

Health Care Compliance Association
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Down the Rabbit Hole: Compliance Investigations, Corrective Action Planning, and Self-Disclosure

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Agenda

- Explore best practices and the roles of Legal, Compliance and outside counsel in conducting internal compliance reviews, corrective action planning, and disclosure decision-making
- Review the analysis for determining whether an overpayment has been received and compliance with the 60 Day Overpayment Rule
- Discuss the benefits and risks of self-disclosure and strategic considerations in deciding where to disclose

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Compliance and Legal As Team

- Compliance and Legal should function as a team
 - Jointly make decisions on risk management
 - Both have interest in compliance
 - For some issues, the organization should make decision to conduct investigation under privilege sooner rather than later



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Overpayment or Potential Fraud Liability?

- Legal Questions
 - Applicable coverage and payment statutes and regulations
 - Manual provisions
 - 60 Day Overpayment Rule
- Factual Questions
 - Who, what, when, where, why
 - Internal investigation/review process
- Optics Considerations
 - Comfort level of explaining the decision to the government or other external stakeholder (e.g. potential buyer) in the future

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Legal Question: Is There an Overpayment

- Primacy of legal authority
 - Statute
 - Regulation
 - Sub-regulatory guidance
 - National Coverage Decisions
 - Local Coverage Decisions
 - CMS Preambles
 - CMS Manuals
 - Contractor Guidance
 - Appeal experience
- Binding requirement or Guidance?
 - Clear or ambiguous?
 - Condition of Payment or Participation?
 - Legal standard or audit standard?

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Conduct Legal Research Early On to Set Framework for Investigation

What Are Company's Legal Obligations?

Ethics = Voluntary

Legal Obligations = Mandatory

Gray areas – manuals, policy statements, sub-regulatory guidance



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Gathering Facts

- Who should direct the investigation
 - Counsel
 - Inside or outside
 - Compliance
 - HR
 - Other
- Who should "conduct" the investigative steps
 - Counsel
 - Auditors
 - Compliance staff
 - HR staff
 - Managers
 - Outside consultants
- What are the investigative steps?
 - Start with preserving and gathering documents
 - Allows you to ask better questions in interviews
 - Gives you important background
 - You may want to ask witnesses about particular documents
 - Audits as a starting point?
 - Can establish whether there is a problem

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Gather Facts: Documents

- Documents drive government and internal investigations
- Fact chronology – create a timeline
- Organize documents in witness folders
- Get the org chart and job descriptions (official and "real")
- Make a process chart
- Issue-specific
 - Space issue = get the lease, floor plan, rental log, and tour



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Gathering Facts: Interviews

- Goals
 - Gather information
 - Assess interviewee's credibility
 - Demeanor
 - Logic and consistency of witness' statement in the context of other information
 - Corroboration
 - Limit unnecessary disclosures
 - Maintain credibility of your investigation
 - Keep people open to talking to you – building trust will get to the truth



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General Interview Guidelines

- The ideal is to conduct interviews in person with two interviewers
- Try not to draw attention to the person being interviewed
- No group interviews
- Take notes, do not tape
- Be conversational, personable, and serious
- Focus on listening, not talking
- Don't put words in the person's mouth
- In general, don't discuss one person's interview with another person
- Don't be opinionated or judgmental
- You can remind employee that refusal to cooperate in an internal investigation may lead to discipline if the person is being evasive or uncooperative

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General Interview Guidelines

- Start by giving an initial introduction
- Corporate Miranda or "Upjohn Warning" – if interview done by counsel
 - Company counsel only represents and advises company, not any individuals
 - Company controls attorney-client privilege, witness must maintain confidentiality
 - Company may disclose interview
- Ask open-ended questions
 - What happened? When? Where? Who did it?
- Follow up with specific questions
 - Who said what? In what order? How long was the conversation? Did he or she say anything else? What did the other person say in response?
- Focus on how the interviewee knows what he or she is telling you

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Privileges and Investigations

- Typically, there is no privilege for routine compliance materials
 - Attorney-client and attorney work-product privileges usually do not apply if cannot meet threshold requirements
 - Self-evaluative privilege not widely recognized
- Types of materials potentially subject to disclosures (unless privileged)
 - Audits (preliminary, draft, etc.)
 - E-mails
 - Compliance committee meeting agendas and reports
 - Compliance reports to board
 - Any other materials

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Privileges (cont.)

- Attorney-Client Privilege
 - Protects communications between attorney and client for purpose of seeking legal advice
 - Protects direct communications with in-house or outside legal counsel for legal (not business) advice
 - Attorney can retain agents to assist
 - Auditors
 - Investigators
 - Consultants
 - Communications between agents and client; or between agent and attorney can be covered by privilege
 - But must be for the purpose of providing legal advice

Overpayment Statute: ACA, Section 6402(a); SSA Section 1128J(d); 42 U.S.C. § 1320a-7k(d)

- **In general.** If a person has received an overpayment, the person shall –
 - report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and
 - notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.
- **What is an “Overpayment?”**
 - The term “overpayment” means any funds that a person receives or retains under subchapter XVIII or XIX of this chapter to which the person, after applicable reconciliation, is not entitled under such subchapter.

Overpayments and False Claims

- **Deadline for reporting and returning overpayments.** The later of –
 - the date which is 60 days after the date on which the overpayment was identified; or
 - the date any corresponding cost report is due, if applicable
- **Enforcement:** If an overpayment is retained past the deadline, it may constitute an “obligation” under the False Claims Act.
 - False Claims Act: imposes liability for “knowingly concealing or knowingly and improperly avoiding or decreasing an obligation” to pay the United States. (31 USC 3729(a)(1)(G))
 - ACA also created new CMPL action for a penalty of up to \$10,000 per item or service and three times the amount claimed and exclusion for “Any person . . . that **knows** of an **overpayment** . . . and does not report and return the overpayment in accordance with [section 6402].”

Final Rule, 81 FR 7954 (February 12, 2016)

- Regulatory provisions interpreting the Overpayment Statute (42 C.F.R. 401.301-5)
 - Lookback period
 - 6 years from the date the overpayment was identified
 - How to report and return
 - Use the "most appropriate mechanism" based on the "nature of the overpayment"
 - Meaning of identified
 - When a provider or supplier "has determined, or should have determined through the exercise of reasonable diligence, that [it] **received an overpayment and quantified the amount** of the overpayment"
 - "Should have determined" means the provider or supplier failed to exercise reasonable diligence and in fact received an overpayment

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When does the 60 day clock start?

- CMS said providers have time to conduct the "reasonable diligence" before the 60 day clock starts to run
 - After receiving "credible information" the provider needs to undertake reasonable diligence
 - CMS articulated a 6 month "benchmark" for conducting reasonable diligence, except in "extraordinary circumstances" such as Stark issues, natural disasters, or states of emergency
 - The 60 day clock starts to run when either:
 - When the reasonable diligence is completed, or
 - On the day the credible information was received and the provider failed to conduct reasonable diligence (and an overpayment in fact was received)

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Hypo Two Midnight

- Shady Pines Hospital GC, Dorothy Zbornak, calls in a panic. Shady Pines is in the last year of its inpatient admission CIA and the IRO says that they believe the Discovery Sample error rate exceeds 5%, which triggers a Full Sample.
- The IRO, Sophia Petrillo, identified 15 out of 50 claims in the Discovery Sample as not qualifying for inpatient payment because the patient was stable at the time the inpatient admission order was written, and therefore, the physician could not have reasonably expected the patient to require inpatient hospital services for two-midnights following the time the inpatient order was written.
 - For these patients, they were in outpatient status for some portion of their hospital stay.
 - Appropriate care was provided and at some point in time prior to discharge, the physician wrote an inpatient admission order.

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Hypo Home Health

- The St. Olaf Medical System in Minnesota is a large, integrated health system that owns a home health agency. Rose Nylund, the GC, calls in a panic – she just received an email from an employee that was fired last week for insubordination that says the agency is committing blatant Medicare fraud.
- The former employee, Blanche Devereaux, says that the agency frequently bills illegally for home health services:
 - With insufficient medical documentation
 - The certifying physician does not conduct a face-to-face evaluation of the patient and the face-to-face evaluation is not done before services begin
 - Before it has received a signed certification from the physician
 - That have defective recertification forms that fail to meet Medicare requirements

Options: Deciding Where to Disclose

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



Self-Disclosure Options

Refund	SRDP	SDP	State Agency	U.S. Attorney
<ul style="list-style-type: none"> • Simple process/ minimizes legal fees • No reduction in amount • No release of any kind • Six-year lookback period 	<ul style="list-style-type: none"> • Track record suggests likelihood of reasonable settlement • Stark only • 1877(g)(1) release • <i>De facto</i> six-year lookback period 	<ul style="list-style-type: none"> • Benchmark 1.5 multiplier • Release of CML and exclusion • Potentially reduce FCA exposure • Updated guidelines • Six-year SOL 	<ul style="list-style-type: none"> • Release of State authorities only • Uncertainty on posture and penalty amount • Experience may vary widely • SOL varies 	<ul style="list-style-type: none"> • Broadest release • Uncertainty on posture and penalty amount • Experience may vary widely • Six-year SOL

Outcomes: Disclosure Pros and Cons

Pros	Cons
<ul style="list-style-type: none">▪ Legal duty if received overpayment▪ Start from positive place<ul style="list-style-type: none">– Good corporate citizen– Effective compliance program▪ Can be prepared▪ Less disruptive▪ Lower multiplier more likely▪ Presume no CIA/exclusion▪ Closure▪ Less reputational effect possible	<ul style="list-style-type: none">▪ Some pathways are less predictable than others▪ Payment usually necessary▪ Not place to get agency's opinion▪ Can be long process▪ Referrals among agencies possible▪ Follow on actions by private insurance or states▪ Some publicity still happens

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Thank you!

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