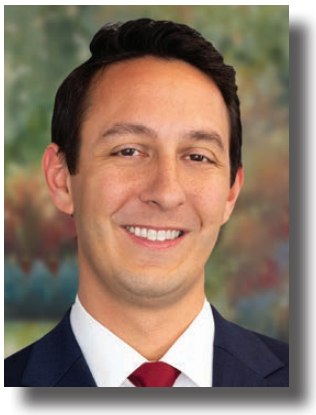
HHS OIG Seeks To Re-Focus And Re-Educate The Healthcare Industry on The Importance of Effective Voluntary Compliance Programs



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by John W. Kaveney

On November 6, 2023 the United States Department of Health and Human Services Office of Inspector General (OIG) issued a new general compliance program guidance document.[1] It was published in accordance with the OIG's efforts "to produce useful, informative resources . . . to help advance the industry's voluntary compliance efforts in preventing fraud, waste, and abuse in the health care system."[2] This document is the first in an upcoming series of new compliance program documents the OIG will be issuing to the healthcare industry.[3] This general compliance program guidance document applies to all individuals and entities involved in the healthcare industry.[4] It will be followed up, beginning in 2024, with several industry segment-specific compliance program guidance documents that will be applicable to different types of providers, suppliers, and other participants in the healthcare industry and tailored to specific fraud and abuse risk areas for each industry subsector.

The OIG has always characterized its publications as "voluntary, nonbinding guidance." Moreover, its publications "do not constitute a model compliance program" nor are they "intended to be one-size-fits-all, completely comprehensive, or all-inclusive" of all considerations and risks for every organization. Nevertheless, providers, suppliers, and other participants in the healthcare industry would be wise to review and update their compliance programs consistent with this latest guidance document.

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The general compliance program guidance document consists of the following four sections, each of which contains valuable and helpful information and links to other important and informative materials. The following are some highlights of the information contained therein.

Healthcare Fraud Enforcement and Other Standards: Overview of Certain Federal Laws

This section of the document begins with an important disclaimer that "[t]his guidance does not create any new law or legal obligations, and the discussions in this guidance are not intended to present detailed or comprehensive summaries of lawful and unlawful activity."[6] Nonetheless, the discussion in this section provides a general working knowledge of applicable federal laws with which those in the healthcare industry should be familiar when developing a new, or re-examining an existing, compliance program.

In terms of substance, the OIG summarizes in this section

the federal anti-kickback statute and physician self-referral law along with identifying key questions to ask and elements to focus on when analyzing a particular arrangement under these laws.[7] It also highlights the False Claims Act along with the various civil monetary penalty (CMP) authorities, including the beneficiary inducements CMP, CMPs related to improper information blocking, and CMPs related to HHS grants, contracts, and other agreements.[8] This section also summarizes the mandatory and permissive authorities bestowed upon the OIG to exclude individuals and entities from participating in Federal healthcare programs.[9] Finally, the section notes the existence of the criminal health care statute and the HIPAA Privacy, Security, and Breach Notification Rules.[10]

Missing from this section of the document are any discussions of State fraud and abuse laws, which those in the healthcare industry must also be cognizant of as part of any compliance review. As noted above, while nothing contained in this section is new law, it serves as a helpful refresher of the various legal authorities upon which the federal government may utilize to pursue civil and criminal claims against providers, suppliers, and other participants in the healthcare industry.

Compliance Program Infrastructure: The Seven Elements

The next section of the OIG's general compliance program guidance document is a discussion of the "7 Elements of a Successful Compliance Program."[11] The OIG continues to believe that "an entity's leadership should commit to implementing all seven elements to achieve a successful compliance program."[12] The following are highlights from the OIG's discussion of each element:

- *Written Policies and Procedures:* Organizations should have a code of conduct along with compliance policies and procedures that are developed by the compliance officer in collaboration with the compliance committee. Both sets of documents should help foster the compliance culture. The OIG suggests that CEOs endorse in writing the compliance program and that applicable stakeholders review the materials at least annually to ensure that they are operationally effective.[13]
- *Compliance Leadership and Oversight:* Leadership must appoint a compliance officer and give the individual sufficient staff and resources to carry out all compliance responsibilities. Moreover, for organizations of sufficient size, there should be a compliance committee comprised of individuals that have received sufficient training along with a full understanding of the organization's expectations of them. Ultimately, the organization's board should provide oversight and ensure that both the compliance officer and compliance committee have both the power, independence, and resources to carry out their responsibilities and also that they are in fact carrying out their responsibilities using the tools and resources provided to them.[14]
- *Training and Education:* At least annually, training and education should be provided to members of the organization both on the general aspects of the compliance program and its efforts, along with more targeted training depending upon the individual's roles and responsibilities and any specific compliance risks related to them. Compliance training and education should be mandatory and a condition of continued employment.[15]
- *Effective Lines of Communication:* Open lines of communication between the compliance officer and entity personnel are critical to a successful compliance program. The specific means of communication to the compliance officer should be well known and posted in physical and virtual spaces. The OIG also emphasizes the importance of protecting whistleblowers against retaliation and ensuring that concerns brought to compliance be thoroughly vetted either by the compliance officer or other relevant individuals depending upon the circumstances of the communication.[16]
- *Enforcing Standards:* There must be well-established and consistently applied consequences for instances of noncompliance, and incentives for compliant conduct.[17]
- *Risk Assessments, Auditing, and Monitoring:* In recent years, the OIG, along with those in the healthcare industry, have placed increasing emphasis on the importance of conducting a formal compliance risk assessment on at least an annual basis. Risk assessments help focus compliance efforts in areas of greatest concern and there are a number of available tools, through the OIG and others in the industry, that can help with this task. Through the risk assessment, areas of concern can be identified to focus auditing and monitoring efforts as part of an annual compliance work plan. The scope of such efforts will depend upon the outcome of the risk assessment, along with staffing and resources available to the compliance department.[18]
- *Responding to Detected Offenses and Developing Corrective Action Initiatives:* Regardless of how comprehensive and diligent a compliance program, it is inevitable that potential concerns will be raised in connection with auditing, monitoring, or hotline calls. Effective compliance programs should have a well-defined investigation process, a set of guidelines for reporting specific types of misconduct to the government, and means to implement necessary corrective action initiatives to ensure such misconduct does not occur again in the future.[19]

Compliance Program Adaptations for Small and Large Entities

This next section of the guidance document discusses ways in which an organization can "right-size" their compliance program

to meet their entity's needs.[20] There is no one-size-fits-all compliance program and thus while the seven elements listed above are the cornerstone of an effective program, how they are implemented requires customization to a particular organization.

For small entities, the OIG recognizes they may face financial and staffing constraints. Small entities should still have either a compliance officer or compliance contact to ensure the entity's compliance activities are completed. Moreover, this individual should still have the ability to report to the board, or in the absence of a board, the owner or CEO. Small entities should still have written policies and procedures, though they may be able to avail themselves of more form template-based documents to minimize the time and expense of developing their own. Moreover, absent a formal disclosure program for compliance concerns, there should still be a user-friendly method to facilitate compliance communications. Finally, though they may not need to be as complicated or resource intensive, a compliance risk assessment should still be performed at least annually, and audits conducted at least annually in the areas identified of greatest concern during the risk assessment.[21]

The OIG also emphasizes the importance of large entities sufficiently scaling up their compliance programs to meet the greater needs of a larger organization. This means the need for entire compliance departments, staffed with individuals of varying skill sets, to meet the needs of the organization. Moreover, such programs require greater involvement from the compliance committee, which should consist of members from various operational components of the organization. Finally, the boards of such organizations should consist of appropriate subcommittees to ensure compliance matters are effectively addressed and resolved at the board level.[22]

Other Compliance Considerations

This final section of the guidance document highlights a few "important compliance considerations related to several generally applicable risk areas."[23] Health care providers, suppliers, and other participants should consider these categories as areas to focus upon when re-evaluating their compliance programs.

- *Quality and Patient Safety:* While most organizations treat quality and patient safety as separate and distinct from compliance, these areas have long been a focus of the OIG and Department of Justice. Many cases have been investigated and settled based upon the submission of false claims for care and thus the OIG notes that this will continue to be an area of focus. Consequently, it is important for quality and patient safety oversight to be incorporated into a compliance program. By doing so, compliance can assist in identifying potential areas of risk and alert the organization to such concerns.[24]
- *New Entrants in the Healthcare Industry:* There has been a significant increase in the number of new entrants into the healthcare industry, including technology companies, investors, and organizations that are providing "non-traditional services in health care settings (such as social services, food delivery, and care coordination services)." The OIG therefore cautions these new entrants to be mindful of the legal landscape surrounding the healthcare industry as business practices in other industries can create risk in health care of civil, criminal, and administrative liability. Moreover, the OIG notes that even existing healthcare entities are expanding into new areas of business and while they may generally be aware of the legal landscape, they should be cautious to pay particular attention to how the laws apply to their new ventures.[25]
- *Financial Incentives:* The OIG has made note of the "growing prominence of private equity and other forms of private investment in healthcare" and has raised concerns about "the impact of ownership incentives (i.e., return on investment) on the delivery of high quality, efficient healthcare." Thus, healthcare entities should carefully scrutinize such ownership arrangements. Similarly, close attention should also be paid to the payment methodologies being utilized to reimburse healthcare entities for items and services they provide. Understanding what payment incentives exist will help the organization identify areas of potential risk requiring greater scrutiny.[26]
- *Financial Arrangements Tracking:* The OIG notes that many healthcare entities, especially larger institutions, have significant volumes of financial arrangements and transactions. While it is important to ensure the terms of those agreements are in compliance with the Federal anti-kickback statute and physician self-referral law, it is just as important to ensure that there is "ongoing monitoring of compliance with the terms and conditions set forth in the agreements." In other words, compliance does not end when the deal is signed, but rather ongoing monitoring is also important to ensure the agreement is carried out consistent with those terms.[27]

The OIG concluded its new general compliance program guidance document by reaffirming the fact that "compliance is a dynamic process" and therefore it will be updating the document as new developments occur and new resources become available. In an effort to partner with industry stakeholders, the OIG welcomes submitted feedback to its email at Compliance@oig.hhs.gov.[28] It also appended a set of links to various OIG resources and processes to aid those in the healthcare industry with their compliance programs.[29] As we move further from the pandemic, and investigation efforts continue to ramp back up, health care entities should take this opportunity to reassess their compliance programs.

About the Author
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Footnotes

[1]https://oig.hhs.gov/compliance/compliance-guidance/
[2]Id.
[3]https://oig.hhs.gov/documents/compliance-guidance/1135/HHS-OIG-GCPG-2023.pdf
[4]Id. at p. 7.
[5]Id. at p. 8.
[6]Id. at p. 10.
[7]Id. at pp. 10-17.
[8]Id. at pp. 17-24.
[9]Id. at pp. 24-27.
[10]Id. at pp. 28-30.
[11]Id. at pp. 32-63.
[12]Id. at p. 32.
[13]Id. at pp. 33-37.
[14]Id. at pp. 37-46.
[15]Id. at pp. 46-49.
[16]Id. at pp. 50-52.
[17]Id. at pp. 53-55.
[18]Id. at pp. 55-59.
[19]Id. at pp. 59-63.
[20]Id. at pp. 65-74.
[21]Id. at pp. 65-70.
[22]Id. at pp. 71-74.
[23]Id. at pp. 76-80.
[24]Id. at pp. 76-78.
[25]Id. at pp. 78.
[26]Id. at pp. 79.
[27]Id. at pp. 80.
[28]Id. at pp. 90.
[29]Id. at pp. 81-88.