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OIG's General Compliance Program Guidance on quality and patient safety: Considerations for compliance officers

by Mary Shirley

Introduction

The U.S. Department of Health and Human Services Office of the Inspector General (OIG) released its *General Compliance Program Guidance* in November 2023.[1] While there was a lot of affirmation of previous guidance and educational assistance with regulatory obligations, such as the main U.S. healthcare laws, there was also some new content that gave a lot for compliance officers to ponder and take to management with suggestions for change to help their organizations better comply with the guidance. The biggest bombshell for me was their recommendations on what constitutes an empowered and independent ethics and compliance function. From a substantive standpoint, however, the aspect that drew my interest the most was the quality and patient safety section, found on page 76, under the "Other Compliance Considerations" of the document.

Guidance on quality and patient safety

Not only did OIG emphasize the importance they give to the areas of quality and patient safety, but they also noted that "entities should incorporate quality and patient safety oversight into their compliance programs." This expectation will likely cause many organizations to consider significant changes to their current operations. As OIG states, "Quality and patient safety are often treated as wholly separate and distinct from compliance, and the compliance program often does not contain quality and patient safety components." From my experience and anecdotally from what I've heard from my peers in discussions, this is a solid reflection of the organizational setup of many healthcare and life sciences companies. For example, I asked peers at other companies whether compliance had any oversight over quality or patient safety at their organizations, and they largely responded no, with one chief compliance officer of a medical device organization going so far as to comment that they thought it was "odd" to be expected to do so. In my view, it would not be surprising if some medical and quality departments had the same reaction. That is often the way when we try something new. However, that's not sufficient reason to decide not to indulge the idea.