HHS Proposed Rule 42 CFR Part 2
Confidentiality of Substance Use Disorder Patient Records

The Health and Human Services department issued a proposed rule published in the Federal Register on February 9, 2016. This proposed rule is in reference to the confidentiality of patient records related to substance use disorders and was last updated in 1987. The current laws and regulations surrounding the confidentiality of these records were developed around the concern that this type of information might be used against individuals and prevent them from seeking treatment. (81 Fed. Reg. 26 (Feb, 9, 2016). The health care system has come a long way since these original rules were established.

According to the proposed rule “…new models of integrated care that are built on a foundation of information sharing to support coordination of patient care, the development of an electronic infrastructure for managing and exchanging patient information, and a new focus on performance measurement…” are all reasons to take a look at the current rules (81 Fed. Reg. 26, (Feb. 9, 2016), p. 7707). The Substance Abuse and Mental Health Services Administration (SAMHSA) wants to ensure that these patients can be included in and benefit from these new models while at the same time ensure that they remain able to seek treatment for substance use disorders.

You can learn more about these proposed changes at https://www.gpo.gov/fdsys/pkg/FR-2016-02-09/pdf/FR-2016-02-09.pdf pg. 6988. The Department of Health and Human Services will be accepting public comments regarding the proposed changes until April 11, 2016.

CIA — What is it?

No it’s not the Central Intelligence Agency.

In the world of compliance, CIA refers to Corporate Integrity Agreement (CIA)

A Corporate Integrity Agreement most often referred to as a CIA is a document that is created between the Office of Inspector General (OIG) and health care providers as part of a settlement following Federal health care program investigations that involve various civil false claims statutes. These agreements detail obligations that providers agree upon in exchange for not being excluded from participation in Federal programs. Reviewing CIA’s in place with other providers can also be an important reference tool in developing your own compliance program.
There are two types of CIAs. Quality of Care and Traditional. The first type, Quality of Care CIA, is used when the alleged fraud has an effect on the quality of care provided. In these cases there is a requirement that providers “...retain an entity with clinical expertise to perform quality-related reviews” (OIG, n.d.b., ¶1). They may also require a provider to retain a clinical expert to review medical necessity of admissions or to evaluate how the provider responds to patient care issues. The Traditional CIA is what is used to resolve allegations that do not have an impact on the quality of care and will be the focus of this article.

CIAs are usually five (5) years in length and can be expensive to implement. According to the OIG, they “... have many common elements, but each one addresses the specific facts at issue and often attempts to accommodate and recognize many of the elements of preexisting voluntary compliance programs” (OIG, n.d.a., ¶2).

Typical CIA Requirements
- Hire a compliance officer/appoint a compliance committee
- Develop written standards and policies
- Implement a comprehensive employee training program
- Retain an independent review organization to conduct annual reviews
- Establish a confidential disclosure program
- Restrict employment of ineligible persons
- Report overpayments, reportable events, and ongoing investigations/legal proceedings
- Provide an implementation report and annual reports to OIG on the status of the entity’s compliance activities. (OIG, n.d.a., ¶2)

In an open letter to health care providers in 2009, the Inspector General indicated that there are various factors taken into consideration when developing the terms of a CIA. Those factors include the severity of the underlying misconduct, the resources of the provider, the existing compliance capabilities and whether or not the case resulted from a self-disclosure. Having a compliance program that has proven to be effective certainly has an impact. “The more a provider can point to tangible, positive outcomes stemming from its compliance efforts, the more reliance we can plan on those measures and integrate them into a CIA” (OIG, 2000, ¶8). The open letter continues by stating that the best evidence in determining if a provider has an effective compliance program is if they can demonstrate that through their program there is a pattern of identification, mitigation, and prevention of improper conduct and full and timely disclosures are made.

In fact, an effective compliance program may deter the OIG from even requiring a CIA or only requiring minor changes to the existing policies and procedures. That decision is influenced by “...the scope and seriousness of the misconduct, the risk of recurrence, whether the disclosed matter was identified and reported as a result of the provider's compliance measures and the degree of the provider's cooperation during the disclosure verification process” (OIG, 2000, ¶10).

These documents can be a valuable resource to compliance professionals by providing insight into the expectations of the OIG. You may view CIA’s currently in place and obtain additional information by visiting http://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp
References:


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