

How to Meet the Challenge of Evidencing Compliance Program Effectiveness

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Overview

Major regulatory and enforcement authorities, including the U.S. Department of Health and Human Services Office of Inspector General (OIG), the Department of Justice and the U.S. Sentencing Commission, stress the importance of independent evaluations to evidence compliance program effectiveness. However, Compliance Officers may find it difficult to differentiate between the recommended evaluation methods since they are often characterized in a way that neither matches how the service is actually conducted nor clearly explains the expected deliverable. To assist Compliance Officers in identifying the right type of method to evaluate the effectiveness of their compliance program, this article breaks down effective methods and explains what goes into each method, how it benefits the compliance program, and how it evidences compliance program effectiveness.

Compliance Officers should consider at least one of these evaluation methods in order to gain valuable insight and receive actionable results on the effectiveness of their compliance program. Additionally, Compliance Officers should consider conducting at least one of these evaluation methods once every two to five years in order to continually assess and improve their compliance program.

The three most common evaluation methods are:

1. Compliance Program Effectiveness Evaluation
2. Gap Analysis
3. Compliance Knowledge Survey

Each evaluation method serves a specific purpose and produces different types of results and recommendations. Additionally, each evaluation method can be scaled to fit any health care organization type, size and structure to independently measure and evidence the compliance program's effectiveness. Compliance Officers must consider the advantages, limitations and purpose of each method to determine the best approach for evaluating their compliance program. Compliance Officers should also understand the type of results they will receive and how to best use those results in order to improve the compliance program.

With all three methods, the individual(s) who performs the evaluation needs to be independent from the organization because Compliance Officers or other internal individuals cannot independently evaluate or audit their own compliance program operations. Additionally, the individual(s) conducting the evaluation must provide convincing evidence that supports the results and clearly shows the effectiveness of the program. Organizations will get the most out of their evaluation if an external health care compliance expert is the one conducting it.

Method 1

Compliance Program Effectiveness Evaluation

Overview

The most comprehensive evaluation method to evidence the state of effectiveness for a compliance program is a Compliance Program Effectiveness Evaluation. The objective of this evaluation is to determine (a) how well the infrastructure and operations are functioning; (b) whether existing metrics provide evidence of compliance program



effectiveness; and (c) the effectiveness of ongoing monitoring and auditing of high-risk areas identified by the OIG. In order to provide this level of assessment, the individual(s) conducting the evaluation must carry out a detailed examination of compliance-related documents and policies and procedures, provide validation testing of compliance processes, such as an anonymous compliance hotline and sanction screening, and perform interviews with executive leadership, Compliance Department staff, key staff and focus groups with frontline staff.

Advantages

A Compliance Program Effectiveness Evaluation is most valuable in determining the outcome of the compliance program when an independent health care consulting firm with the necessary expertise and experience is the one conducting the evaluation. The organization gains expert insight about effective operations, industry recommended practices, and the government's expectations for an effective compliance program from the results of this extensive assessment. Compliance Program Effectiveness Evaluations should draw from a number of authorities, including the U.S. Sentencing Commission's Guidelines Manual, the OIG's numerous Compliance Program Guidance documents, Centers for Medicare & Medicaid Services, the Department of Justice, as well as requirements under the Anti-Kickback Statute, the False Claims Act, the Stark

Law, the Health Insurance Portability and Accountability Act and the Sarbanes-Oxley Act, when applicable.

At the conclusion of the Compliance Program Effectiveness Evaluation, the organization should receive a detailed report that explains the firm's methodology and process used to conduct the assessment, findings and opportunities for improvement, and specific recommendations as to how the organization may overcome any deficiencies that were identified.

When outside experts conduct independent assessments such as Compliance Program Effectiveness Evaluations, the results hold more credibility with Boards of Directors and outside authorities because any actual or perceived bias is eliminated. Many times, the firm that conducts the assessment will present their findings and recommendations to the Board, which gives the Board an opportunity to ask questions and exercise their oversight responsibilities for the compliance program.

Considerations

This type of evaluation is best for mature compliance programs because it takes an in-depth look at all compliance program components, some of which may not be in place yet in newly-established compliance programs. Due to the nature and scope of a Compliance Program Effectiveness Evaluation, it is critical for the organization to engage a firm with expertise in the health care industry and that assigns consultants with real-world experience working in or with an organization similar to their own. Compliance Officers should beware that some firms use a bait-and-switch approach by substituting less qualified consultants to perform the work.

Method 2

Gap Analysis



Overview

A Gap Analysis identifies areas of deficiencies and opportunities for improvement in the compliance program. This evaluation method is a process review that focuses on the elements that the compliance program already has in place and those that are missing but need to be implemented. As such, this type of evaluation method can be thought of as a checklist review of documents. A Gap

Analysis does not take an in-depth look into how the compliance program is functioning, but instead focuses on output metrics such as whether policies and procedures are implemented, a confidential and anonymous hotline is in place, and exclusion checks are conducted.

Advantages

A Gap Analysis is best for organizations with a new or incomplete compliance program in which the Compliance Officer needs help identifying the proper elements to fully develop the compliance program. Compliance Officers can use the results as a road map to identify missing elements that are needed to complete the seven elements of a compliance program.

This evaluation approach is also beneficial to use when an organization is acquiring another organization. In this instance, a Gap Analysis is employed as part of the due diligence process so the acquiring organization has a clear picture of the state of the compliance program in the organization with which they are merging.

Considerations

Organizations may consider a Gap Analysis as an alternative to a more extensive review of their compliance program. However, because a Gap Analysis is carried out in a checklist fashion, the results do not examine the outcome of the program or evaluate whether it is effective. The results of a Gap Analysis should still be specific to the organization's compliance program and offer actionable recommendations on how to improve the current components of the compliance program.

Method 3

Compliance Knowledge Survey

Overview

Compliance Knowledge Surveys are used to identify the parts of the compliance program the workforce best understands, and highlight which elements warrant more focus and training from the Compliance Department. This evaluation method is most beneficial for organizations with a mature compliance program. The OIG notes in its Compliance Program Guidance documents to health care providers that surveys are an effective method to solicit impressions of broad cross-sections of the organization's workforce. Results from surveys such as Compliance Knowledge Surveys can yield valuable information about the workforce that can lead to actionable changes in the compliance program. Compliance Knowledge Surveys should provide both statistical results and include a detailed analysis and recommendations that are actionable by the Compliance Officer.

Advantages

Compliance Knowledge Surveys are extremely useful in measuring employees', managers' and executives' commitment to compliance. Rather than focusing on output metrics related to process, the Survey provides outcome metrics by measuring the workforce's understanding and knowledge about the compliance program. In order to gain the most insight and participation from the workforce, Compliance Officers should engage an outside firm to administer the Survey and analyze the results. Using a credible, independent firm to conduct the Survey adds a level of confidence and trust to the survey process.

For example, some workforce members may be uncomfortable responding honestly to survey questions if they believe that their identity (i.e., name or email address) will be tied to their response. But when workforce members know that an outside firm is administering the Survey, they don't have to worry that someone in the organization might know their response.

Another benefit of having an outside firm conduct the Survey is that the Board of Directors and executives may place a higher value on the results because they were generated independently and objectively from the organization. Outside firms who provide this service will attest that the Survey was conducted in an ethical and objective manner and will provide their methodology for the survey process to back up their claims.

Another advantage to the Compliance Knowledge Survey that many Compliance Officers may not know about is the ability to benchmark results against the universe of health care organizations that have completed the same Survey. Benchmarking results can provide valuable insight on how the compliance program compares to others, further revealing the strengths and weaknesses of the program. Additionally, Compliance Officers can benchmark results from previous years to the current results to identify areas that have improved or weakened over time.

A final advantage of the Compliance Knowledge Survey is the low cost. Typically, the cost of a Compliance Knowledge Survey is one-third the cost of a Compliance Program Gap Analysis and one-fifth the cost of a Compliance Program Effectiveness Evaluation. For a relatively low cost, Compliance Officers can gain valuable insight on how effectively the compliance program is operating and receive recommendations on how to take the compliance program to the next level.

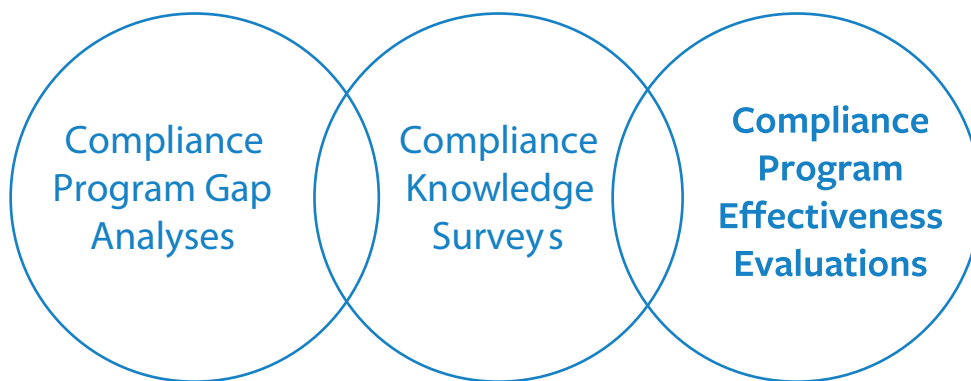
Considerations

A Compliance Knowledge Survey provides a “snap-shot” of the compliance program, as employees, managers, and executives have experienced it. In order for the workforce to supply the most honest answers, and thus to yield credible and reliable results, it is critical to use a professionally-developed and tested Survey that is administered independently. The workforce may be suspicious of in-house Surveys as being biased and steered towards producing favorable results. Engaging a firm with expertise in health care compliance is also important because they are able to provide practical, actionable advice related to an organization’s specific Survey results.

Any survey tool health care organizations use should also be well-tested and validated to generate reliable results. But Compliance Officers should remember that a Compliance Knowledge Survey is not a substitute for a Compliance Program Effectiveness Evaluation. As a result, many organizations alternate years conducting Compliance Surveys and more in-depth evaluations to ensure they have evidence of their compliance program’s effectiveness every year.

Combining Evaluation Methods

While Compliance Knowledge Surveys have many benefits, one of their greatest and most valuable benefits is that they reach every individual in the organization. This provides a holistic picture of the workforce's understanding of compliance. Therefore, a Compliance Knowledge Survey is an ideal evaluation method to couple with either the Gap Analysis or the Compliance Program Effectiveness Evaluation. The Survey can help validate and reinforce the findings of a Gap Analysis or Effectiveness Evaluation, increasing the overall quality of the evaluation and value of the final results.



What's Next?

Each evaluation method serves a specific purpose and produces different types of results and recommendations. Compliance Officers need to understand the differences in each type of evaluation and their results to learn which method will benefit their compliance program the most at that time. Regardless of the option chosen, Compliance Officers should review the past work of the potential individual(s) and firms who will be conducting the evaluation with at least three references to ensure they are getting quality service from an experienced professional.



Strategic Management Services (Strategic Management) has decades of experience managing and providing specialized support to health care compliance programs, including providing the services of all three evaluation methods. Founded in 1992 by the former Inspector General of HHS, Richard P. Kusserow, Strategic Management was the first health care consulting firm to focus on

corporate compliance and ethics initiatives. Strategic Management is the undisputed industry leader, having helped more than 2,000 health care organizations with highly-specialized, actionable regulatory compliance services.

Strategic Management's team of compliance specialists have unparalleled insight and a holistic understanding of regulatory compliance in the health care industry. Strategic Management provides clients with solutions that not only meet regulatory requirements, but that are highly specialized to their organization and are clear and actionable. The Strategic Management team has experience working in compliance leadership roles within top health care organizations, as well as in executive roles within federal enforcement and regulatory agencies. Strategic Management's experience includes working with organizations in all areas of the health care industry including health systems, academic medical centers, long-term care organizations, pharmaceutical companies, physician practices, laboratories, and managed care organizations.

Because of this wide range of experience, Strategic Management can help Compliance Officers determine which evaluation method makes the most sense for their organization's compliance program. Strategic Management's quality consultants and actionable regulatory and compliance services can help Compliance Officers develop and strengthen their compliance programs, ensuring stable and effective operations for years to come.

If you would like to learn more about how we can help support and improve your compliance program, visit our [compliance program services page](#). Or, contact us now by calling 800-683-9601 or filling out our online contact form at <https://compliance.com/contact-us/>.

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