

## **Effective Compliance Program Elements - #7 Responding to Detected Offenses and Developing Corrective Actions**

**By: Philip Hammarberg and David Traskey**

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**Philip Hammarberg:** Welcome to the Garfunkel Wild Podcast. My name is Philip Hammarberg, and I'm here with David Traskey. We're both partners with Garfunkel Wild.

**Philip Hammarberg:** Today, we're going to discuss the features that make up effective compliance programs. OIG has identified 7 elements of an effective compliance program. We're going to be discussing element 7: responding to detected offenses and developing corrective actions.

**Philip Hammarberg:** David, what can you tell us about responding to detected offenses and developing corrective action?

**David Traskey:** Hi, Phil, thanks for having me. No matter how good a compliance program is, eventually the compliance team is going to have to conduct an investigation regarding possible allegations of noncompliance.

**David Traskey:** If this is not happening within your organization, I would suggest that it might be a sign that the compliance program is not as effective as it could be, or that perhaps that it's not functioning as intended. But when we're thinking about investigations, oftentimes people are maybe unsure of where to start or why conducting these investigations are so important and why it's important that they be handled promptly.

**David Traskey:** To that end, what I would say is that violations of a compliance program, as well as violations of applicable laws, rules, and regulations, can have a really negative impact on your organization. These violations damage employee morale, potentially have a negative public perception, or have adverse consequences to your reputation. But in addition, it could also result in patient harm or other types of legal consequences, whether it's a criminal or civil action from the Department of Justice, or whether it's some type of administrative action from the OIG.

- David Traskey:** And so, for that reason, allegations of noncompliant behavior must be promptly investigated, and the outcome of those investigations should be shared with the executive leadership of the organization, the Board of directors, and depending on what the investigation shows, you may also have to report or share information with State or Federal government regulators. And so, as a preliminary step, the compliance officer or in-house counsel should take appropriate steps to secure or prevent the destruction of documents or other evidence relevant to your investigation.
- David Traskey:** You also are likely going to be conducting interviews, and it's important that you make sure that you understand and share with those who are being interviewed, what their rights are, and so that they can be able to make informed decisions about whether to speak with you or not.
- David Traskey:** But once the investigation is underway, it's important to keep a contemporaneous record of what was done, and when it's .... when it was done.
- Philip Hammarberg:** And David, with respect to investigations, what should you really be doing first?
- David Traskey:** So when we think about creating a contemporaneous record of what's been happening in the investigation, we want to think about a few things. First, we want to think about documentation related to the alleged violation.
- David Traskey:** Second, we want to be able to keep notes on the investigative process itself, describe what's happening, what you're doing.
- David Traskey:** And we also want to keep copies of interview notes and other key documents.
- David Traskey:** Number 4, we also want to be looking at keeping a log of the witnesses that we interviewed, and the documents that we reviewed, as well as the results of the investigation, and lastly, documenting any disciplinary action that was taken, or corrective actions that may have been implemented.
- David Traskey:** And so, having an investigative plan and an investigative record is very important, not only so that you can get to the correct resolution of whatever the issue was that was raised, but it all demonstrates a level of seriousness and commitment if, in the event that you have to report to the Government, and they ask, you know, sort of, what you've done before coming to them.
- Philip Hammarberg:** Now that you've discussed the types of things that should be included in the contemporaneous record. Is there anything else we should discuss about investigations before moving to reporting?
- David Traskey:** No, I think we're good. We can move to reporting. And one of the things that I'd like to touch on first, is the reason that prompt reporting is so important is because it demonstrates number one, the potential effectiveness of a compliance program, but it also demonstrates an organization's good faith and willingness to work with internally within their own processes and procedures, but also with Government

authorities to correct and identify, to identify and correct whatever the problem was. And depending on the issue that's being investigated, you know, reporting may have to happen quickly.

**David Traskey:** So, for example, in the case of quality of care, patient harm. Those issues might be reported sooner, or might need to be reported sooner than say, for example, something else that could be, take a little bit more time like, for example: reporting something to the OIG if you're under a corporate integrity agreement or if you're trying to quantify an overpayment. Those things may take a little while longer and may not have to be done, or can be done as expeditiously.

**Philip Hammarberg:** And who are these reports typically made to?

**David Traskey:** So there's a variety of entities to whom an organization may have to report. You know, internally, you're going to be reporting to the chief executive officer and the Board of Directors. But from an external standpoint, you may have to report to the Justice Department, including, you know, the US Attorney's Office. You may have to report to the Office of the Inspector General, the OIG. You may also be reporting to CMS, the Medicare Contractor, or even the Medicaid Fraud Control Unit in your particular state.

**Philip Hammarberg:** And has Medicare recently updated its regulations regarding the reporting times?

**David Traskey:** They did, Phil, and you bring up a really good point. So if you recall, Medicare overpayments have to be reported and returned within 60 days after the date on which the overpayment is identified. Prior to this year, the 60 day clock did not start until the overpayment was both identified and quantified.

**David Traskey:** But starting at the beginning of this year, CMS revised the 60 Day Rule to mean that a person has identified an overpayment when that entity or individual quote "knowingly receives or retains an overpayment." And that the term "knowingly" in this case means having actual knowledge of the overpayment or acting in deliberate ignorance or reckless disregard of that overpayment.

**David Traskey:** For those of you who spend a lot of time in the compliance space, you'll probably recognize that this language about actual knowledge or deliberate ignorance or reckless disregard mirrors the knowledge requirement that is seen in the Federal Civil False Claims Act. Under the new rules, the 60 day clock starts when the overpayment is identified, even if it hasn't yet been quantified. And so that really speeds up the clock for providers, because that means they have 60 days to identify, quantify, and repay any overpayment.

**David Traskey:** Now, under the new rules, the 60 day clock can be temporarily suspended for up to 180 days, if the provider is conducting a timely, good faith, investigation to determine the existence of any related overpayments. Importantly, though the time between identifying the initial overpayment and starting any investigation is included in that 60 day calculation.

- David Traskey:** So, as an example, if a person began a timely, good faith, investigation related to overpayments 20 days after identifying that initial overpayment, there would be 40 days left on the clock for the person to report and return that overpayment once the 180 day investigation period ended.
- David Traskey:** This example, of course, presumes that the person uses the entire 180 day investigation period. But that might not always be the case. So I share this with you because it's really important when you're thinking about overpayments in particular, not only to know that the rules have changed about how the 60 day clock is calculated, but also to be aware of the fact that you have this requirement to do, you know, to identify and to repay the amounts timely.
- Philip Hammarberg:** So with respect to corrective actions. What types of things are typically addressed in a corrective action?
- David Traskey:** So just like anything, or, as the old lawyer's answer goes, is, is, it depends right? So the corrective actions can take a variety of different forms depending on what the misconduct is. So, for example, one type of corrective action is one that we just talked about, right? Refunding an overpayment. And you can refund the overpayment either to the Medicare contractor or to the OIG through its self-disclosure protocol. There's advantages and disadvantages for using one method over the other. But that's one type of a corrective action is refunding overpayments. Another type of corrective action that we commonly see is to enforce an organization's policies and procedures, including those related to discipline.
- David Traskey:** So, depending on the nature and severity of the offense, an organization is going to look to their disciplinary policies and procedures and recognize that if it's a serious offense, the consequences could range all the way up to and include termination if it's necessary. On a much lower scale, an example might be re-educating your staff. It might be re-education on how to properly bill and code something. It might be re-educating your staff on, patient contact or readiness, or something to that effect. Sometimes just simply reminding staff of what the expectations are will suffice.
- David Traskey:** Another type of corrective action is to update or make any changes to your existing policies or procedures to reduce the likelihood of a recurrence of the very thing that you're talking about. And then, lastly, as we talked about a minute ago, you may also have to file a report with the responsible Government agency.
- David Traskey:** So, there's lots of different ways that one can take corrective action. And again, as we talked about, the corrective action that you take is going to depend on the circumstances of your particular matter. Whether or not the corrective action happens before the reporting or after the reporting also largely depends on the facts of your particular case.
- Philip Hammarberg:** That's interesting to know. And unless there's anything else to discuss regarding Element 7, I just wanted to thank you and thank the listeners. And we look forward to discussing future interesting healthcare topics on future podcasts.

- David Traskey:** Phil, if I could. Right before we wrap up, I want to just make 2 other points that I think the listeners will find helpful.
- David Traskey:** One is about corrective action. While corrective action is important, it's also important to make sure that you do a deeper dive to understand what happened, why it happened, and what can be done to reduce the likelihood of the recurrence in the future. Some people might call this a root cause analysis.
- David Traskey:** And so, in addition to undertaking the corrective action, it's also important to do that root cause analysis. And the last thing I would say is that government regulators don't expect perfection in compliance. They recognize that that's not possible. But, they do expect to see significant effort and appropriate action taken in response to potential or actual episodes of noncompliance.
- David Traskey:** Again, this highlights the importance of having that effective compliance program.  
**David Traskey:** And thank you so very much for having me talk to you about the 7 elements of an effective compliance program.
- Philip Hammarberg:** Thank you.