDP)
  - Stark Self-Referral Disclosure Protocol (SRDP)



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# Proposed Repayment Rule

- Participation in OIG Self-Disclosure Protocol ("SDP") or Stark Self-Referral Disclosure Protocol ("SRDP"):
  - Suspends time for refund under Repayment Law.
  - For SDP, timely disclosure to OIG per SDP constitutes report for purposes of repayment rule.
  - For SRDP, must still make report within 60 days to:
    - Government agency
    - State
    - Fiscal intermediary or contractor.



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# Proposed Repayment Rule

- Open issues from Proposed Rule include:
  - Definition of “identification”
    - Some argue that no definition allows for greater flexibility
  - Length of look-back period
  - Interplay with other processes

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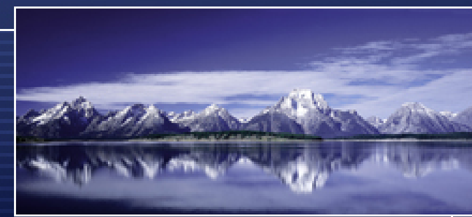
# Proposed Repayment Rule

- Proposed Rule is now industry standard
- CMS has made it clear that the 60-day rule is self-implementing and the reality even without a published final rule
- *United States ex. Rel. Kane v. Healthfirst, Inc. et al.*
  - U.S. District Court for the Southern District of New York – 2014
  - DOJ intervened in *qui tam* case alleging defendants tried to return payments in compliance with the ACA repayment rule
  - Former employee identified 900 claims (hospital) that may have been erroneously submitted in February 2011
  - Repayment not made until March 2013 following Civil Investigative Demand
  - Question raised is whether discovery of "suspect records" equal "identifying overpayments"?

# OIG Self-Disclosure Protocol (63 FR 58399)



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# OIG Self-Disclosure Protocol

- Voluntary program
- Benefits
  - OIG may reduce penalties if fully disclose and cooperate.
  - Probably no corporate integrity agreement (CIA).
  - May preclude *qui tam* lawsuits.
  - Suspends repayment under Proposed Repayment Rule.



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# OIG Self-Disclosure Protocol (SDP)

- Risks
  - No guarantee that OIG will reduce penalties.
  - Penalties may bankrupt provider.
  - OIG may broaden investigation.
  - New matters discovered by OIG are outside protocol.
  - Failure to fully disclose or cooperate may result in additional penalties.
  - OIG may report to other government agencies.
  - Participation is burdensome.
  - Likely will waive of privilege.
  - Information may become public.



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# OIG Self-Disclosure Protocol

- SDP should only be used to resolve matters that "potentially violat[e] Federal, criminal or civil or administrative laws. Matters exclusively involving overpayments or errors that do not suggest that violations of law have occurred should be brought directly to the attention of the [contractor]."  (63 FR 58400)
  - Generally, SDP applies to violations that involve:
    - Actual knowledge
    - Reckless disregard
    - Deliberate ignorance
  - Not honest mistakes or errors.
  - Not Stark violations.

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# OIG Self-Disclosure Protocol

Self-Disclosure Information | Compliance | Office of Inspector General | U.S. Department of Hea - Windows Internet Explorer pro

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

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## Self-Disclosure Information

Providers who wish to voluntarily disclose self-discovered evidence of potential fraud to OIG may do so under the Provider Self-Disclosure Protocol (SDP). (See 63 Fed. Reg. 58,399.) Self-disclosure gives providers the opportunity to avoid the costs and disruptions associated with a Government-directed investigation and civil or administrative litigation.

OIG endeavors to work cooperatively with providers who are forthcoming, thorough, and transparent in their disclosures in resolving these matters. While OIG does not speak for the Department of Justice or other agencies, OIG consults with those agencies, as appropriate, regarding the resolution of SDP matters. More information is available below:

- Open Letter to Health Care Providers (PDF) (March 24, 2009)
- Provider Self-Disclosure Protocol Federal Register Notice (PDF) (October 30, 1998 [63 Fed. Reg. 58,399])
- Open Letter to Health Care Providers (PDF) (April 15, 2008)
- Open Letter to Health Care Providers (PDF) (April 24, 2006)
- Selected Settlements Under the Provider Self-Disclosure Protocol

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
- RAT-STATS
- Safe Harbor Regulations



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# OIG Self-Disclosure Protocol

SDP Process

- If discover ongoing fraud, contact OIG immediately.
- Otherwise, conduct initial investigation to confirm SDP applies.
- Submit initial written disclosure to OIG, including:
  - Info about provider – address, NPI, Tax ID, organizational chart.
  - Complete description of conduct disclosed.
  - Description of internal investigation or estimate for completion.
  - Estimate of damages to federal programs, method for calculation or estimate for completion.
  - Whether under investigation.
  - Laws potentially violated – must be specific in identifying laws implicated (not general "federal laws, rules and regulations").
  - Must acknowledge conduct is a partial violation
  - Individual authorized to enter into settlement
  - Certification

# OIG Self-Disclosure Protocol

- Disclosures may be submitted through OIG's website at: https://oig.hhs.gov/compliance/self-disclosure-info/index.asp
- Hard copy submission of disclosures to OIG
- No fax submissions
- SDP provides guidance on what to include for specific conduct (e.g., excluded persons, false billing, etc.)



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# OIG Self-Disclosure Protocol

## SDP Process

- Internal investigation
  - Nature and extent of improper practice.
  - Discovery and response to matter.
  - Self-assessment of impact on federal programs.
  - Certification.
  - Complete investigation within 3 months.

    (*See* OIG SDP and Open Letter dated 4/15/08).
- OIG verifies information in report
  - Access to all audit and other papers without regard to privilege.
  - Respond timely to OIG requests for additional information.
- Payment
  - Do not make payments while SDP is pending without OIG approval.
  - Encouraged to place subject money in interest bearing escrow account.



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# OIG Self-Disclosure Protocol

- "The disclosing entity's diligent and good faith cooperation throughout the entire process is essential…. [T]he OIG expects to receive documents and information from the entity that relate to the disclosed matter without the need to resort to compulsory methods. <u>If a provider fails to work in good faith with the OIG to resolve the disclosed matter, that lack of cooperation will be considered an aggravating factor when the OIG assesses the appropriate resolution…. Similarly, the intentional submission of false or otherwise untruthful information, as well as the intentional omission of relevant information, will be referred to the DOJ or other Federal agencies and could, in itself, result in criminal and/or civil sanctions</u>…." (63 FR 58403)
- OIG may expel provider from SDP if fail to cooperate.

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# OIG Self-Disclosure Protocol

- OIG has periodically modified the SDP.
  - Open Letter dated 4/15/08
    - Simplified initial disclosure requirements.
    - Presumption of no corporate integrity agreement if participate in SDP.
  - Open Letter dated 3/24/09
    - No longer accept Stark disclosures in SDP.
    - Minimum $50,000 settlement for Anti-Kickback settlements.
  - Most recent update April 17, 2013
    - Minimum of $10,000 settlement for all non-AKS matters disclosed.



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# OIG Self-Disclosure Protocol

- Do not assume that you will avoid all penalties.
- OIG seems to established formulas or protocols for handling certain types of claims (e.g., excluded providers).
- Under FCA, disclosure within 30 days reduces penalties to 2 times damages.

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# OIG Self-Disclosure Protocol

- In 2014, recovery of over $23M under SDP.
- Hospital operation of ASC and potential AKS violation
  - – $1.7M settlement.
- Home health provider billed hospice services without required certification documents
  - – $2M settlement.

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# Stark Self-Referral Disclosure Protocol (OMB # 0938-1106)

WHEN YOU SEE A RELATIONSHIP RED FLAG, SAY SOMETHING!

# Stark Self-Referral Disclosure Protocol ("Stark")

- Voluntary program
- Benefits
  - CMS may reduce penalties if fully disclose and cooperate.
  - May preclude *qui tam* lawsuits.
  - Suspends repayment under Proposed Repayment Rule.
  - Allows for some finality.
  - May maintain more confidentiality versus OIG SDP.
    - Names included on website.
- If an issue relates to both SRDP and OIG SDP, it should be reported under OIG SDP

# Stark Self-Referral Disclosure Protocol (“Stark”)

- Risks
  - No guarantee that CMS will reduce penalties.
  - CMS may broaden investigation.
  - Failure to fully disclose or cooperate may result in additional penalties.
  - CMS may report to other government agencies.
  - Participation is fairly burdensome, but not as bad as OIG SDP.
  - Reopening periods run from date of initial disclosure.
  - Waiver of appeal rights concerning any overpayment.
  - Likely will waive privileges.
  - Information may become public.



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# Stark Self-Referral Disclosure Protocol

- Use SRDP for confirmed Stark violations.
  – Assume you are going to pay.
- Use alternative processes to obtain CMS guidance.
  – CMS Advisory Opinion process at 42 CFR 411.370 *et seq.*
  – CMS Stark Frequently Asked Questions.



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# Stark Self-Referral Disclosure Protocol

- Must disclose within 60 days.
  - Per Proposed Repayment Rule, must disclose within 60 days after overpayment identified.
  - Per Stark SRDP, must repay within 60 days after receipt of payment pursuant to improper referral or subject to $15,000 penalty per claim submitted.
- Submission as part of SRDP suspends the 60-day repayment obligation under Repayment Law; repayment will be handled through the SRDP settlement process.



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# Stark Self-Referral Disclosure Protocol

CMS.gov
Centers for Medicare & Medicaid Services

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 by the President 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 ("SRDP") 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.

The SRDP requires health care providers of services or suppliers 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). Section 6409(b) of the ACA, gives the Secretary of HHS the authority to reduce the amount due and owing for violations of Section 1877 of the Act.

The SRDP is intended to facilitate the resolution of only matters that, in the disclosing party's reasonable assessment, are actual or potential violations of the physician self-referral law. Thus, a disclosing party should make a submission under the SRDP with the intention of resolving its overpayment liability exposure for the conduct it identified. As provided in the physician self-referral law, no payment may be made for designated health services that are provided in violation of the physician self-referral law.

The SRDP (link below) was revised on May 6, 2011, to make editorial changes and to clarify the information that should be submitted by disclosing parties. In addition to reporting the actual or potential amount due or owing, the SRDP now requires that as part of the initial submission to CMS, disclosing parties should provide the total amount of remuneration a physician(s) received as a result of an actual or potential violation(s) during the applicable "look back"

http://www.cms.gov/medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html



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# Stark Self-Referral Disclosure Protocol

SRDP Process

- Initial disclosure
  - Electronic submission to 1877SRDP@cms.hhs.gov.
  - Hard copy submission to CMS.
    - Hard copy of certification required in any event
  - No fax submissions
- Significant backlog currently.
- CMS may refer initial disclosure to OIG or DOJ, so disclosure should be carefully drafted.

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# Stark Self-Referral Disclosure Protocol

- Required information:
  - Description of actual or potential violations
    - Address, NPI, Tax ID
    - Organizational chart
    - Why the disclosing party believes a violation occurred
    - Actions taken to address disclosed matter
    - Whether the disclosing party has a history of similar conduct
    - Description of compliance program
    - Description of notices to other government agencies, if necessary
  - Financial analysis
    - Total amount, by year, potentially due based on look back period
    - Methodology
  - Certification

# Stark Self-Referral Disclosure Protocol

- Repayment limited to 4-year lookback period.
- “A disclosing party will satisfy … the SRDP by submitting a financial analysis setting forth the total amount actually or potentially due and owing for claims improperly submitted and paid within the time frame established for reopening determinations at 42 CFR 405.980(b).” (CMS FAQ6089)
- “[U]ntil the proposed [repayment] rule is finalized, providers and suppliers of services disclosing actual or potential violations of the physician self-referral law under the [SRDP] may perform the financial analyses required under … the SRDP using the applicable time frame and requirements for reopenings established in the existing reopening regulations at 42 CFR 405.980(b).” (CMS Stark FAQ6093)



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# Stark Self-Referral Disclosure Protocol

SRDP Process

- CMS verification
  - CMS must have access to all financial statements, notes, disclosures and other supporting documents without assertion of privilege or limitations.
  - CMS may request additional information; disclosing party will have 30 days to respond.
  - "Matters uncovered during the verification process, which are outside the scope of the matter disclosed to CMS, may be treated as new matters outside the SRDP."

# Stark Self-Referral Disclosure Protocol

SRDP Process

- Payments
  - Do not make payments while SRDP is pending without CMS approval.
  - Encouraged to place subject money in interest-bearing escrow account.
  - Must repay individuals who were improperly billed for service per improper referral, e.g., repay co-pays.

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# Stark Self-Referral Disclosure Protocol

- "The disclosing party's diligent and good faith cooperation throughout the entire process is essential…. CMS expects to receive documents and information from the disclosing party that relate to the disclosed matter without the need to resort to compulsory methods. If a disclosing party fails to work in good faith with CMS to resolve the disclosed matter, that lack of cooperation will be considered when CMS assesses the appropriate resolution of the matter. Similarly, the intentional submission of false or otherwise untruthful information, as well as the intentional omission of relevant information, will be referred to DOJ or other Federal agencies and could, in itself, result in criminal and/or civil sanctions, as well as exclusion from participation in the Federal health care programs." (SRDP)
- Provider may be expelled from SRDP if fails to cooperate.

# Stark Self-Referral Disclosure Protocol

- Factors considered in reducing amounts owed:
  - Nature and extent of improper or illegal practice.
  - Timeliness of self-disclosure.
  - Cooperation in providing additional information related to the disclosure.
  - Litigation risk associated with the matter disclosed.
  - Financial position of the disclosing party.
- "While CMS may consider these factors…., CMS is not obligated to reduce any amounts due and owing."



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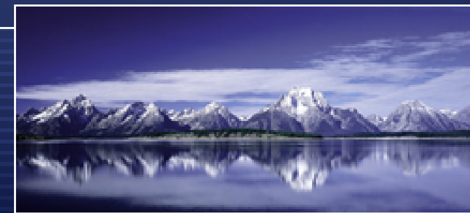
# Stark Self-Referral Disclosure Protocol



- Settlement
  - After considering the factors, CMS will determine the settlement amount.
  - Don’t count on being able to negotiate.
  - If provider is under financial difficulty, it may be able to enter long-term payment plan.
  - Settlement agreement does not relieve disclosing party of criminal, civil, or other actions except Stark.

  (*See* SRDP Report to Congress (2012))
- Withdrawal
  - If party does not accept settlement, it may withdraw.

# Stark Self-Referral Disclosure Protocol

- "Sanctions for violating [Stark] are often severe and sometimes lead to disproportionately large damage amounts compared to the severity of the violation… The statute's overpayment sanction creates a significant potential financial burden on health care providers."
- "CMS [is] using the authority granted by Congress to reduce disclosed overpayments in a manner that is proportional to the nature of the disclosed violations…."

(SRDP Report to Congress (2012))



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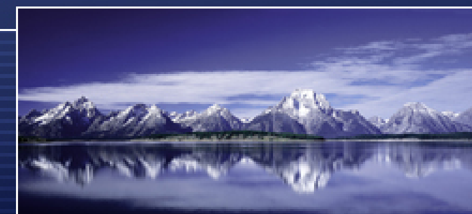
# Reported SRDP Settlements



- Have limited information re SRDP settlements

| Violation | Exposure | SRDP Settlement |
|---|---|---|
| Failed regulatory requirements applicable to service contracts with physicians | $14,500,000* | $579,000<br><br>Approximately 4% of potential exposure |

** Based on news accounts*

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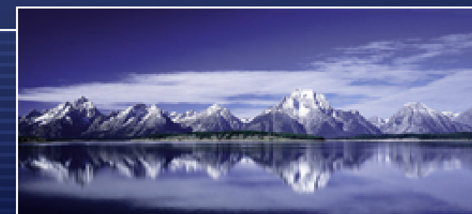
# Reported SRDP Settlements



| Conduct | Settlements |
| --- | --- |
| Exceeded annual total for non-monetary compensation exception | $4500<br>$6700<br>$6800 |
| Failed lease requirements | $42,000 |
| Failed employment requirements | $74,000 |
| Failed independent contractor requirements (e.g., expired contract) | $22,000<br>$22,000<br>$59,000<br>$125,000<br>$130,000<br>$208,000 |

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# Reported SRDP Settlements

- Recent settlements include:
  - 12/2014 – MN hospital arrangements with physicians
    - $231K
  - 12/2014 – NC physician group arrangements with physicians
    - $180K
  - 11/2014 – MI hospital arrangements with physicians
    - $60K
- Note lower amounts when compared to OIG SDP



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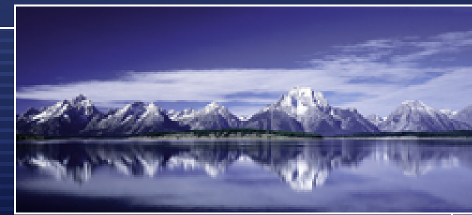
# Report to Dept. of Justice ("DOJ")



# Report to DOJ

- Provider may disclose noncompliance to the DOJ or local US Attorney's Office.
- Benefits
  - 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.
- Risks
  - DOJ is in the business of prosecuting.
  - DOJ is unknown commodity.
  - No defined process for resolving matters.

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

# Remember State Laws

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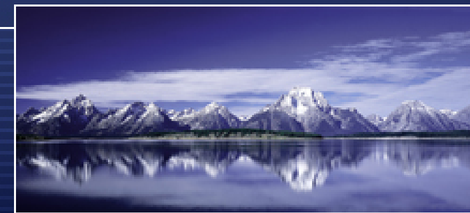
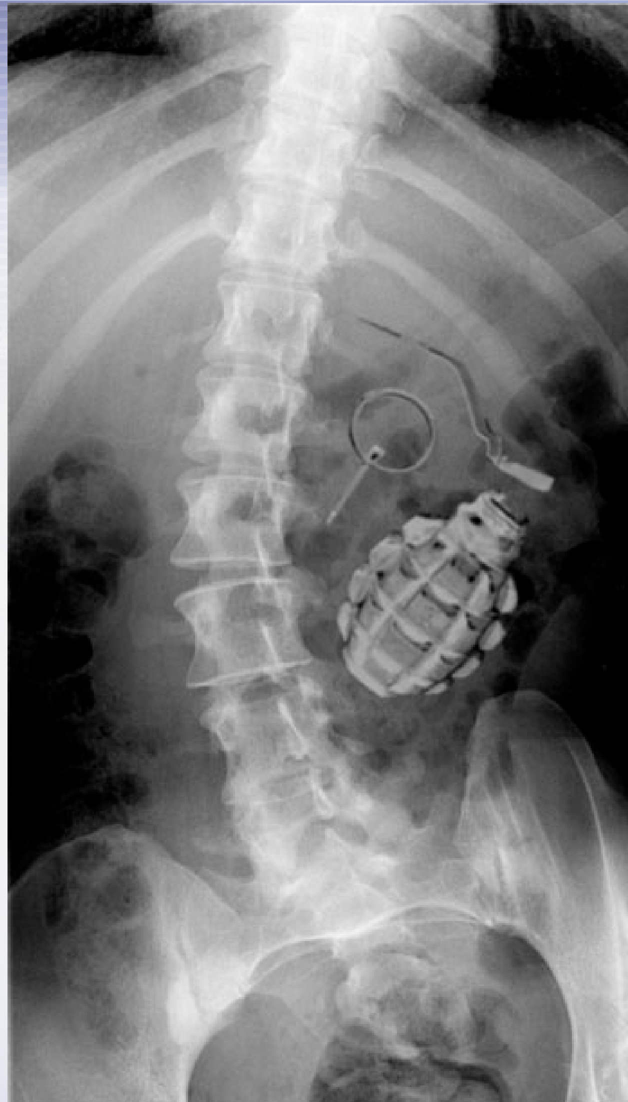
# State Laws

- 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.

# Non-Compliance and Repayment





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# Better to Comply

- Understand the relevant fraud and abuse statutes
  - "High risk" issues identified by OIG Work Plan.
    - Coding and billing issues
    - Anti-Kickback Statute
    - Stark
    - Civil Monetary Penalties Law
    - State fraud and abuse laws
  - Resource materials
    - OIG Compliance Education Materials available at https://oig.hhs.gov/compliance/101/index.asp.
    - Compliance Program Guidance at https://oig.hhs.gov/compliance/compliance-guidance/index.asp.
    - OIG *Roadmap for New Physicians: Avoiding Fraud and Abuse*
  - State fraud and abuse laws

# Better to Comply

- Implement an effective compliance program
  - See OIG Compliance Program Guidance, available at https://oig.hhs.gov/compliance/compliance-guidance/index.asp.
    - Compliance officer / Compliance committee
    - Compliance policies and procedures
    - Open lines of communication
    - Training and education
    - Auditing and monitoring
    - Responding to non-compliance
    - Discipline for non-compliance
  - May help ensure compliance.
  - May mitigate exposure if fail to comply.
  - Compliance plans will become mandatory soon.



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# Better to Comply

- Check and periodically audit financial relations with physicians and other referral sources if referrals involve government 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, and Civil Monetary Penalties Laws

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# Better to Comply

- 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

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# If there is a problem…

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# Responding to Non-Compliance

- 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?
  - Amount and type of payments involved?
- Consider involving knowledgeable healthcare attorney.
  - Expertise in evaluating relevant laws and regulations.
  - May provide some protection if act on advice of counsel.
  - May maximize attorney-client privilege.

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# Responding to Non-Compliance

- Immediately investigate – the clock is ticking.
  - Remember 60-day deadline; must act with “all deliberate speed”.
  - 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.

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# Responding to Non-Compliance

- Determine whether a violation actually occurred.
  - Consider all relevant regulations and exceptions.
  - Did transaction involve federal program payments?
  - Was remuneration paid to referral source?
  - Were there improper referrals?
  - For AKS situations, was there intent to induce referrals?
  - Are there applicable exceptions?
    - Need only satisfy one exception or "safe harbor"
    - Indirect compensation definition or exception
    - 6-month holdover exceptions
    - Limited exception for failure to obtain signatures
    - Temporary non-compliance
    - Isolated transactions




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# Responding to Non-Compliance

- Apply regulations that were relevant at the time.
  - Regulations have been amended at times.
  - Apply exception as it existed during relevant time period.
- Consider official commentary and decisions relevant to the compliance issue.
  - Advisory Opinions
  - Preamble to regulations published in Federal Register ("FR")
  - Advisory Bulletins and Fraud Alerts
  - CMS Frequently Asked Questions
  - Local guidance



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# Responding to Non-Compliance

Potential exception for providers "without fault"?

- "A provider is liable for overpayments it received *unless* it is found to be without fault…. The FI or carrier considers a provider 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 FI or carrier's attention."

  (Medicare Fin. Mgmt Man. Ch. 3 § 90)
- A provider is presumed to be without fault after 3 years. (*See* 42 CFR 1395gg(b)-(c)).

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# 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.

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# 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.



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# Responding to Non-Compliance

- If confirm repayment obligation, timely report and repay overpayments within 60 days.
  - Repayment Law
    - 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

- Once you take the step to self-report, there is no turning back…

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# 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 government will check your facts and analysis.
  - Assume that government investigation may go beyond your initial disclosure to consider other issues.

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# Responding to Non-Compliance

- When calculating exposure, verify actual payments received from federal programs during relevant period.
  - Were payments received for DHS?
  - Were there cost report adjustments or write-offs?
  - Were there co-pays from patients?
  - Was referring physician the admitting physician?
  - Did referrals affect the DRG payment?
- Limit analysis to relevant look-back or other period.
  - 4-year look-back period for Stark.
  - Others?

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# 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 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 government's proposed settlement.
  – May withdraw.
  – 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 government to prove; less incentive to pursue additional claims.

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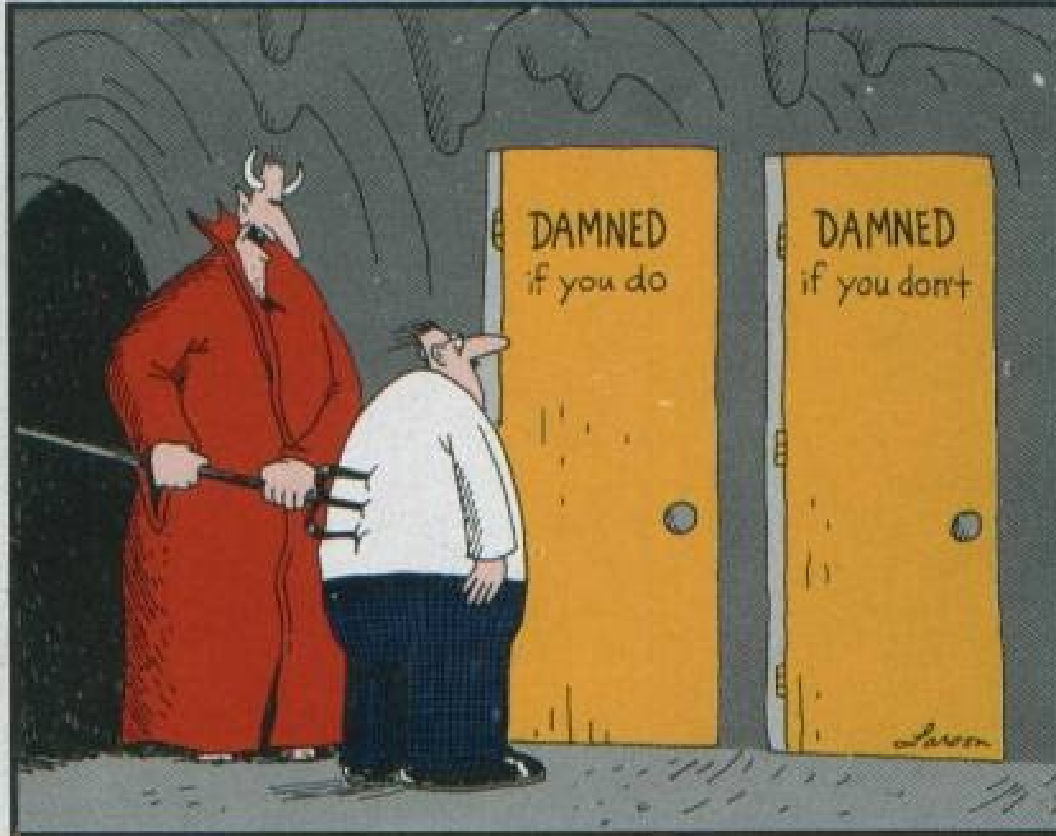
# Responding to Non-Compliance




"C'mon, c'mon — it's either one or the other."

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# Additional Resources

- OIG fraud and abuse website, https://oig.hhs.gov/fraud/
  - Compliance 101 training
  - Fraud Alerts, Advisory Opinions, Special Advisory Bulletins
- OIG Compliance Program Guidance, available at https://oig.hhs.gov/compliance/compliance-guidance/index.asp
  - OIG Compliance Program Guidance for Hospitals
  - OIG Supplemental Compliance Program Guidance for Hospitals
  - OIG Compliance Program Guidance for Physician Offices
  - Similar guides for other segments
- Lots of materials available on internet

* *Beware of out-of-date or bad information.*



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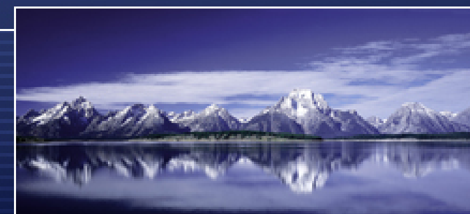
# Additional Holland & Hart Resources



- Future webinars
  - 2/4/16 *HIPAA Privacy and Security Rules*
  - 2/11/16 *HIPAA for Business Associates*
  - 2/18/16 *Responding to HIPAA Breaches*
  - 3/3/16 *Provider Networks*
  - 3/10/16 *Network Adequacy*
- *Healthcare Update* and *Health Law Blog*
  - Under "Publications" at www.hollandandhart.com
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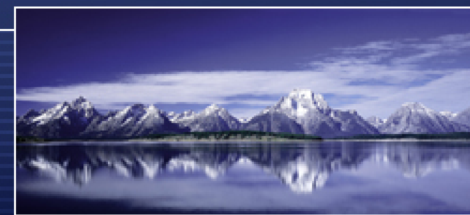
# Contact Information

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