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Compliance program annual review: A game plan

» Compliance program evaluations are expected (and required for nursing facilities).

» Your annual review should consider the seven compliance program elements.

» A comprehensive review will also assess compliance risk areas.

» Your review should verify processes exist—and can be proven.

» Don't forget to include culture to maximize program effectiveness.

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A compliance program evaluation is recommended (and expected) by federal enforcers. Two sources of federal guidelines are recommended for compliance program reviews. Although the focus of this article is compliance program annual reviews, the same methods are applicable to baseline assessments for new compliance programs.

First, the Federal Sentencing Guidelines (FSG) are used by federal judges when assessing sanctions for federal crimes, such as violations of the False Claims Act or Anti-Kickback Statute. The FSG are not mandatory, but they reflect the government's expectations, and it would be wise to adhere to them. Section 8B2.1(2)(b)(5)(B) of the Guidelines states, "The organization shall take reasonable steps … (B) to evaluate periodically the effectiveness of the organization's compliance and ethics program."

The second federal source of guidance is the Health and Human Services (HHS) Office of Inspector General (OIG) Compliance Program Guidance documents (CPGs). The OIG consistently recommends that healthcare compliance programs include regular review. For example, the CPG for Nursing Facilities states, "…the OIG recommends that all nursing facilities evaluate their current compliance policies and procedures by conducting a baseline assessment of risk areas, as well as subsequent reevaluations."[2]

As another example, the OIG's CPG for Hospitals states, "An effective compliance program should also incorporate periodic (at least annual) reviews of whether the program's compliance elements have been satisfied."[1]

For some providers, compliance program reviews are mandatory. A compliance program review is required for nursing facilities. The Affordable Care Act mandated compliance programs for all nursing facilities and requires an annual review:

(e) *Annual Review.* The operating organization for each facility must review its compliance and ethics program annually, and revise its program as needed to reflect changes in all applicable laws or regulations and within the operating organization and its facilities to improve its performance in deterring, reducing, and

detecting violations under the Act and in promoting quality of care.[2]

This requirement goes into effect November 28, 2019.

Evaluating compliance program elements

Use your annual review to make sure your compliance program adequately addresses the seven compliance program elements recommended by the OIG:

- 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

In addition, I recommend including an eighth element, which is discussed later in this article:

- Culture of compliance

If your organization is a nursing facility with five or more facilities, your review should also include the following components:

- Mandatory annual training program
- Designated compliance officer who reports directly to the governing body
- Designated compliance liaisons at each facility

If you need help deciding what to look for when assessing each compliance program element, you will find lots of ideas in *Measuring Compliance Program Effectiveness: A Resource Guide*, published jointly by the HCCA and the OIG.

Evaluating your compliance risk areas

Reviewing your compliance program elements is a great place to start, but it is not possible to make a comprehensive assessment without looking at your risk areas.

Examples of risk areas include billing and claims accuracy, medical necessity, quality assurance, Health Insurance Portability and Accountability Act (HIPAA), patient rights, cost reporting, records, kickbacks, and employee and contractor screening. Much of the work your compliance program does within the seven compliance program elements involves your risk areas. For example, you should have policies, training, and audits addressing each risk area. Information about each risk area is reported to the governing body, and each compliance report or complaint probably ties to a risk area.

Risk areas are listed in the OIG CPGs. Additional risk areas are regularly named by the OIG in its Work Plan, which is updated monthly. You can also find new compliance risk areas by reviewing settlements in the news, as well as updates from other agencies, such as Centers for Medicare & Medicaid Services (CMS) and the HHS Office for Civil Rights (OCR).

Once you identify your risk areas, determine whether each one is properly addressed with policies, training, audits, and board

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and compliance committee communication. Assign a risk level to each risk area so you can plan your compliance workflow accordingly. Higher risk items might need more frequent auditing. A risk area might be higher risk if it is a top OIG or OCR priority, if it has not been fully addressed within your organization, or if it is the subject of significant complaints in your organization.

When you have assigned levels to each risk area, you can plan your approach to mitigate those risks, starting with your highest ranked items.

Goals for the annual review

Whether you are evaluating a compliance program element or a risk area, some common goals apply:

▶ **Verify that a compliance action item is complete.** This could mean that a policy is in place, compliance committee meetings occur regularly, or 100% of employees signed your code of conduct.

▶ **Verify that you can *prove* the compliance task is complete.** For example, meeting agendas, sign-in sheets, and minutes can prove that compliance committee meetings occur regularly.

▶ **Make sure you can prove this immediately.** How long would it take to find those compliance committee minutes if the OIG was waiting in the next room?

▶ **Identify strengths and weaknesses.** Continuing with our compliance committee example, review the meeting minutes to find your strengths and weaknesses. What percent of members regularly attend meetings? Are minutes detailed and

legible? Is there documentation of meaningful discussion?

▶ **Establish a game plan.** Let's say your review found that compliance committee meetings are typically attended by half the committee members, and little discussion occurs. Your game plan might include rescheduling the meeting to a different time to increase attendance, brainstorming questions to add to the agenda to foster compliance discussion, and determining whether committee members need more education in order to better engage with compliance.

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A note on culture

I include a culture of compliance as the eighth compliance element, because a compliance program is only as strong as the culture that accompanies it. Fortunately, there are several ways to measure your compliance culture.

Employee surveys

As part of the review process, conduct anonymous employee surveys designed to evaluate employee comprehension and perception of your compliance program. Ask staff, "Would you feel comfortable using the compliance hotline? Do you know who the compliance officer is? Do your co-workers behave according to the code of conduct?" Responses will reveal a lot about your compliance culture.

Compliance committee surveys

Likewise, anonymous compliance committee surveys can be used to assess whether the committee believes their work is effective, valued, and important. A strong compliance

committee is key to a strong compliance culture.

Employee recognition

Interview staff and/or review HR files. Do supervisors recognize employees who show commitment to the compliance program? Review compliance reports and questions logs. Does someone follow up with individuals to thank them for reporting or asking a question? Each of these actions supports a culture of compliance. The annual review is an ideal time to see if employee efforts to adhere to the compliance program are recognized.

Exit interviews

If your organization conducts exit interviews, this documentation can hold clues to your compliance culture. Do departing employees mention retaliation for making compliance complaints? Have they witnessed non-compliance? Did they fear reporting? Did they make any comments about your organization's culture?

Performance reviews

What criteria are used in employee performance reviews? Do these criteria include compliance? If so, review performance reviews and determine how employees are performing in this area. If performance reviews do not address compliance, consider adding compliance-based measures to the review process (e.g., completed compliance training, exhibited conduct that adheres to compliance program). If your organization offers incentive compensation, can the incentives be tied to compliance?

Your assessment of your organization's compliance culture might reveal areas where you can improve. For example, if the anonymous survey reveals that a significant percentage of employees would not feel comfortable calling the compliance hotline, you will need to spend some time promoting the hotline. Make posters, include information about the hotline in routine in-services, and encourage supervisors to speak to staff about your hotline protection policies (e.g., anonymity, non-retaliation, and confidentiality). In addition, review compliance investigation files and interview staff to determine if these policies are followed.

Conclusion

We know that a compliance program assessment is recommended (and expected) by federal enforcers and will soon be mandatory for nursing facilities, but there are many other reasons to complete this process. The annual review helps you identify compliance successes to celebrate with your team—and strengthen your culture of compliance. The review will also find compliance challenges and weaknesses, allowing you to tackle them and improve your compliance program, year after year. And, the compliance program assessment generates useful data to share with your compliance committee and board to keep them informed of your compliance efforts—and provide justification for compliance resources. By taking the time to perform a review, your organization will make an investment in an effective, lasting program. ⓖ

1. United States Sentencing Commission, *Guidelines Manual*, Section 8B2.1(2)(b)(5)(B). November 2016. Available at https://bit.ly/2OSBij7
2. 65 Fed Reg 14289—14306 (OIG Compliance Program Guidance for Nursing Facilities) March 16, 2000. Available at https://bit.ly/2PF6lPY
3. 63 Fed Reg 8987—8998 (OIG's Compliance Program Guidance for Hospitals) February 23, 1998. Available at https://bit.ly/2yLodl1
4. 42 CFR Section 483.85 (Compliance and Ethics Program) Available at https://bit.ly/2OkCEah
5. OIG's Compliance Program Guidance for Individual and Small Group Physician Practices, 65 Fed. Reg. 59434, October 5, 2000, available at https://bit.ly/2mZsj3a
6. 73 Fed Reg 56832 on page 56847 (OIG's Supplemental Compliance Program Guidance for Nursing Facilities, IV. A. An Ethical Culture) September 30, 2008. Available at https://bit.ly/2RVTYk4
7. Ibid, Ref #4
8. HCCA-OIG Compliance Effectiveness Roundtable: "Measuring Compliance Program Effectiveness: A Resource Guide" March 27, 2017. Available at https://bit.ly/2MtT1MM
9. OIG: Compliance Guidance index. Available at https://bit.ly/2kZMqx1
10. OIG Work Plan and updates. Available at https://bit.ly/2fV7PUP