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by Ann Bittinger, Esq.; William J. Holahan, Esq.; and Caroline Kubovy, Esq.

Establishing a baseline compliance pulse for hospital and physician groups: Evaluations by outside counsel

- » Initial baseline questions focused on the seven compliance elements are effective.
- » The collection of baseline information is vital to identifying compliance deficiencies.
- » Well-crafted, broad questions provoke all-encompassing baseline responses.
- » Baseline information helps clients understand their compliance deficiencies.
- » Initial broad questions identify where corrective measures are needed.

Ann Bittinger (ann@bittingerlaw.com) is Principal, and William Holahan (william@bittingerlaw.com) and Caroline Kubovy (caroline@bittingerlaw.com) are Associates, with The Bittinger Law Firm in Jacksonville, FL.

> ou are an outside legal counsel or compliance professional hired by a new client to implement and administer a tailored compliance program for a hospital or physician group. You want to work effectively and efficiently with your new client and not seem like a



Bittinger

burden on their compliance team's time. Or perhaps you are an in-house counsel or an in-house compliance professional and need to gauge the pulse of your outside legal counsel's or compliance professional's work. Is he/she really trying to understand your practice, or are they simply printing your name on their template compliance documents?

The purpose of this article is to provide in-house and outside legal counsel and compliance professionals with insight into the type of questions we as "outsiders" have found to be effective in obtaining information from clients

regarding the comprehensiveness and maturity of their compliance program and, likewise, indicate who truly understands the provider's compliance risks, challenges, and operations.

Our suggested sample questions are focused upon generating information surrounding the seven elements that the U.S. Department of Health and Human Services, Office of Inspector General (OIG) has routinely included in guidance documentation and identified as being fundamental to every compliance program for all industry sectors. We have found the collection of this baseline information to be vital in identifying initial deficiencies in a physician group's

or hospital's current compliance structure, in assisting clients to understand why their compliance structure is deficient or lacking in sufficiency, and in instituting corrective measures to ensure a robust and functioning compliance program is fully operational.



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OIG seven fundamental compliance elements

- Conducting internal monitoring and auditing
- Implementing compliance and practice standards
- Designating a compliance officer or contact
- Conducting appropriate training and education
- Responding appropriately to detected offenses and developing corrective action
- Developing open lines of communication
- Enforcing disciplinary standards through well-publicized guidelines

Designating a compliance officer and compliance committee

For hospitals and physician groups, it is of the utmost importance to ensure that there is an individual and/or a core compliance committee that is responsible for overseeing its compliance program. By appointing an individual or compliance committee to be responsible for the organization's compliance program, each entity is able to create a central point from which the senior management of the hospital or physician group can obtain information related to compliance program functions. We as "outsiders" have routinely found that such a designation prevents misunderstanding among leadership within the hospital or physician group setting as to who is ultimately in charge and responsible for the various components of the compliance program.

In determining who is responsible for compliance at either a hospital or physician group, we have found the following questions to be beneficial in gaining baseline information:

Does your organization, parent organization, or any corporate affiliate employ a compliance officer? If so, is your compliance officer a full-time employee? What is his/her job description, and is he/she evaluated on each of the job description criteria?

These questions establish who plays the role of compliance officer at the organization and how they are employed by the organization.

Is a compliance committee in charge of overseeing the compliance program at your organization? What are its duties, expectations, and deliverables? What happens if deliverables aren't delivered or duties not met?

These questions establish whether and what type of committee structure is in place in addition to the compliance officer role.

- How involved is your compliance officer in operational and compliance activities? Would you categorize their involvement as heavily detailed?
- Is your compliance officer responsible for performing normal job duties outside of their compliance role?

These questions help to establish how much time an individual, appointed or hired to be a compliance officer, is actually dedicating to compliance-specific activities within the organization and how heavily involved he/she is in the intricacies of the compliance program.

Implementing written policies and procedures

A well-structured physician group or hospital compliance program must have written policies and procedures committed to tangible form to ensure it provides an adequate explanation of the program's policies to all employees. In addition, an explanation of the process by which the monitoring of policies will take place within the program and the corrective action policies and procedures that will be instituted to address non-compliant activity are also necessary to ensure these policies are clearly stated and followed.

When conducting a baseline assessment to evaluate the extent to which a physician group or hospital has written standards and procedures in place, we find the following questions most effective:

Has your organization committed policies and procedures or any other standards utilized by your organization to written form?

We have found this question to serve as a great "catchall" in determining what, if anything, has been written down by the organization and followed.

If we are able to determine that written policies and procedures do exist, we often use the following additional questions to determine the comprehensiveness of these policies and procedures:

Do your policies clearly explain your adherence to all applicable federal and state statutory and regulatory legal requirements?

We have found this question to serve as a great "litmus test" in determining to what extent compliance personnel within an organization are fully cognizant of all the legal and regulatory responsibilities and requirements

their organization must adhere to, as well as the amount of legal risk to which the organization is currently exposed.

Do you feel your organization's policies successfully implement the operation of the compliance program?

This interrogatory is utilized to elicit the opinion of the organization's current compliance personnel as to what, if anything, is lacking from the program from an operational perspective. It must also be asked to providers, coders, and other operations personnel.

If I picked up your compliance plan, policies, and procedures, how would I know it is yours and not some other group's? In other words, how is it tailored to your problems at your place of work?

These questions act as a great measure to capture details surrounding how the group or hospital has tailored its policies and procedures to address specific compliance issues it has already encountered.

Do your policies and procedures provide for standards of conduct to be followed? Please explain how.

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This serves as another solid "catchall" question to determine what particular standards a physician group or hospital requires its employees to follow to ensure compliance with all laws and regulations applicable to the organization.

If baseline policies and procedures are established, we like to ask the following questions to determine how an organization effectively communicates its policies and standards of conduct to employees to ensure their compliance with each:

- How are your policies and procedures and standards of conduct disseminated to your employees? At what point in time do you communicate them to your employees?
- At what point in time do you communicate updates for your policies and procedures to your employees?

We have successfully used the following questions to discover how, if at all, a physician group or hospital has established necessary policies for addressing non-compliant activity within their organization:

- Do your policies address situations when non-compliant activity is discovered by employees and provide instruction on how employees should handle and report such information and to whom it should be reported?
- Do your policies provide instruction on how employees are to convey non-compliant information to the compliance officer or compliance committee?
- Do your policies contain protocols for exploring non-compliant activity and resolving allegations of instances of non-compliance?

Conducting effective training and education

A physician group or hospital must provide effective education and training to its compliance officer, members of its compliance committee, and its employees. Education and training are vital components of a compliance program, as these components directly assist members of the organization with understanding federal and state statutory and regulatory requirements and in turn, the legal risk the organization faces. Fully understanding the legal risk facing an organization for non-compliance and the method in which employees can mitigate this risk by adhering to a well-constructed compliance program is vital. For physician groups and hospitals, education and training become even more vital for those individuals whose job functions can inherently expose the group or hospital to legal liability, such as physicians, nurse practitioners, physician assistants, and personnel responsible for handling Medicare billing and coding matters.

Throughout initial interviews with clients, we have consistently found the following questions to be instrumental in establishing an accurate picture of the education and training programs used by a physician group or hospital:

Does your organization provide any training or education on compliance matters? If so, does this education and training contain instruction on the laws and rules comprising fraud, waste, and abuse prohibitions as well as HIPAA security and privacy requirements concerning patient information? Please explain how.

These blanket questions are used to establish what level of training exists at a physician group or hospital and also to determine if the proper amount of educational and training concerning legal risk is being presented to employees.

Is education and training provided to all employees or just full-time employees? Is training provided to the board of directors?

We use these questions to determine who, if anyone, is excluded from education and

training and what, if any, additional legal risk this may pose to the organization. Remember, just because an individual may be a volunteer does not mean they can't expose a physician group or hospital to legal liability.

- At what point in time is training for employees and board members provided to them? Is this done on a monthly, quarterly, or annual basis, or just upon hire?
- How have you tried to implement training sessions? What has been the most effective technique (e.g., PowerPoint presentation, video, training exercise, handout, quiz, small group activity)?

These questions are used to establish through what method and how often training actually occurs on compliance topics for employees. This, in turn, allows us as "outsiders" to understand how more timely and effective training can help physician groups or hospitals to mitigate compliance risks.

Do you incorporate instruction on Medicare requirements that relate to employee job functions in your education and training?

In a healthcare world full of recoupments for allegedly improper coding and billing, training on Medicare requirements for employees whose job functions are intricately linked with such requirements is paramount to ensuring your organization is compliant with the complicated patchwork of Medicare regulations and standards in order to avoid penalties.

Developing effective lines of communication

Open and effective lines of communication are necessary for a compliance officer or compliance committee to swiftly communicate information to employees and for all employees of a physician group or hospital to report non-compliant activities. Further, a mechanism for anonymous and confidential reporting should be in place for employees who observe non-compliant activities occurring. Such a reporting mechanism must also ensure that employees are able to report non-compliant activities without experiencing any form of retaliation for doing so.

To decipher what current lines of communication exist at a physician group or hospital and the type of content that is communicated, we routinely use the following questions to query our clients:

- How does your organization use a particular method for your compliance officer or compliance committee to communicate information to employees?
- What type of information does your compliance officer communicate?
- Does this information include changes to legal requirements impacting the organization?

To ensure effective compliance among all employees at all times, a compliance officer must ensure that statutory, regulatory, and sub-regulatory guidance changes are communicated quickly and effectively to all employees.

Written policies for physician groups or hospitals must ensure employees are aware of their duty to report non-compliant activities. In addition, the organization must ensure that records of compliance reports and compliancerelated questions from employees are kept to preserve a historical record of all efforts made to ensure compliance. The following question has been effective in garnering this type of baseline information:

Do your written policies establish duties for your employees to report non-compliant activity, such as violations of fraud, waste, and abuse laws? If so, do you have a formal structure to receive and document compliance reports and compliance questions from employees?

Mechanisms for anonymous reporting and confidentiality for all information reported by employees concerning allegedly non-compliant activity must exist at a physician group or hospital to ensure employees are comfortable relaying such activity to the compliance office or compliance committee instead of filing whistleblower actions. The following questions are aimed at determining whether such reporting safeguards exist.

How does your organization's reporting structure allow for anonymous reporting and ensure confidentiality? Does this apply to providers as well as administrative personnel?

Conducting internal monitoring and auditing

Continuous internal monitoring occurs when a compliance officer or compliance committee engages in ongoing observation of the compliance program to ensure processes are working as they are intended. This process is often used to detect compliance and risk issues related to a physician group or hospital's standard activities and is essential to any compliance program. By monitoring through a continuous process, compliance officers are able to pinpoint and report deficiencies within a compliance program.

A formal auditing process should be used by a physician group or hospital to review the past performance of a particular department, service line, procedure, or individual within a physician group or hospital to determine their compliance with the organization's compliance policies and procedures. Internal auditing processes by a physician group or hospital should effectively utilize an organized procedure and audit tools to complete the process.

When working to discover the type of internal monitoring and auditing activities that are currently utilized by a physician group or hospital, the following questions have proven to be edifying in constructing a realistic picture of such activities currently taking place:

- Describe the structure your organization has in place to continuously monitor and audit to determine whether your organization is compliant with federal and state statutory, regulatory, and sub-regulatory requirements (including Medicare regulations)?
- How often is each physician's coding audited? Is auditing done by a certified professional coder? Is auditing done inside or outside of the hospital or physician group? Is auditing done for in-office work, procedures, evaluation and management (E&M) codes, or all work?

Further, we have found the following question to elicit helpful information surrounding an organization's need to conduct audits in the face of the volume of its annual Medicare billings:

Given the amount of Medicare billings your organization submits, do you feel your organization devotes adequate resources to conducting routine audits to ensure compliance with Medicare regulations?

Finally, the next questions have proven helpful to us as outside counsel in understanding the process by which audit results are conveyed to a compliance officer or compliance committee:

Are audit reports containing the results of routine audits directly communicated to your compliance officer or compliance committee to ensure any necessary corrective action is taken? Are they performed under attorney-client privilege?

Responding appropriately to possible or detected offenses

A compliance officer at a physician group or hospital must move to investigate all instances of non-compliance by the group's or hospital's employees. This includes investigating reports under attorney-client privilege of non-compliant activities to determine their cause and the gravity of the activity. For any non-compliant activity, corrective action plans should be instituted by physician groups or hospitals and be imposed on non-compliant employees to prevent the noncompliant activity from ever occurring again, as well as to ensure full compliance will be met by the individual in the future. These plans themselves should assist the individual to understand why their activity is noncompliant with the organization's policies and procedures and should be tailored to the gravity of the non-compliant activity.

When engaging in discussions with physician groups and hospital compliance personnel, we have found the following questions to be useful in gathering baseline information related to detection activities and current corrective action plans that exist at physician groups and hospitals:

Does your organization take reasonable steps to investigate all compliance issues/incidents, regardless of their perceived size or magnitude? Are your investigations documented?

These questions establish whether the organization takes steps to investigate compliance issues and whether or not they document such activities for recordkeeping purposes.

How quickly are your investigations initiated after learning of potential instances of non-compliant activity?

This question determines the speed at which the organization takes action to address non-compliant activity. It also reflects staffing issues, reliance on outside counsel, and the urgency the group or hospital places on compliance.

Does your organization have corrective actions in place that are tailored to correct non-compliant behavior? If so, are they tailored to address particular violations of fraud, waste, and abuse prohibitions and other federal and state statutory and regulatory requirements in your company?

These questions survey whether or not the organization has any corrective action plan apparatus in place and to what extent the organization has tailored corrective action plans to ensure future mitigation for noncompliance related to specific violations of law.

How are your corrective action plans monitored after you have implemented them so that you can ensure they are working?

With this question we gauge how the corrective action plan is monitored after its implementation, if at all. An organization must adhere to a policy of monitoring corrective actions plans to determine their effectiveness and prevent repeat non-compliant activity from occurring.

Enforcing standards through well-publicized disciplinary guidelines

Enforcement of the standards of a compliance program in some instances requires a physician group or hospital to take disciplinary action against employees who engage in non-compliant activity. Such measures must be undertaken to ensure that the organization's pledge to strict compliance is established in order to prevent frequent or, worse yet, frequently repeating non-compliance.

To establish whether disciplinary policies exist at physician groups or hospitals, we often pose the following question:

Has your organization instituted disciplinary policies and procedures and ensured they are in place to address non-compliant behavior?

To establish whether a physician group or hospital has effectively communicated the disciplinary policies for non-compliance to individuals, we always ask the following question:

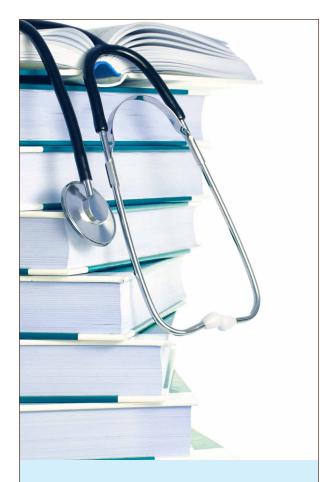
How do you widely publicize disciplinary standards to your employees?

To establish the speed and consistency in which discipline is enforced throughout a physician group or hospital for a breach of compliance standards, we ask the following question:

How do you provide swift and consistent enforcement of compliance standards throughout your organization?

Summary

For physician group or hospital clients, these suggested sample questions have proved extremely fruitful for us as outside counsel. The questions yield information to establish whether a baseline pulse beats for proper compliance and whether a compliance program exists in any meaningful state. They can be used by outside legal counsel and compliance personnel to efficiently conduct initial interviews with physician groups and hospitals, to understand their current compliance activities and begin assisting them to achieve a robust compliance program that promotes full adherence to federal and state laws. Further, for in-house counsel or in-house compliance professionals, these questions can be reviewed with outside legal counsel and compliance professionals to ensure you are conveying all necessary baseline information to them as they assist you with your compliance needs.



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Compliance Program Guidance for Individual and Small Group Physician Practices (65 Fed. Reg. 59434; October 5, 2000); Compliance Program Guidance for Hospitals (63 Fed. Reg. 8987; February 23, 1998).