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When you receive a complaint: Ten tips for conducting an internal investigation

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For compliance officers, the handling of complaints and internal investigations can be both frustrating and valuable. Almost all compliance officers will be faced with this daunting task at some point during their tenure. For health care facilities and providers (collectively, the "Providers"), an internal investigation, unlike routine auditing and monitoring activities, requires the compliance officer to review allegations of potential wrongdoing to determine the scope of the review and whether any corrective actions are required. From putting together the investigative team to reviewing the results of the investigation, the compliance officer needs to keep an eye on the details and recognize that the handling of the internal investigation will have a direct impact on the corrective actions that are implemented, future decisions regarding voluntary disclosure, refunds, and/or professional misconduct reports, among other things.

Ten tips to consider when conducting an internal investigation

1. Stop questionable practices immediately

While seemingly obvious, it is of paramount importance that compliance officers take steps to stop any potential wrongdoing immediately and prevent any future incidents, as soon as they have knowledge of a potential compliance problem or legal violation. While a preliminary review may be needed to confirm that there is a potential issue, when sufficient information of a potential compliance concern is discovered, steps must be taken to prevent the inaccurate submission of claims or other continued violation of applicable law. Such interim steps may be made while a complete investigation is being conducted to determine the extent of the problem. For example, if a Provider learns that it may not have sufficient documentation to bill for a certain procedure, the Provider may hold those claims while the investigation is conducted. When the investigation is complete, a decision can be made whether or not to submit the claims, and if necessary, policies can be revised to address any deficiencies identified. Regardless of the steps taken, failure to stop questionable practices, at least while the investigation is conducted, may subject the Provider to significant civil and criminal penalties if it has knowledge of a potential legal violation.

2. Determine the intended scope of the investigation

The U.S. Department of Health and Human Services Office of Inspector General (OIG) recommends in its Supplemental Compliance Program Guidance for Hospitals (the "Supplemental Guidance") that all allegations of possible fraud and abuse be investigated. The Supplemental Guidance, however, is silent with respect to the extent and scope of such investigation. The compliance officer is generally responsible for determining the credibility of the issues, overseeing the investigation, and establishing the scope of review. When outside legal counsel is involved, such counsel may direct the investigation, but the compliance officer or other designated individual should generally oversee the process.

When deciding the scope of an investigation, it is important to consider how the alleged wrongdoing was raised and to initially gather as much information as possible. The scope of the investigation requires consideration of the specific practice at issue, which employees should be interviewed, the types of documents to be collected, and whether any audit should be conducted. With respect to conducting an audit, consideration must be given as to whether the audit should involve a retrospective or prospective review. The type of review is inherently based on the type of misconduct alleged and may change subject to the findings of the investigative team. It is also important to remember that if the Provider is under a Corporate Integrity Agreement (CIA) the Provider may have specific requirements governing the need for, and scope of, the investigation. CIAs may also dictate the time frame for such investigations and require that the OIG be informed when an investigation is being conducted.

3. Assemble an investigative team

When needed, the compliance officer should assemble an appropriate investigative team. The OIG recommends in its Supplemental Guidance that the investigative team be comprised of representatives from the compliance, audit, and other relevant functional areas, such as departmental supervisors or staff. The composition of the team will vary, however, depending on the nature of the alleged wrongdoing. Therefore, the compliance officer must consider the nature of the allegation, the confidentiality of the issue,

the affected departments or personnel, the expertise and position of the potential investigative team members, any conflict of interest, and the appropriate size team for the investigation. It is also important for the compliance officer to appreciate the balance that must be struck when selecting potential team members, especially when a matter is particularly sensitive and confidential. All members of the investigate team must be in a position to both understand the issues related to the investigation and be able to competently and confidentially handle the investigation, wherever it might lead.

4. Consider involving outside counsel

At the outset of an internal investigation, the compliance officer should consider whether the Provider would be better served by having outside counsel involved in the investigation. This requires the weighing of budgetary constraints and other financial concerns against the benefits offered by outside legal counsel. When deciding whether outside counsel should be retained, there are several things that should be considered. Most importantly, if there is any involvement or potential involvement by any state or federal regulatory agency, it is highly advisable to obtain outside legal counsel.

In addition, depending upon the nature of the problem, outside counsel can provide expertise in certain specialized areas, particularly laws, regulations, and billing requirements. Outside counsel can also be important if the compliance officer finds it difficult to establish an unbiased investigative team. Bringing in outside counsel may provide the neutrality that is necessary for the team to come to an accurate, unbiased determination. For example, if the investigation involves a person in administration, such as the CFO, members of the team may fear retribution if they suggest that the CFO has engaged in wrongdoing. In this case, outside counsel can be useful in presenting objective and accurate information at the conclusion of the investigation.

Finally, outside legal counsel should be involved if the situation is particularly sensitive or contentious. If properly structured and handled, having outside counsel to oversee the investigation may protect the investigation and its findings under the attorney-client privilege and attorney work product doctrine. These protections encourage the candid exchange of information and permit a more thorough investigation so that outside counsel can appropriately advise the Provider on how to handle any findings of wrongdoing to the extent they are detected. We note, however, that these privileges should never be used to mask wrongdoing. Compliance officers should be aware that there is an increasing trend for the protections offered by the attorney-client privilege and attorney work product doctrine to be waived upon request of federal and/or state regulatory agencies.

5. Preserve and secure documents and data

Once the investigative team has been assembled and the scope of the investigation determined, immediate steps must be taken to preserve and secure any and all documents and data that may be relevant to the investigation. This is particularly important when there is a risk of a possible government investigation or a chance that the entity will end up making a voluntary disclosure.

The first step in this process is identifying the universe of documents that may be relevant to the investigation. As soon as these documents are identified, the employees in possession of them must be notified that they are not to be destroyed. Once all of the documents are collected, they should be maintained in a secure location, such as the compliance officer's office. The investigative team will then be charged with reviewing these documents as part of conducting the internal investigation. During this process, careful consideration must be paid to how the overall investigation is being conducted, and in particular, how the documents are being gathered, secured and preserved. The investigative team should always be cognizant of the possibility of a government investigation and should make sure that the actions it takes in conducting the internal investigation cannot later be alleged as an obstruction of justice by the government.

6. Interview employees and other involved parties

At the same time documents and data are being collected, key employees and other involved parties should be identified and interviewed by members of the investigative team. It is without question that an interview conducted by a team of senior management can cause fear in employees, especially if legal counsel is involved. Unfortunately, this fear may hinder the open dialogue and free flow of discussion that is essential to the effectiveness of the investigation. Therefore, the type and number of persons conducting the interview are key factors in making the employee feel at ease. For instance, a laboratory technician may be less likely to openly communicate when he or she is seated across a table from five members of senior management who comprise the investigative team, but may be more forthcoming if interviewed by two less-intimidating team members.

Compliance officers should, however, always include at least two interviewers when meeting with staff. Although one-on-one interviews may seem less intimidating, when two interviewers are involved, it is more likely that the information will be interpreted and remembered correctly. The location of the

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interview should also be taken into consideration. An individual may be more comfortable in his or her office, or a private room on the employee's unit. While the comfort of the employee is a significant consideration, the primary consideration is that the interview be conducted in a manner and place so as to preserve the confidentiality of the investigation.

It is also important to note that at the beginning of the interview, the employee must be notified that the loyalties of the interviewer lie with the Provider. In particular, if the interview is being conducted by outside counsel, the attorney must advise the employee that he or she is employed by and represents the Provider, and not the individual employee. This also presents an opportunity for an appropriate dialogue to ease the employee's concern of his or her own legal liability.

7. Prepare a report of the investigation

Upon the conclusion of an internal investigation, the results should be reported to the compliance officer (if he or she was not part of the investigative team), the Compliance Committee (if there is one), and the governing board of the Provider, or a committee thereof. Typically, the initial report includes: (1) a statement about what caused the investigation; (2) the actions taken by the investigative team; and (3) the findings that were ascertained during the investigation, including where necessary, a chronology of events. Subsequent reports should also include an assessment of the potential legal and regulatory exposure, proposed corrective actions, proposed monitoring of the practice that caused the investigation, and recommendations for whether the Provider should make a voluntary refund or self-disclosure.

The form of this report, however, warrants careful consideration. The compliance officer or legal counsel must determine, based on the particular facts and circumstances of the investigation, whether the report should be in written or oral form. To the extent that a written report is prepared, it should be drafted with full knowledge that this document may ultimately be read and/or used by the government if the government elects to conduct its own review and the attorney-client privilege has been waived.

8. Determine whether any voluntary disclosure or repayment is required

Where the investigation involves an error in billing third party payors (e.g., federal health care programs, commercial payors) and it is determined that the Provider has received monies to which it was not entitled (i.e., overpayments), the compliance officer or legal counsel will be required to determine the amount of overpayment and must consider whether a voluntary disclosure or repayment is warranted. Self-disclosure, however, carries with it certain risks. While a full examination of the risks and benefits of self-disclosure and repayment are beyond the scope of this article, we will summarize some of the primary considerations.

Generally speaking, if a Provider has received monies to which it was not entitled and it has knowledge of such overpayments, the monies may need to be refunded and/or the overpayment disclosed. For example, under the Social Security Law (42 USC § 1320a-7b), it is a criminal offense to not disclose information when an individual has knowledge of an event affecting the Provider's continued right to payment with respect to federal health care programs. The government has taken the position that this, therefore, requires the alleged overpayment to be refunded. That said, it is advisable that, if not already involved in the investigation, in-house or outside counsel be consulted before any repayment or disclosure is made, as the applicable laws may be interpreted differently depending upon the facts and circumstances of the situation. Furthermore, the Provider's subsequent actions may have the potential to implicate several federal and state laws that carry with them substantial criminal, civil, and administrative penalties. This is of particular importance when the investigation reveals indicia of intentional wrongdoing.

It should be noted that, even when an inadvertent billing error is discovered, the submission of a refund to the applicable payor (e.g., fiscal intermediary, Medicaid, other government payor, or commercial payor), can still have ramifications. For example, fiscal intermediaries or other third party payors who receive refunds may be obligated to question the Provider about the process used to evaluate the need for the refund and the corrective actions the Provider has taken to prevent such error from occurring in the future. Payors may also refer the refund over to the OIG or other relevant agency for further investigation.

If, however, the compliance issues involve fraudulent misconduct, the stakes are higher and the potential penalties more significant. If a voluntary disclosure is contemplated, there must be careful consideration of how and to whom (e.g., fiscal intermediary, CMS, OIG, US Attorney's Office, or State Attorneys General), the disclosure should be made. One available option when the error involves federal health care programs is the OIG's Provider Self-Disclosure Protocol (Protocol) which outlines how providers should approach the government when they discover evidence of violation of Federal criminal, civil, or administrative laws. The OIG has stated that when a provider discloses potential violations pursuant to the Protocol and fully cooperates with the government, there may

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be reduced exposure to criminal, civil and/or administrative fines and penalties; however, this is not definitive. Therefore, it is very important that compliance officers are aware of all of the penalties that could potentially be imposed when making a disclosure.

9. Implement corrective action

Reporting to the governing board and making a voluntary repayment or disclosure does not end the Provider's or compliance officer's responsibilities with respect to acting on the findings of an internal investigation. Part of overseeing a Provider's compliance program requires that appropriate policies and procedures are in place to prevent potential compliance problems from arising in the future. This may involve the creation of new policies and procedures or revising existing policies and procedures when they are found to be insufficient to detect or prevent problems or errors.

Restructuring the Provider's policies and procedures is an important step in taking appropriate corrective action, but it is ineffective unless staff who are affected by the changes are educated on the new or revised policies and procedures. Therefore, the compliance officer should ensure that affected staff are receiving appropriate education and training whenever policies and procedures are developed or revised, and that this education and training is adequately documented.

It may be necessary to discipline staff who engaged in the wrongdoing. The affected department's director or supervisor, in conjunction with the compliance officer, should determine the appropriate course of action. This may include retraining the person or instituting disciplinary action. The extent of the disciplinary action will depend on the nature of the error, and may include a warning, suspension, or even termination. To the extent the employee remains employed in his or her same capacity, the

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compliance officer should make sure that the employee's work is monitored and checked on a regular basis until such time that the employee's superiors believe the employee no longer poses a risk with respect to the problem.

10. Monitor ongoing compliance

Providers should have general monitoring and auditing processes in place. Indeed, in many of the OIG's compliance-related guidances, and in the most recent open letter to providers, the OIG has articulated that the existence of effective internal auditing and monitoring systems is essential to the operation of an effective compliance program. Therefore, the compliance officer should make sure that the systems currently in place for monitoring and auditing the Provider's processes are sufficient to detect and prevent the types of problems that caused the investigation.

In additional to regular, routine monitoring, specific monitoring of the identified error should be incorporated into the corrective action plan. This is necessary to ensure that the same mistakes do not happen again. If, upon re-review, stated goals are not met, the corrective action needs to be modified and again reviewed, until the compliance officer has determined that the questionable practice has been corrected. It may be easy to explain away a mistake the first time, but subsequent errors of the same kind will be looked at with less leniency. ■

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