

## Compliance Today – December 2020 Rethinking conflict of interest training

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As part of a robust corporate compliance program, many organizations will require periodic disclosures of financial interests and relationships, including some familial relationships and certain outside activities, from board members, senior leaders, and other designated employees. For healthcare-centric organizations, such as large multidisciplinary healthcare providers and academic medical centers, researchers, faculty, physicians, advanced practice providers, and other key personnel must also periodically disclose their financial interests to the organization.

Usually organizations require these disclosures on an annual basis. Disclosures are also expected to be updated promptly—with an exact time frame that is defined by institutional policy—when an employee's financial interests, relationships, outside activities, and familiar interests and/or relationships change. Depending on an organization's size, this can amount to hundreds, if not thousands, of individuals providing disclosures on an annual basis.

### Training requirements

Those hundreds to thousands of employees submitting disclosures should receive training. The Public Health Service (PHS) regulations<sup>[1]</sup> for research funded by PHS (e.g., through the National Institutes of Health) require training on conflict of interest (COI) prior to engaging in research related to any PHS-funded grant and then once every four years, or more often if there is a change in institutional policy that affects disclosure requirements, and immediately when an investigator is noncompliant with institutional policies.<sup>[2]</sup> Investigators with ongoing PHS-funded research who change institutions must also receive training at their new institution.

Another relevant regulatory agency for healthcare organizations, the Food and Drug Administration, also maintains its own set of COI-related regulations and the associated guidance for financial disclosures by clinical trial investigators.<sup>[3]</sup> However, those regulations are silent on the subject of training.

Most organizations establish a periodic training requirement, regardless of whether the PHS regulations are applicable to them. Over the past few years, providing COI or related training has become a best practice within healthcare compliance. Training focused on COI can certainly contribute to an organization's and compliance office's successful efforts to maintain employee compliance to organizational and applicable federal disclosure requirements.

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