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The Implications of Corporate Integrity Agreements: What Providers Should Expect

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For corporate health care providers involved in a civil health care fraud investigation, entering into a corporate integrity agreement (CIA) with the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services (HHS) is often a necessary condition to resolving the matter. If there is a parallel criminal investigation, CIAs are usually, although not necessarily, included as part of any global resolution.

Under the terms of the CIA, HHS will require the corporate provider to accept a number of detailed, compliance-related obligations. In exchange, the corporate provider is given the opportunity to avoid being barred from participating in Medicare, Medicaid, or other Federal health care programs – a financially devastating outcome for any entity.

Although a provider often has little, if any, practical choice but to accept these obligations if it wants to continue operating, it does not mean that it should overlook the implications of operating under a CIA or underestimate the requirements for success. The failure to appreciate the practical realities of a CIA will only lead to further problems in the future. Indeed, even for an organization that is not involved in a Federal health care program investigation, appreciating the implications and burdens of a CIA may help it better understand what the government expects of its own compliance program.

Standard Elements

CIAs are intended to be tailored to the specific facts of the case and the particulars of the corporate provider at issue. Nevertheless, there are a number of elements that HHS has identified as common to any CIA. A provider should anticipate that these elements – most of which would be components of any effective compliance program – will be incorporated, in some form, into any CIA it may enter:

- hiring a compliance officer, appointing a compliance committee, or both;
- developing written standards and policies for ensuring compliance and proper employee conduct;
- implementing a comprehensive employee training program;
- retaining an outside organization to conduct periodic reviews of the compliance program and accompanying policies;
- creating a confidential disclosure program for employees;
- ensuring that persons who are not eligible to participate in activities related to Federal health care programs do not do so;
- maintaining complete transparency with OIG with respect to overpayments, “reportable events,” ongoing investigations, and legal proceedings; and
- periodically reporting to OIG on the status of the provider’s compliance activities. Each of these general principles is incorporated into the details of the CIA. For example, for a pharmaceutical company, the CIA will contain specific provisions governing its promotional materials, including detailed steps for review and approval.

Ensuring CIA Success: Critical Components

Buy In. To be successful, the corporate provider needs to make sure that everyone within the organization – from its board of directors to its officers and executives to its business managers and division heads – is engaged in the process and committed to its implementation and, ultimately, its success. It is not simply a matter for the legal or compliance departments to handle. Indeed, CIAs will often require employees at various levels throughout a company to “certify” that particular compliance requirements are being met; this is not something reserved for the most senior executives. CIAs will also require the compliance officer to report directly to the board of directors to ensure greater oversight within the organization over compliance-related matters. It is, therefore, vital that everyone within the organization be willing to take on the obligations required.

Resources. A CIA requires significant resources and expense to implement and thereafter to maintain compliance with its terms. As noted above, many of the conditions in a CIA are parts of an effective compliance program. For a provider that lacked these foundations, therefore, there will undoubtedly be substantial upfront costs and dedication of resources.

Institutionalization. Although a CIA comes into play at the end of what is likely a lengthy government investigation, the obligations it imposes are only the beginning of a process that will outlast the typical five-year term of the CIA. The government views CIAs as tools that promote model standards for ensuring compliance with health care laws. Consequently, although certain obligations (for example, conditions related to oversight by outside entities) will not continue past the term of the CIA, a fair number of its requirements should remain in place to ensure that the provider maintains a comprehensive compliance program.

Internal Monitoring. It is important to appreciate that HHS carefully monitors its CIAs and vigorously responds to a breach of its terms. The failure to comply with the terms of CIA, itself, may lead to additional penalties, an extension of the terms of a CIA, or at worse, debarment. In a recent case involving repeated and flagrant violations of the terms of the CIA, HHS barred the provider from further participation in Federal health care programs. Such enforcement efforts only underscore the need for a corporate provider operating under a CIA to carefully monitor that it is satisfying its obligations to the government.

In sum, a CIA may be a useful – and required – tool for resolving a civil health care fraud investigation. But, as discussed above, there are significant implications for a corporate provider that has to operate under one. For an entity considering entering into a CIA, understanding at the outset the obligations – and burdens – that will be imposed upon it will help the provider be successful in staying in compliance. Appreciating the reality that these obligations can be onerous should also caution a corporate provider negotiating a CIA to avoid terms that are greater than necessary given the particulars of the provider and the actual compliance risks it faces.