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New Providers/Entrants Beware – Ignorance Is Not a Defense

An updated compliance program guidance (the Guidance) has been published by the U.S. Department of Health and Human Services Office of Inspector General (OIG) in an effort to provide a framework and other useful information to bolster the compliance programs of healthcare providers, including new entrants like IT companies. Unlike the previous iterations, the updated, user-friendly Guidance is published on the OIG website and is anticipated to be updated with greater frequency.

Addressing the expansion of participants providing or supporting healthcare, OIG specifically states that such "new entrants" in the healthcare industry, such as technology companies, investors, and those providing nontraditional services such as care coordination services, are required to have a compliance plan in place. These "new entrants" are encouraged to thoroughly familiarize themselves with federal and state laws and regulations, the Guidance, advisory opinions, reports, and other available compliance materials. The Guidance pointedly reminds "new entrants" that business practices that are common in other industries may lead to potential criminal, civil, and administrative liability in the arena.

OIG further recognizes the number of existing organizations that are expanding beyond their traditional businesses into new ventures in the healthcare space. The Guidance reminds these entities that the risks may not be common to all lines of business and urges them to understand the compliance risks specific to their new venture.

In an effort to further educate entities in these growing areas of business, OIG renews its commitment to provide industry-specific guidance in the future, so stay tuned.

Other parts of the Guidance are substantially similar to the previous versions, providing a primer on relevant federal laws and the seven elements it believes are crucial in a compliance program infrastructure. While these seven elements remain largely intact, the new Guidance has expanded them in substance, drawing from decades of experience in monitoring corporate integrity agreements, along with experience from enforcement actions and investigations as well as feedback from the industry stakeholders.

Notably, OIG is continuing with its top-down value approach for compliance; the Guidance strongly encourages the integration of boards and senior leadership to include the chief compliance officer in effective compliance programs.

Day Pitney's Healthcare practice represents numerous healthcare organizations, providers, and technology companies in the formation and implementation of effective compliance programs. We are available to assist companies and practitioners in navigating the complexities of federal and state laws and their application to your line of business.

Authors



Magda C. Rodriguez
Partner

Miami, FL | (305) 373-4010

mrodriguez@daypitney.com



Kritika Bharadwaj
Partner

New York, NY | (212) 297-2477

kbharadwaj@daypitney.com



William J. Roberts
Partner

Hartford, CT | (860) 275-0184

wroberts@daypitney.com



Mindy S. Tompkins
Partner

Hartford, CT | (860) 275-0139

mtompkins@daypitney.com



Stephanie M. Gomes-Ganhão
Associate

Hartford, CT | (860) 275-0193

sgomesganhao@daypitney.com



John F. Kaschak
Associate

Parsippany, NJ | (973) 966-8034

jkaschak@daypitney.com



Colton J. Kopcik

Associate

Washington, D.C. | (203) 977-7362

ckopcik@daypitney.com



Phoebe A. Roth

Senior Associate

New Haven, CT | (203) 752-5045

proth@daypitney.com