

Conducting Internal Investigations

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Disclosure

- *Bryan Nowicki and Emily Solum*, faculty for this educational event, have no relevant financial relationships with ineligible companies to disclose.

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Learning Outcomes

- Upon completing this session, participants will be able to:
 1. Conduct an internal investigation
 2. Distinguish between complaints that may impact payment from those that raise general compliance concerns

Roadmap: Stay Calm & Navigate On

- Accept the "Realities" – They Are Not All Bad
 - Debunking the common myths
 - What is a complaint? What is involved in an investigation? What are the government's expectations?
- The Key Concepts That Must Guide You
 - Putting the 60-day repayment principles into practical terms
 - A reminder on the issues that impact payment
- Your Plan of Action
 - The steps for an effective and efficient investigation
- Have the Resources: Today's toolbox:
 - Handout: "Overview of the Final 60-Day Repayment Rule"
 - Handout: "Medicare Hospice Regulatory Conditions of Payment"
 - Handout: "Sample Investigation Plan"

Preface

- This presentation is meant to provide an overview of some key issues hospices face related to compliance and evaluating potential repayments through an internal investigation
- This presentation does not constitute legal advice, and is not intended to take the place of legal advice

Accept the “Realities”: Debunking Common Myths

Myth: We are a good hospice; we rarely have "complaints"

- Reality: While they may not come with a label, everyone receives complaints and you need to identify them as such
 - Complaints can be wide ranging: Quality of care, licensure, technical documentation issues, clinical issues
 - They come in many forms: Anonymous hotline, personnel issue, billing issue, service standards
 - They can come for many different sources: The government (audit findings*, claim denials, PEPPER Reports), departing employees, current employees, patients, families

*81 Fed. Reg. 7654,7667 (Feb. 12, 2016)

Myth: We are a good hospice; we rarely have "complaints" (cont.)

- Failing to identify an issue as a "complaint" and dealing with it accordingly can lead to bigger problems
 - Increase risk for whistleblower actions
 - Could be viewed as acting in "reckless disregard" or "deliberate ignorance" under the False Claims Act
 - Potential individual liability under the Yates Memo:
 - Guidance to all DOJ attorneys (very significant statement of enforcement priority) reiterating DOJ's commitment to hold individuals who perpetrate corporate wrongdoings personally accountable

Myth: All complaints I investigate are expected to result in a repayment

- Reality: Only those small sets of issues that implicate a condition of payment are likely to result in an overpayment
 - See Handout, "Medicare Hospice Regulatory Conditions of Payment"

Myth: A repayment is a "black eye" leading to further government scrutiny

- Reality: Repayments are expected by the government and considered a byproduct of an effective compliance program
 - The government will judge you by:
 - What you knew
 - When you knew it/should have known it
 - What you did about it
 - How you made sure it won't happen again

Myth: We are not professional investigators; I don't know or have the resources to conduct an investigation

- Reality: Sure you do; the steps of an effective investigation are largely "common sense"
 - What happened, when, by whom, why and how?
 - Like other areas of your business, you need to develop:
 - A process for conducting an investigation
 - A person(s) responsible who will build experience, knowledge and consistency
 - Not all investigations need to involve legal counsel
 - Likely to be dependent on any number of factors, such as the need for privilege, complexity, scope and potential implications of the issue

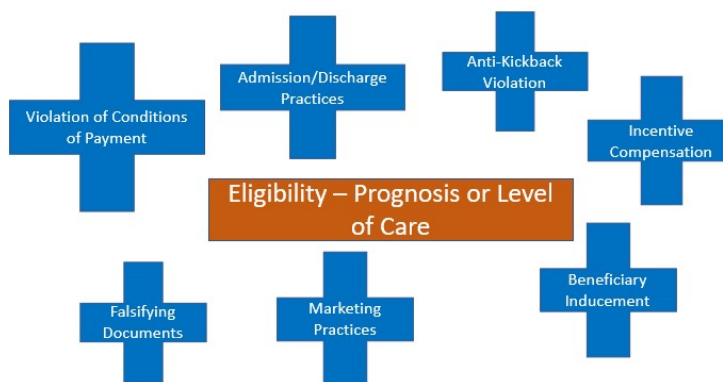
The Key Concepts That Must Guide You

Overview of AKS & FCA

	Anti-Kickback Statute ("AKS") (42 U.S.C. s. 1320a-7b(b))	False Claims Act ("FCA") (31 U.S.C. s.3729)
Violation to:	<ul style="list-style-type: none"> Offer, pay, soliciting or receiving "Remuneration" (anything of value) Directly or indirectly, overtly or covertly, in cash or in kind In return for <u>referrals</u> or for <u>arranging for or recommending</u> goods, facilities, services or items 	<ul style="list-style-type: none"> Knowingly or with deliberate ignorance Submit or cause to be submitted A false or fraudulent claim for payment to the government Violation of AKS now <u>per se</u> violation of False Claims Act
Potential Ramifications:	<ul style="list-style-type: none"> Felony (criminal) Fined not more than \$25,000 Imprisoned for not more than 5 years Or both 	<ul style="list-style-type: none"> Between \$13,000 and \$27,000 per claim 3 times amount of damages Attorneys fees
Who is Liable:	Both Parties to an improper transaction	Party that submits the false claim or causes the false claim to be submitted

Hospice FCA Risk Areas: Clinical Eligibility Plus

- Typically, patient eligibility central plus at least one or more other factors



The 60-Day Repayment Rule: The Standard

- Providers must report and return overpayments within 60 days after the identification of the overpayment
 - Failure to do so can lead to a "reverse" false claim under the False Claims Act
 - **60 days** from the day the provider received "credible information of an overpayment" if the provider does not undertake any investigation into the existence and amount of overpayment
 - See [Handout](#), "Overview of the Final 60-Day Repayment Rule"

The 60-Day Repayment Rule: Key Questions

- How Long Do I Have to Conduct My Investigation? It is clear that it may take longer than 60 days.
 - "At most **6 months**" plus 60 days if the provider conducts a reasonable investigation into the existence and amount of overpayment*
 - But CMS has recently proposed changes to this 6-month standard – to rely on when a provider had actual knowledge or acts in reckless disregard or deliberate ignorance (the broadly worded standard used in the statute itself)
- How Far Must I Look Back? Will depend on root cause, but may be up to 6 years from the date person identifies the issue
 - What are your "bookends" (start and stop)?
 - "Funnel" down the issue

*81 Fed. Reg. 7654, 7662 (Feb. 12, 2016); 87 Fed. Reg. 79452, 79559 (Dec. 27, 2022); *see also* 89 Fed. Reg. 30448, 30457 (Apr. 23, 2024) (noting that CMS has received inquiries, the proposal remains under consideration, and CMS intends to issue a final rule soon)

The 60-Day Repayment Rule: Key Concepts

- **Credible Information:** It is information that supports a reasonable belief that an overpayment may have been received
- **Reasonable Diligence:** It is an investigation conducted in good faith in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment
- **Identification:** Once you complete an investigation and identify you have an overpayment
- **Overpayment:** It is "any funds that a person has received or retained under title XVIII [*i.e.*, Medicare] of the Act to which the person . . . is not entitled"

Conditions of Payment

To be covered, hospice services must meet the following:	Key considerations for investigations:
1. Services must be reasonable and necessary for the palliation and management of the terminal illness as well as related conditions.	Eligibility for hospice benefit and levels of care
2. The individual must elect hospice care in accordance with § 418.24.	Technical; note cross-reference
3. A plan of care must be established and periodically reviewed by the attending physician, the medical director, and the interdisciplinary group of the hospice program as set forth in § 418.56.	Technical; note cross-reference; may also be implicated with personnel issues
4. A plan of care must be established before hospice care is provided.	
5. The services provided must be consistent with the plan of care.	
6. A certification that the individual is terminally ill must be completed as set forth in § 418.22.	Technical; note cross-reference

Your Plan of Action: Work Your Investigation

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The Key Infrastructure: Complaint and Investigation Processes

- Complaint Process: Prerequisite to an effective internal investigation process is an open and effective method for people to identify and communicate compliance concerns
 - Written policy for reporting compliance concerns
 - Well publicized reporting process
 - Allow confidential or anonymous reporting
 - Easy to communicate concerns
 - Multiple potential recipients of communication
 - All recipients should transmit complaint to compliance officer if it concerns a compliance matter
 - NO RETALIATION
- Investigation Process: Have a plan in place regarding who and how compliance concerns will be addressed
 - Compliance officer is main point of contact to establish plan and coordinate investigation
 - See Handout, "Sample Investigation Plan"

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Overview Of Investigation Process

Steps for Identifying and Addressing Potential Overpayments	
1. Receive Report/Complaint	
2. Immediate Actions/Interventions	
3. Consult Legal Counsel	
4. Perform Investigation: The 5 Ws (and an H)	What: Identify the real issue
	Who: Determine who is involved in the issue
	When: Determine when the issue began
	Where: Determine where the issue occurred
	Why: Understand the why to help narrow issue
How: Understand the how to help assess corrective actions	
5. Document Investigation	
6. Quantify Overpayment	
7. Report and Repay	
8. Implement and Monitor Additional Corrective Actions	

Step 1: Receive Report/Complaint

- What is the nature of the complaint?
 - A patient reports that a CNA was abrupt with her
 - Human Resources learns that a registered nurse did not renew her license
 - You begin receiving ADR denials for undated face-to-face attestations
 - An employee alleges that certain patients are not clinically eligible
- Is the complaint "credible information" of a potential overpayment?
 - Does it impact payment?
 - Condition of Participation versus Condition of Payment
 - Has the government indicated it is material?
- If yes, develop your plan for a "reasonable inquiry" (e.g., develop your investigation plan)
 - Process should follow same basic steps, but allow flexibility
 - Evaluate what methods of investigation might be necessary
 - Examples: Interviews, record reviews
 - Identify who will perform/assist in investigation

Step 2: Immediate Actions/Interventions

- Does the complaint require immediate action to be taken?
 - Does an employee need to be placed on administrative leave?
 - Example: Unlicensed registered nurse
 - Is a bill hold necessary?
 - Example: Patients for which clinical eligibility is being challenged
 - Is a pre-billing review necessary?
 - Example: Conduct pre-billing review on face-to-face visit attestations

Step 3: Consult Legal Counsel

- What involvement, if any, should my legal counsel have?
 - Legal counsel involvement can vary from fairly low to very high.
 - Guiding considerations:
 - Potential to protect investigation from government disclosure through attorney-client privilege
 - Nature of the complaint; the complainant (e.g., potential whistleblower); the scope; the potential dollar value at issue
 - Not every interaction is "privileged." Do not have a false sense of security
 - Privilege is created by state law, so each state may have a different approach

Step 4: Perform Investigation

- Plan investigation
 - Remember: Steps will be the same, but details will evolve based on what you are learning
- Goals for the investigation:
 - Define the issue - may end up being different than the complaint
 - Define the timeframe
 - What was the "root cause"/trigger event?
 - A person, a team, a new process/EMR
 - When did it stop?

Step 4: Perform Investigation (cont.)

Questions	Considerations
The What?	Identify the issue – IS it a repayment issue? <ul style="list-style-type: none"> - Evaluate whether issue relates to a Condition of Payment vs. a Condition of Participation - DOCUMENT conclusions, particularly if determined the information is NOT credible information of potential overpayment
The Who?	Identify individuals involved <ul style="list-style-type: none"> - Goal to limit issue to certain team, individual, etc. - Interview individuals, as needed (have two people present) <ul style="list-style-type: none"> - Complainant/reporter (if possible), other individuals involved, witnesses, etc.

Step 4: Perform Investigation (cont.)

Questions	Considerations
The When?	Present vs. Past (or both) and One Time vs. Ongoing - May need to look back - but <u>creep back</u> - Goal to limit time period/scope to a single event/activity or certain personnel, but evaluate carefully (e.g., "funnel the issue down," "find your bookends")
The Where?	Determine whether issue can be limited to a certain place/location
The Why?	Understanding why the issue occurred can help narrow the scope or timeframe of the issue - Also critical to determining what corrective actions may need to be implemented
The How?	Understanding how the issue occurred is <u>critical</u> to determining scope of <u>reasonable diligence</u> - Also important for determining what corrective actions may need to be implemented

Step 5: Document Investigation

- Prepare an Investigation Summary
 - See next slide for general structure
- Considerations:
 - Write the summary as though it may be reviewed by the government
 - Purpose is to summarize the issue and conclusion; not necessarily document the statements of each individual interviewed
 - Document list of people interviewed
 - Document list of documents reviewed
 - Document actions taken

Step 5: Document Investigation (cont.)

Investigation Summary

1. Define the issue
2. Summarize the evidence reviewed
3. State the findings/conclusion (did the issue occur as alleged)
4. Explain the actions taken to address the issue, if any (e.g., repayment)
5. Describe the corrective actions/preventive measures taken

Step 6: Quantify Overpayment

- Need to carefully determine time period of review to ensure compliance with 6-year lookback, if applicable to situation
 - Considerations
 - Remember "root cause" analysis – when did the issue start and end?
 - Circumstance may be self-limiting (e.g., problem limited to new physician, only with organization 3 months)
 - Full claim periods (e.g., a month's payment) may not always be at issue – could be less or more
 - What, if anything, can be "cured"
 - For example, the government generally permits attestations to be completed for missing dates on signatures

Step 7: Report and Repay

- If conclusion and recommended action is to refund, prepare refund submission
 - There is a MAC voluntary refund form for a reason, use it
 - Can generally use a spreadsheet to identify multiple claims at issue
 - Prepare check for amount of refund
 - Consider whether a refund cover letter would be helpful to describe any nuances related to the repayment
 - Keep a copy of everything submitted (including the check) and use a mailing method that allows you to track delivery
 - It's also important to track all claims included in a repayment in the event of a future audit involving those same claims
- **Common Question:** If overpayment within past year, can I just back out and adjust my claims?
 - Not always advantageous
 - Can raise red flags if making many adjustments
 - Not as easy to keep a copy of what was "submitted" (given limits in accessing claims data after a year hard to prove repaid if no hard copy)
 - As stated above, there is a form for a reason, use it!
- **Note:** Carefully document reasons/rationale if not refunding

Step 8: Corrective Action to Prevent Reoccurrence

- Investigation should reveal "why" this happened and suggest opportunities for improvement
 - Identify broad areas for improvement based on the "root cause" analysis
 - What are the categories of the issues that led to the problem/event?
 - Identify specific action items
 - How will you achieve the improvement?
 - What are the specific implementation measures that will address each area?
 - Typically multifaceted with, at a minimum, policy, education and monitoring components (See next slide)
 - Identify implementation details
 - Who is responsible for the improvement and when?

Step 8: Corrective Action to Prevent Reoccurrence (cont.)

- Three core components of corrective actions
 - Review and revise processes
 - Evaluate policies and procedures implicated by investigation
 - Determine if revisions are necessary to safeguard against similar issue
 - Educate on revisions
 - Determine who/which departments should be trained and whether any individualized training is needed
 - Document training and evaluate retention through post-tests
 - Audit/Monitor
 - Consider whether this is an area for pre-billing reviews or if a more frequent interval of review/check-in is necessary (e.g., weekly documentation review, weekly calls)

Takeaways

- Complaints come in many different shapes and sizes
 - Not one size fits all, but – importantly – the process is the same
- Let the tools guide you
 - Keep your 60-day repayment rule concepts in mind
 - Follow your investigation plan/process
 - Remember your threshold steps for determining whether payment could be implicated
- Be flexible
 - Just like the case scenarios, there will be changes in facts to navigate

References

- **60-Day Repayment Rule**
 - 42 C.F.R. §§ 401.301-.305
- **False Claims Act (“FCA”)**
 - 31 U.S.C. s. 3729

Team Discussion Questions

- What did the faculty share that you found thought provoking?
- What can we replicate in our organization?
- Who else on our team would benefit from this information?



Q & A

Thank You!

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