

Compliance Program Effectiveness: Do You Really Need Outside Counsel, and How Does That Relationship Work?



Daniel E. Gospin is a partner in the Health Care and Life Sciences practice in the Houston, Texas office of Epstein Becker Green. His practice is focused on counseling clients in areas of federal and state fraud issues, including anti-kickback, self-referral, and false claims. Mr. Gospin advises clients in connection with government investigations and audits, including all phases of RAC and ZPIC audits. He can be reached at 713/300-3211 or by email at dgospin@ebglaw.com.



Lesley R. Yeung is an associate in the Health Care and Life Sciences practice in the Washington, DC office of Epstein Becker Green. Ms. Yeung advises clients on legal and regulatory matters arising under Medicare, Medicaid, and other third-party reimbursement programs. She also advises health care entities on the development and implementation of corporate compliance programs and assists in the evaluation of corporate compliance programs for clients. She can be reached at 202/861-1804 or by email at lyeung@ebglaw.com.

Engaging Outside Counsel Can and Should Be a Collaborative and Productive Process

Daniel E. Gospin / Lesley R. Yeung

As compliance officers are well aware, one of the key factors of any corporate compliance program is that it must be “effective.” Accordingly, an organization’s corporate compliance program should be an evolving program that is evaluated from time to time, resulting in modifications and potential “retooling” to ensure its continued “effectiveness.”

There can be a variety of reasons for why it has come time to do a compliance program effectiveness review. Maybe the organization has internal or external reporting obligations that require an evaluation of the compliance program to be conducted, maybe the organization has experienced a compliance breach, maybe the organization is about to go through an acquisition or due diligence process, or maybe it has just been a while. Whatever the reason, it is important for the organization to determine whether to engage outside counsel to assist with the review process. And if outside counsel is engaged, it is important to understand how that relationship generally works to ensure that a productive and meaningful evaluation is conducted.

REASONS FOR ENGAGING OUTSIDE COUNSEL

Having an ongoing process for internal review of the organization’s corporate compliance program is a valuable and cost-effective mechanism for ensuring the organization’s compliance with applicable federal and

state laws and regulations and for detecting areas of risk or vulnerability. However, gaining objective, external feedback on the compliance program, how it has been operationalized, and how it can be refined is equally important to ensure that the program remains effective and appropriately adaptable over time.

Offering an Outside Perspective

Outside counsel will view an organization's corporate compliance program through a different lens than those internal to the organization. Even if the compliance professionals performing compliance-related functions within the organization are well-versed in the key risk areas relevant to their particular health care sector, outside counsel's experience often can provide added value to the review process.

Outside counsel will bring to bear a broad understanding of trends in the regulatory landscape, lessons learned from other compliance program effectiveness reviews, as well as experience with the activities of federal and state enforcement agencies. This outside perspective can be helpful in establishing the scope of the effectiveness review up front and putting the evaluation and resulting recommendations into context with respect to compliance activities and enforcement in the industry.

Operating Under the Attorney-Client Privilege

A compliance program effectiveness review conducted by outside counsel also has the benefit of being protected under the attorney-client and attorney work product privileges, as appropriate. Even if the final work product is eventually shared externally by the organization, and therefore not ultimately maintained under privilege, there are benefits to having the underlying process and communications about the review conducted under privilege. Significantly, communications and work product regarding confidential information created under the applicable privileges, within the

scope of the attorney-client relationship, may be protected from compulsory disclosure to regulatory authorities or in court proceedings.

While the organization may have internal resources available to provide legal advice on compliance-related matters, the organization's senior management should consider how best to utilize the attorney-client and attorney work product privileges for such matters. For example, if the compliance officer makes blanket or routine assertions of the privileges for routine auditing and compliance monitoring activities, that could undermine the vitality of the asserted privilege and diminish the credibility of the compliance program. However, engaging outside counsel for the purpose of providing legal advice on the compliance program will help ensure that the applicable privileges are protected if potential legal exposures are identified.

Further, conducting the evaluation through outside counsel, under privilege, should provide some level of comfort to the organization and encourage more detailed work product and a robust discussion regarding opportunities for improvement.

SETTING THE STAGE FOR AN EFFECTIVENESS REVIEW

Once the organization has decided to engage outside counsel to conduct a compliance program effectiveness review, it is important to invest time at the beginning of the engagement with outside counsel to "set the stage" for the review process.

First, the organization should identify the appropriate people internally to work with outside counsel to develop a work plan and a budget for the review. This will help guide the process going forward and ensure that everyone is on the same page about what will be reviewed, how long the review should take, and how the results and recommendations will be communicated to the organization.

The size of the organization generally will help dictate the scope of the effectiveness

review. The team developing the work plan and budget must be realistic and sensible with the organization's available resources — the goal is to conduct a review of the corporate compliance program and not to substantially deplete the budget of the Compliance Department or the organization itself.

Some key questions that the organization should address with outside counsel when establishing the work plan and budget include:

1. What is the purpose of the review?
2. Who will be helping with the review process; what internal resources will the organization make available to outside counsel?
3. Who will be responsible for coordinating document requests, scheduling interviews, and responding to questions from outside counsel?
4. Who will participate in interviews and/or be asked to provide documentation and information about the compliance program?
5. Will outside counsel go onsite to conduct interviews and review documents? If so, does the organization have multiple sites, and is there value in visiting more than one location?
6. Are there time constraints related to the availability of key employees, or with respect to the delivery of the final work product?
7. How will the final report be communicated to the organization; who will be notified of the results; will the results be communicated orally, through a written report, or through some other presentation?

Establishing the four corners of the review, and making sure that the appropriate people are involved in that process, will lay a solid foundation for the relationship with outside counsel as the evaluation gets underway.

CONDUCTING THE EFFECTIVENESS REVIEW

Having outside counsel lead or participate in the review process can, at first, disrupt

the day-to-day workflow of the compliance officer, the Compliance Department, and others in the organization that will be involved with the review. Members of the organization have to get organized, locate documents, and prepare for and participate in interviews. This takes time and commitment to the review process, sometimes at the expense of other work priorities. Outside counsel should work closely with the compliance officer (or other appropriate people) to build productive working relationships within the organization, allay potential concerns about the reasons for and the time and effort needed to complete the evaluation, and establish plans and effective solutions for overcoming any hurdles that might arise during the review process.

Communicate the Work Plan

Defining the scope of the work plan, as well as the budget for the review, up front will help everyone understand the expected flow and timing of the review. Sharing those expectations with the members of the organization that will be involved in helping to complete the evaluation will mitigate the disruption to everyone's daily schedule and workload. The creation of the work plan may be an iterative process. It certainly must be a collaborative one. There is no doubt that the compliance professionals within the organization know their program best. Outside counsel should utilize this knowledge base to establish a work plan that is appropriately tailored to the compliance program and organization.

Have a Kick-Off Call

Outside counsel will have a steep learning curve at the start of the review. They understand the type of service or product that the organization provides and the regulatory landscape that applies to that service or product, but they may not know the internal workings and politics of the organization. It is helpful to have a kick-off call with the organization's compliance officer,

or other appropriate person (perhaps the chief executive officer (CEO) or someone from the senior management team), to provide background on the organization and management, the people that outside counsel will be interacting with, and the establishment of the compliance program. Having the right person explain the culture within the organization, including the compliance culture, will help outside counsel know what documents to request and who to speak with, and to be able to put those documents and interviews into context when conducting the evaluation.

Provide the Requested Documents

At the start of the evaluation, outside counsel generally will provide a list of documents that they would like to review. This can sometimes seem like an unwieldy number of requests. However, to determine the “effectiveness” of a compliance program, outside counsel needs to understand how the organization addresses each of the seven elements recognized as fundamental to an effective corporate compliance program.

These seven fundamental elements include:

1. Implementing written policies, procedures, and standards of conduct.
2. Designating a compliance officer and compliance committee.
3. Conducting effective training and education.
4. Developing effective lines of communication.
5. Conducting internal monitoring and auditing.
6. Enforcing standards through well-publicized disciplinary guidelines.
7. Responding promptly to detected offenses and undertaking corrective action.¹

Accordingly, outside counsel needs to see not only the standard compliance policies and procedures documents but also documents evidencing how the compliance program has been operationalized within

the organization. This could include, for example, annual work plans, risk assessments, internal and external audits, evidence of compliance monitoring activities, compliance hotline complaint logs, resolution memos, discipline actions, training materials, and board or management-level compliance committee meeting minutes and reports.

Outside counsel should be mindful to not create a document request list that reads like a subpoena. This type of review is not designed to over task a Compliance Department or create a feeling of panic. With that said, to truly evaluate a compliance program, outside counsel will need access to documents. Establishing this balance is critical, and it requires constant and candid communication between the organization and outside counsel. Once the parties are frustrated with the process, it is likely too late.

Participate in Interviews

Effectiveness reviews generally include an interview process, either onsite or telephonically. There are certain benefits to conducting onsite interviews, although these benefits must be weighed against the time and resources necessary to complete the interviews as well as any negative perceptions that may result from having someone “outside” the organization be onsite. Further, the timing of the interviews is important. Outside counsel should be in communication with the organization on a regular basis. However, the interviews are most productive after outside counsel has had an opportunity to digest a majority of the requested documents. The interviews should be an opportunity for outside counsel to talk through aspects of the compliance program that may not be captured in or fully appreciated through the review of documents. The interviews also can help outside counsel identify additional topic areas or document requests that would be beneficial to address or include as part of the review process.

The onsite interview process can include both scheduled interviews with the individuals directly responsible for the day-to-day activities of the compliance program as well as interviews with a random sample of employees from different departments within the organization. Being onsite and conducting a random sample of interviews can help outside counsel assess employees' awareness of the compliance program in general, the compliance training they have received, the compliance program policies and procedures, the compliance hotline, and other specific components of the compliance program. Speaking to people in-person also can help outside counsel gain a better sense of the "compliance culture" within the organization. Understanding the culture can have an important impact on what recommendations are made as part of the evaluation and how those recommendations are communicated to the organization.

Regardless of whether interviews are conducted onsite or telephonically, the information gained through the interview process is invaluable for outside counsel to get a feel for how the compliance program has been implemented, which is not always immediately obvious from the review of documents alone.

DELIVERING THE RESULTS

Once outside counsel has had the opportunity to learn about the organization, review key compliance documents, and talk with people who are responsible for operationalizing the compliance program and others within the organization, the results of the review must be organized and communicated to the organization in a meaningful way.

The results generally will identify any areas of concern or shortcomings with the compliance program and focus on discrete opportunities to further refine the compliance program to ensure that it remains "effective" on an ongoing basis. There are a number of ways in which

it might be appropriate to convey this information, depending on the findings and the intended audience.

The final work product could be an oral report given by phone or in person, a PowerPoint presentation, or a formal written memorandum. The intended audience could be all or a subset of the following: the board of directors, executives and senior management, the compliance officer and/or Compliance Department, the Compliance Committee, or front-line employees. It is up to outside counsel, in consultation with the organization, to tailor the final work product to the intended audience or create multiple reports that are used to convey the information in different ways and for different purposes. A report to the board of directors, which may be interested in a general overall assessment of the program, will not necessarily require as much minutia or details as a report intended for the compliance officer and/or Compliance Department that will be tasked with implementing the recommended changes to the compliance program.

Similar to the considerations regarding whether to conduct onsite interviews, outside counsel should consider whether there is value in giving an oral report of the findings and recommendations over the telephone or in person. Outside counsel generally can gauge the audience's perception of the presentation much better when physically present with the audience. Having an in-person meeting for outside counsel to present and discuss the findings also could help the organization focus more clearly on addressing the recommendations that result from the evaluation.

WHAT HAPPENS NEXT?

Engaging outside counsel to conduct a compliance program effectiveness review can and should be a collaborative and productive process that results in meaningful action items and next steps for the organization. Setting the stage and establishing the four corners of the review up front is

important for managing expectations and building positive relationships that will make the review process run smoothly. Working with outside counsel to understand what is needed to complete the evaluation, and providing access to both relevant documents and key employees, will allow outside counsel to deliver a final work product that is useful to the organization.

Once the findings have been presented, the relationship with outside counsel does not have to come to an end. Outside counsel has gained institutional knowledge about the organization and its culture

and therefore can play a valuable role in assisting an organization's compliance officer and/or Compliance Department with implementation of the recommendations that result from the evaluation. Further, including outside counsel in the implementation process can keep momentum going and avoid having the final work product end up on a shelf and forgotten about.

Endnote:

1. See e.g., Office of Inspector General, Health Care Compliance Program Tips, *available at* oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf.



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