



In November 2023, the U.S. Department of Health and Human Services Office of Inspector General (OIG) released their long-awaited General Compliance Program Guidance.

One area of new emphasis in this document includes the mention of new entrants in the health care industry. Many of these new entrants come from other industries where they might not be as familiar with laws and regulations that prohibit certain activities in health care that are regularly allowed in other industries.

Some of the new entrants identified within the OIG guidance include:

- Technology companies (both established and start-up companies)
- New investors
- Organizations providing non-traditional services in health care settings (such as social services, food delivery, and care coordination services)

The OIG states that "...business practices that are common in other sectors create compliance risk in health care, including potential criminal, civil, and administrative liability. New entrants should take steps to ensure that they and any business partners possess a solid understanding of the Federal fraud and abuse

laws, in addition to other applicable laws, and that they possess an understanding of the critical role an effective compliance program plays in preventing, detecting, and addressing potential violations."

One of the significant new players in the health care industry is investors from private equity. In her keynote address at the HCCA Compliance Institute in April 2023, Christi Grimm, the Inspector General, stated:

"...Health care has generally been seen as a "safe bet" from an investment perspective. More investors, such as private equity, have jumped in. The presence of private equity in the industry is increasing, with more than \$1 trillion dollars in 8,000 deals over the past decade. Private equity investment in nursing homes and other sectors is prompting tough questions about its impact on the quality of care that is provided, as well as the potential for profit considerations to take priority over patient care."

It is not just the Inspector General who has raised the potential concern of profits over patient care with investors. In a study published by the Journal of the American Medical Association (JAMA)¹, researchers examined the question of whether private equity acquisition of nursing homes is associated with the quality or cost of care for long-stay nursing home residents. Their

research concluded that private equity acquisition of nursing homes was associated with increases in certain types of emergency department visits and hospitalizations and higher Medicare costs.

Additionally, in November 2023, the U.S. Department of Justice (DOJ) announced a \$45 million dollar settlement with six nursing homes as well as the management company and its owner that oversaw the nursing homes. Many in the private equity sector have taken notice of this case because the DOJ specifically included the management company and its owner in the settlement obligations in addition to the nursing facilities themselves. This type of settlement signals the DOJ's interest in going beyond the providers themselves by looking at the actions of the management companies and key individuals within those companies.

In addition to new entrants showing up on OIG's radar, it should be noted that many existing players in health care are expanding their business strategies into other areas within health care that are new for them. For example, providers are offering managed care plans and developing health care technology. While these organizations may be familiar with compliance risks applicable to their current business, they should also evaluate and familiarize themselves with new risk areas associated with new and different lines of health care business.



In this regard, the OIG refers such organizations to their specific provider type compliance guidance that has been published for many years. In addition to this long-standing guidance, the OIG has announced their intention, in 2024 and likely beyond, to publish new industry segment-specific compliance program guidance documents (ICPGs) for different types of providers, suppliers, and other participants in health care industry subsectors or ancillary industry sectors relating to Federal health care programs. ICPGs will be tailored to fraud and abuse risk areas for each industry subsector and will address compliance measures that the industry subsector participants can take to reduce these risks.

CONCLUSION

The message from the OIG is clear. They are aware of the influx of new entrants into the health care industry. They plan to watch these organizations and are letting them know now that the laws and regulations affecting health care entities are often different than those found in other industries. Both new entrants as well as current entities that might be venturing into new business lines within health care, need to be aware of the compliance obligations in these areas that are new to them.

The OIG's guidance specifically makes a plea with entrants new to the health care space. It states, "New entrants should take steps to ensure that they and any business partners possess a solid understanding of the Federal fraud and abuse laws, in addition to other applicable laws, and that they possess an understanding of the critical role an effective compliance program plays in preventing, detecting, and addressing potential violations." If you or your organization is new to health care compliance, you should consider existing tools to help you meet the requirements of an effective compliance program.

Healthicity's Compliance Manager is an all-in-one tool that can significantly support an organization's efforts in building and maintaining an effective compliance program. Compliance Manager helps organizations with each of the seven elements of an effective compliance program including elements such as incident management, compliance training, risk assessment, auditing and monitoring, policy management, attestations, and reporting on compliance data.

¹ Braun RT, Jung H, Casalino LP, Myslinski Z, Unruh MA. Association of Private Equity Investment in US Nursing Homes With the Quality and Cost of Care for Long-Stay Residents. JAMA Health Forum. 2021;2(11):e213817. doi:10.1001/jamahealthforum.2021.3817

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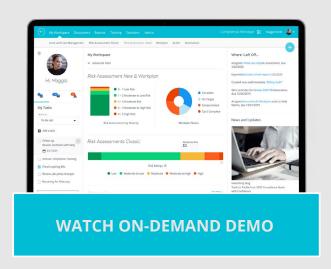
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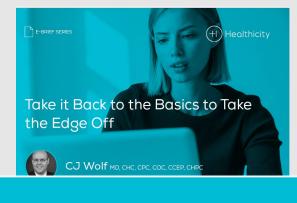


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