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Enforcement Trends Part II: When You Identify a Compliance Failure, What Next?

(PLUS What to Do When the Feds Come Knocking)

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Disclosure

- NONE.

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Learning Objectives

- The health care business in general, and the radiology business in particular, are complex endeavors. And although most everyone strives to stay in compliance with “all applicable laws,” no one is perfect. It’s almost inevitable that every radiology business will eventually encounter some type of compliance failure. When it does, the obligations a radiology business faces today are different than in the past. The various alternative approaches for handling a compliance failure have differing advantages and disadvantages. Perhaps most significantly, for Medicare reimbursement, the business could very likely have an affirmative, Federally-mandated, repayment obligation.
- At the conclusion of this session attendees will be able to:
 - Understand the affirmative repayment obligation under the Affordable Care Act (“ACA”).
 - At least on a preliminary basis, be able to weigh the relative pros and cons to the various approaches for responding to a compliance failure.
 - And in a worst case, know what to do when the Feds “come knocking.”



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“60 Day Rule”

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Affordable Care Act

“60 Day Rule”

- 60 Day Rule requires providers to report and refund overpayments within 60 days of “identification.”
- “Overpayment” is defined in Section 6402 of the ACA as any funds a person receives or retains under Medicare or Medicaid to which the person, “after applicable reconciliation,” is not entitled.
- An overpayment is “identified” when a person has or should have, through the exercise of reasonable diligence, determined that an overpayment was received.
 - “Reasonable diligence” is demonstrated by timely, good faith investigation, which CMS indicates is at most 6 months from the receipt of credible information regarding a potential overpayment absent extraordinary circumstances.
 - An overpayment is not “identified” until it is quantified (unless a provider fails to exercise reasonable diligence).
 - Overpayments identified by a probe sample need not be returned until the full overpayment amount is identified.

Affordable Care Act

“60 Day Rule” (cont’d)

- Failure to exercise reasonable diligence to investigate credible information regarding a potential overpayment will result in a violation of the 60 Day Rule under the “should have known” standard if an overpayment was received.
- CMS advises providers to maintain records of their reasonable diligence efforts.
- **BE AWARE OF THE IMPLICATIONS FOR FAILURE TO COMPLY WITH THE 60 DAY RULE:** Any overpayment retained past the deadline is an “obligation” under the reverse false claims provision of the False Claims Act (“FCA”).
 - FCA penalties are not less than \$5,500 nor more than \$11,000 per claim plus treble damages.
 - THIS MEANS: the “fix it and move on” approach is no longer viable.



Self-Disclosure

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Self-Disclosure Options

- Updated OIG Self-Disclosure Protocol (“SDP”).
- CMS Self-Referral (Stark) Disclosure Protocol (“SRDP”).
- State Provider Self-Disclosure Protocols.
- Department of Justice/U.S. Attorneys Office.
- Routine Report and Refund Channels.





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OIG Self-Disclosure Protocol

Potential Benefits of SDP

- Presumption against corporate integrity agreements.
- Lower damages multiplier.
- Suspends 60-day rule.
- Mitigates FCA exposure.
- Nearly always releases parties from permissive exclusion.





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OIG Self-Disclosure Protocol Background

- Conduct that may violate federal criminal, civil or administrative laws for which civil monetary penalties (“CMPs”) are authorized.
 - Does not include matters exclusively involving overpayment or errors.
 - Does not include “Stark only” disclosures.
 - Requires additional disclosures.
 - Internal investigation and corrective action must be completed within 90 days of submission (subject to extension).
 - Requires disclosing party to screen all current employees and contractors against the List of Excluded Individuals and Entities (“LEIE”) before making “excluded persons” disclosures.



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OIG Self-Disclosure Protocol Baseline Disclosure Requirements

- Information regarding disclosing party.
- Concise statement of conduct disclosed, including conduct giving rise to the matter, time period, and the names of implicated parties, including an explanation of their roles in the matter.
- Statement of the federal criminal, civil or administrative laws that are potentially violated by the disclosed conduct.
- Federal health care programs affected by the disclosed conduct.
- Damages estimate.
- Description of corrective action taken upon discovery of the conduct.
- Whether the disclosing party has knowledge that the matter is under current inquiry by a Government agency or contractor.
- Name of individual authorized to enter into a settlement agreement on behalf of the disclosing party.
- Certification statement.



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OIG Self-Disclosure Protocol

Additional Disclosure Requirements

- New requirements for false billing disclosures, including a minimum sampling requirement of 100 items.
- Excluded persons disclosures.
- Greater detail regarding why disclosed conduct potentially violated the Anti-Kickback Statute (“AKS”) and Stark Act, if applicable (*e.g.*, why arrangement was not commercially reasonable).
 - Also requires estimate of amount paid by federal health care programs for services associated with and total remuneration paid under unlawful arrangement.



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OIG Self-Disclosure Protocol Settlement Parameters

- \$10K floor for non-AKS disclosures/\$50K floor for AKS disclosures.
- 1.5 times multiplier presumed.
- Damages in false billing disclosures based on all affected claims or random sample, without “netting” of underpayments.
- AKS/Stark settlements typically based on multiplier of remuneration conferred by referral recipient to referral source.
- Previously refunded amounts will be credited.
- Presumption against corporate integrity agreements.
- Criminal matters referred to Department of Justice for resolution.
- Financial inability to pay must be documented with assessment of how much can be paid.



CMS Self-Referral (Stark) Disclosure Protocol Resolution

- CMS has the authority to accept a reduced overpayment (*i.e.*, less than 100%).
- CMS is clear to point out that it is under no obligation to accept the disclosing party's calculation of its financial liability or to compromise the overpayment at all.
- There are no limits on the reduction that CMS may make.
 - Theoretically, CMS may reduce the overpayment to \$0.
- Refund does not have to accompany the initial submission made under the SRDP.



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CMS Self-Referral (Stark) Disclosure Protocol Limitations

- Parties have no guarantee of acceptance into the SRDP.
- CMS will not waive the “refund to individuals” requirement in section 1877 of the Social Security Act which requires refund of any amounts collected that were billed in violation of the Stark law.
- Does not prohibit intervention by law enforcement.



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CMS Self-Referral (Stark) Disclosure Protocol Requirements

- Thorough description of the parties, financial relationship, time period of non-compliance, designated health services (“DHS”) at issue, and roles of the individuals involved in the matter.
- Analysis of the application of the Stark law to the conduct at issue, including which elements of the relevant exception were met and not met.
- Complete financial analysis identifying the 100% overpayment amount:
 - Can include alternate theories of the overpayment amount.
 - Recent CMS FAQ clarified that the financial analysis should be based on the applicable reopening period.
- Description of compliance efforts prior to and since the discovery of the Stark violation.
- Agreement to forfeit appeal rights.

Tips For Handling Self-Disclosures

- Adopt and implement policies to ensure satisfaction of the 60 day rule.
- Define “identification” of overpayments to occur following investigation and validation that overpayment was received and determination of the amount of the overpayment.
- Develop timely investigation and audit plan that avoids need to report and refund on a rolling basis to satisfy the 60 day rule when possible.
- Investigate “root cause” of overpayments to determine if they arose from intentional misconduct or reckless disregard of applicable law (ideally before quantifying damages).
- Limit investigation/audit scope to arrangements/claims where there is reason to believe that violations may have occurred.
- Consider pros and cons of reporting under a protocol v. to local U.S. Attorneys Office or through routine channels.
- Ensure that disclosures satisfy all requirements and anticipate Government concerns.

The logo for RBMA 2017, featuring the text "RBMA" in blue and "2017" in orange.

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What to Do When the Government “Comes Knocking”

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Who Is That Knocking (or NOT Bothering to Knock)?



- Federal and state regulators, law enforcement, prosecutors, whistle-blowers, auditors and inspectors general including:
 - Federal: FBI; HHS OIG; DOJ; IRS.
 - State: Attorneys General; State OIGs; state law enforcement; medical licensing boards.
 - Regulators: CMS; CDC; RAC auditors, ZPICs.
 - Undercover agents, confidential sources and whistle-blowers (and their attorneys).

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*But trouble usually first
comes in the mail...*



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Subpoena

To:

1.

2.

☒ 3.

☒

YOUR

Notice

☐

☐

☐

Atty. N

Name:

Atty. for

Address

City/State

Telephone

☒ I s

by

I p

☐ I s

I p

AO 110 (Rev. 06/09) Subpoena to Testify Before a Grand Jury

UNITED STATES DISTRICT COURT
for the
NORTHERN DISTRICT OF ILLINOIS

SUBPOENA TO TESTIFY BEFORE A GRAND JURY

To: [REDACTED]

YOU ARE COMMANDED to appear in this United States District Court at the time, date, and place shown below to testify before the Court's Grand Jury. When you arrive, you must remain at the court until the judge or a court officer allows you to leave.

Place:

Dirksen Federal Building, Rm. 1625

219 S. Dearborn

Chicago, Illinois 60604

Grand Jury: SPECIAL JULY 2016 GRAND JURY 13 GJ 928

Date and Time:

February 9, 2017

1:30pm

You must also bring with you the following documents, electronically stored information, or objects (blank if not applicable):

Date: February 2, 2017



CLERK OF COURT

Thomas G. Butler

Signature of Clerk or Deputy Clerk

The name, address, e-mail and telephone number of the United States Attorney, or Assistant United States Attorney, who requests this subpoena, are:

Tyler C. Murray (tyler.c.murray@usdoj.gov)

Assistant United States Attorney

219 S. Dearborn, Rm. 500

Chicago, Illinois 60604

(312) 353-7846

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Papers with consequences!

Civil/Administrative

- ZPIC letters.
- DOJ Civil Investigative Demands.
- OIG Subpoenas.

Criminal

- Grand Jury Subpoenas.
- State AG Subpoenas.
- Search Warrants.

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Read it carefully!

- Who issued it?
- Can I tell if I am a target, subject or just a witness?
- Is there a deadline? Was it served properly?
- What are they asking for? What do they really need?





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What to do next

- Document receipt – how was it received (proper service could be an issue).
- Call your lawyer immediately.
- Preserve all relevant documents and information/ Disable any auto-delete functions. (Not a good time to suddenly lose your phone).



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What Are They Carrying?

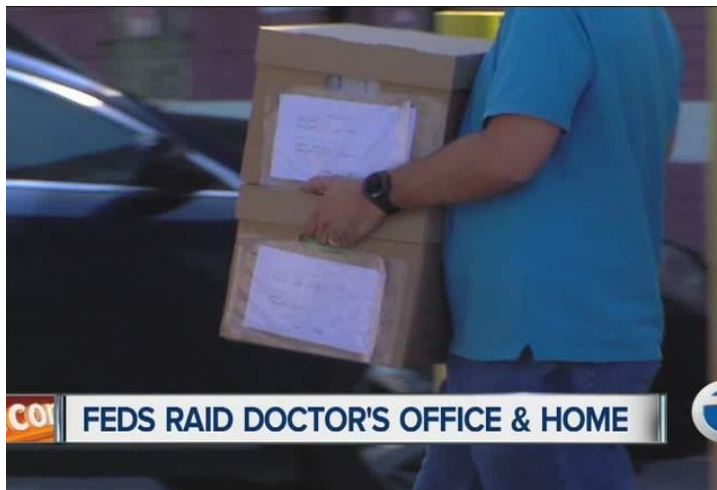
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- Search warrants.
- Subpoenas.
- Requests for interviews.
- Inspection demands (*i.e.*, medical records; office protocols).
- Books and records audits.
- Other.





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Search Warrant

- Issued by a judge based on “probable cause” that criminal conduct has occurred.
- Grants law enforcement agents the right to enter a location, search it and seize certain documents, physical items and electronic data and specifies:
 - The location/premises to be searched, AND . . .
 - The items to be searched.
- Often accompanied by an affidavit. Ask to see it.
- Unless the affidavit is “sealed,” you have a right to see the document.



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Search Warrant

What you can do

- There is very little you can do at the time the search warrant is executed other than contacting counsel immediately:
 - You may be able to raise objections to the search warrant at a later date.
 - Politely request the agents' delay starting the search until counsel arrives BUT the agents likely will not.
 - Review the warrant and make sure the search does not exceed the scope. DO NOT CONSENT to have other areas/items searched.
 - Create inventory of any items taken.



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Search Warrant

What NOT to do

- DO NOT volunteer information:
 - Any statements can be admissions (not under arrest so *Miranda* warnings not required).
 - You do not have to authenticate documents or respond to any questions except as to the location of documents described in the warrant.
 - Provide only truthful information.
- DO NOT obstruct the search:
 - This can itself be a criminal offense.
 - What constitutes obstruction can be at the discretion of the agents conducting the search.





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Search Warrant

What you should do

- Call internal crisis management team leader and outside counsel immediately.
- Note the area to be searched and try to direct the agents accordingly.
- Obtain and keep a copy of the warrant and the receipt for items seized.
- Record the identity of every agent involved and his/her agency:
 - Ask for credentials/ID and business card.
- Politely ask questions about the purpose of the search.
- Accompany the agents to the extent permitted to help identify the areas described in the warrant.
- Maintain your own inventory of seized items.

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Requests for Interviews

What are they?

- Unannounced Surprise! Surprise! Surprise!
- Frequently will contact you at home or in the parking lot outside of work.
- Often accompanied by service of subpoena or execution of a search warrant.
- It is routine to seek to interview corporate officers and employees when serving a subpoena or executing a search warrant.
- Agreeing to an informal interview does not eliminate the possibility of a grand jury subpoena.



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Requests for Interviews

What you should do

- Contact internal crisis management team leader and outside counsel immediately.
- Identify the lead officer or prosecutor.
- Ask for credentials/ID and business card.
- Appear friendly and courteous.
- Express interest in cooperating with the government.
- Try to find out the scope and focus of the government investigation.





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Requests for Interviews

What NOT to do

- Employees should understand their right NOT to speak with the agent about anything substantive without counsel present.
- Employees DO NOT have to let the agents inside their residences or buildings unless there is a search warrant.
- DO NOT destroy or alter documents.
- DO NOT lie.





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Requests for Interviews

What to advise employees NOW and THEN

- Employees should be advised of these basics and their “rights” now (during training) so that they are aware of it long before the government requests an interview.
- Advise employees and executives that the company will make an attorney available to be present during any interviews:
 - Employees can be advised that the company requests a company lawyer to be present at any interview.
- If they speak with an agent without company counsel, ask them to “de-brief” the company afterward.
- If they agree to an interview, they have the right to request a time and place of their own choosing.
- They have the right to insist on the presence of counsel.
- They should always tell the truth:
 - Failing to do so may itself be a violation of law.



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Subpoenas and Document Requests

- A subpoena is essentially a formal request for documents.
- Can be costly in time and expense to comply.
- Typically request production of certain documents by a specific date.
- It is routine for subpoenas to request e-mails and voice mail.
- Recipients can be the Target, Subject, or a third party witness in an investigation.



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Subpoenas and Document Requests

What to do

- Forward the subpoena to outside counsel for review.
- Comply with the subpoena.
- The response must be coordinated and supervised by counsel.
- The counsel should contact the government agency issuing the subpoena to discuss its scope:
 - A request can be made to modify the subpoena to lessen the burden.



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Subpoenas and Document Requests

Inform your employees

- Counsel should review the subpoena with employees and make themselves widely available to answer questions.
- Circulate a written set of procedures to employees on how, when, and to whom documents should be sent.
- Circulate a timeline of when documents need to be turned over to the company's counsel for review.
- Ask each employee to fill out a tracking sheet.
- Require employees to sign a declaration that they conducted thorough searches.





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Document Preservation Protocol

- Take reasonable steps to preserve relevant evidence from loss or destruction when you know the evidence is relevant to pending investigation or anticipated proceeding.
- Suspend otherwise applicable record retention policies and auto-delete functions.
- Preserve electronically stored information when you have notice that the evidence is relevant to litigation or future litigation.
- Just because electronically stored information is “not reasonably accessible” does not relieve a party’s duties to preserve evidence.
- Legal Hold: A legal hold notice is a written notice, informing each person that is reasonably likely to have information or documents related to a pending or anticipated proceeding, that they must preserve them:
 - Critical to consult counsel immediately upon receipt of subpoena so that counsel can prepare and circulate a Legal Hold Memo promptly.



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Thank you!

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