Best Practices for Conducting Compliance Investigations

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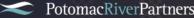
"Another hallmark of a compliance program that is working effectively is the existence of a well-functioning and appropriately-funded mechanism for the timely and thorough investigations of any allegations or suspicions of misconduct by the company, its employees or agents."

U.S. DOJ Guidance on the Evaluation of Corporate Compliance Programs (updated June 2020)



What does a "well-functioning" investigation process look like?

- Investigations are sufficiently funded and resourced
- Conducted by qualified personnel
- Investigations are properly scoped
- The response is timely and appropriately handled
- Results are tracked and analyzed for patterns of misconduct or other red flags of compliance weaknesses

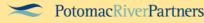


Who conducts your investigation?

Initial question



Should the investigation be conducted under attorneyclient privilege?



Who conducts your investigation?

- Initial question
- Who are "qualified personnel"?



- Independent and objective regarding the alleged misconduct
- Understands the organization and background of the issues being investigated
- Trained in investigation best practices
- Comfortable asking difficult questions and pushing back if necessary



Who conducts your investigation?

- Initial question
- Who are "qualified personnel"?
- Common investigators



- Compliance officers
- Members of legal team
- HR (employee relations)
- Auditors
- External investigators
 (e.g., external counsel, consultants)

What are you investigating?

• Define the scope of your investigation

- What is the alleged misconduct?
- Does it violate a policy, law, or regulation?
- What group in the company owns the area where misconduct occurred?



"What are you investigating?

- Define the scope of your investigation
- Does the alleged misconduct suggest a broader review of business functions is needed?
- How will you handle new issues that come up during the investigation?



How will you conduct the investigation?

- What is your communication process with the reporter?
- What documents do you need to collect to understand the alleged misconduct?
- Who will you interview?

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- Who do you need to inform of the investigation?
- What documentation will you create as part of the investigation (interview memos, investigation reports)?
- How will you track and record the investigation?

Consider putting in place: Standards for timely response to all reporters and timely completion of investigations



Why are you investigating?

- Who evaluates the findings to determine whether misconduct occurred?
- Who determines appropriate discipline?
- Investigation findings should be recorded and follow-up tracked
- For significant investigations, consider an after-action review
- Set a regular schedule for analyzing investigations and findings

- Define the group responsible for discipline and an escalation mechanism
- Evaluate both the target of the alleged misconduct <u>and</u> the functioning of the relevant compliance procedures



Today's Investigation



Investigation Scenario

Navilla Therapeutics

- Boston-based company
- Focused on developing therapies for rare genetic disorders

1 Commercial Product (Approved Feb 2022)

- CYSTIZIA, indicated for first-line treatment of nephropathic cystinosis
- Adults and pediatric patients 1 year and older
- Approved label requires the CTNS gene mutation; first to market for CTNS
- Similar products treat nephropathic cystinosis with different genetic mutations

Functionally-separate, field-based teams including:

- Field Sales (50)
- MSLs (5)
- Field Reimbursement (10)



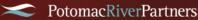
Refer to the Company Profile handout for additional information.

Please note:

All information provided is fictional and for educational purposes only.

"The game is afoot."

— Adventure of the Abbey Grange





MSL Natalie left the following message:

Hi, my name is Natalie Jackson; I'm an MSL in the Northeast region. I recently received a call from one of the Field Reimbursement Specialists, Jason, and I think he may be filling out prior auth forms for CYSTIZIA.

He called to tell me one of his HCPs requested some data. During the call, he said he'd been spending a lot of time in that office to help them get access. You can reach me at 609-555-1212. "It is a capital mistake to theorize before one has data. Insensibly one begins to twist facts to suit theories, instead of theories to suit facts."

– A Scandal in Bohemia





What do you do now?

- Do you call Natalie to gather additional information? If yes, how soon?
- Do you do any background research prior to speaking with Natalie?
- How do you assess the likelihood of litigation related to this complaint?
- Does this warrant an investigation?

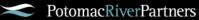


- Compliance department decided to contact Natalie
- Took additional notes on follow-up conversation with Natalie
- Compliance Department found the report credible and decided to open a formal investigation



"You know my methods, Watson."

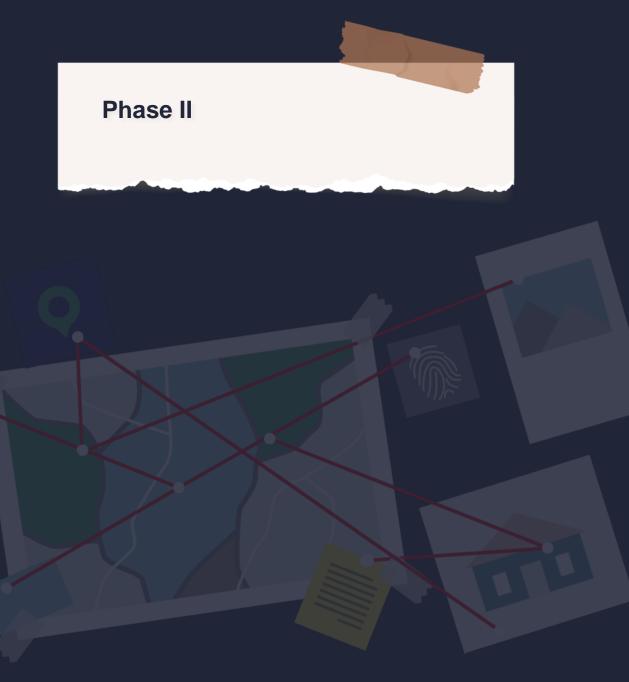
— The Crooked Man





What do you do now?

- How do you structure the investigation?
- Will the investigation be conducted under privilege?
- Who will conduct the investigation?
- What documents, data, or other information do you need?
- Who will you interview?



- Compliance decided to conduct investigation under privilege
- Outsourced investigation based on limited internal resources and expertise
- Prior to conducting interviews, investigators requested and reviewed FRS job description, training decks, policy documents, and call data
- Decided to interview Jason's Manager and Jason
 - Decided to *not* interview Natalie (again), other FRS, or HCP office at this time

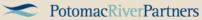
"How often have I said to you that when you have eliminated the impossible, whatever remains, however improbable, must be the truth?

– The Sign of Four



What do you do now?

- In what order will you conduct interviews?
- What questions will you ask?





Prior to interviews:

- Investigations team identified:
 - HCP Interactions policy lacked clarity regarding MIRF process
 - Market Access policy and FRS training did not address unsolicited requests for off-label information
- Team reviewed Jason's call log history to identify patterns

Interview process:

- Informal interview with Jason's manager
- Formal interview with Jason:
 - Asked easy questions first; consistently received straightforward answers
 - Follow-up questions about HCP office in general terms; then narrowed to specific activities related to allegation



Interview process:

Investigations team believed Jason's answers were credible

"It is of the highest importance in the art of detection to be able to recognize, out of a number of facts, which are incidental and which vital."

- The Reigate Puzzle



What do you do now?

- Is the allegation substantiated?
- What follow up action is needed?
- How do you close out the investigation?



Substantiated:

- High-level review of PA forms & testing results for completeness prior to submission
 - Root cause: Jason focused on avoiding PHI; made own conclusion
- Did not submit a MIRF for HCP request (referred via phone instead)
 - Root cause: Lack of clarity in policy and training



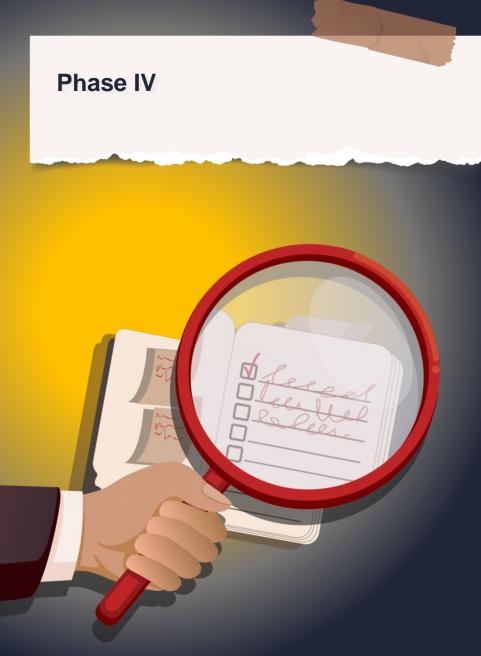
Unsubstantiated:

- Unauthorized access to patient PHI
- "Completing" PAs on behalf of office



Recommended Disciplinary Action:

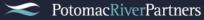
Oral warning supported by written note to file



Recommended Follow-Up Actions:

- Close out communications
 - Confirm closure with Reporter
 - Confirm with HR that they will notify and close out with Jason and his manager
 - Document resolution in case management tool
- Corrective Action
 - Policy and training updates to close identified gaps

Thank you.





For more information, contact us at: ContactUs@potomacriverpartners.com

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