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Leveraging CIAs as a compliance tool: Analyzing trends to identify and mitigate compliance risks for pharmaceutical and medical device manufacturers

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Identifying, monitoring, and addressing potential risk areas is a critical component of an effective compliance program. Indeed, the Office of Inspector General (OIG) within the U.S. Department of Health & Human Services recommends that healthcare organizations participating in federal healthcare programs conduct periodic risk assessments and engage in internal review processes with the aim of identifying and prioritizing risks, developing and implementing internal auditing and monitoring work plans related to such risks, and developing and implementing corrective action plans in response to the findings, as applicable.[1]

This article is the last in a series designed to equip compliance personnel with data—derived from recent government enforcement activity—that can help them better understand the government's current enforcement priorities and, thus, inform how they rank potential risks to their organization.

Recent corporate integrity agreements (CIAs) and integrity agreements (IAs) imposed by the OIG,[2] as well as associated settlement agreements and litigation filings, provide a wealth of information regarding the agency's priorities, areas of focus, and compliance expectations. (IAs are similar to CIAs but typically have a shorter term and contain fewer compliance obligations.) By understanding the circumstances under which the OIG has imposed a CIA or IA, federal healthcare program participants can better understand the agency's enforcement emphasis and identify internal practices that may require closer scrutiny.

Unfortunately, while the OIG maintains a publicly available database of its active CIAs and IAs (and associated materials),[3] the data is not organized in a way that easily allows for quantitative and qualitative analysis. Each article in this series is designed to provide targeted data analysis of recent CIA and IA enforcement activity related to a specific type of provider or supplier. This article focuses on recent CIAs involving pharmaceutical and medical device manufacturers.

Trends among CIAs imposed on pharmaceutical and medical device manufacturers

During the period from January 1, 2020, through November 15, 2021, the OIG appears to have imposed 11 CIAs on pharmaceutical and medical device manufacturers (Manufacturer CIAs). All 11 Manufacturer CIAs were imposed

in connection with a settlement with the U.S. Department of Justice (DOJ) to resolve alleged violations of the federal civil False Claims Act.[4] Notably, several of these settlements also reference separate settlement agreements, which had been entered into or would be entered into with the state attorney general and/or other state authorities to settle actions brought under the state equivalent of the False Claims Act for claims submitted to the state's Medicaid program.

A study of these Manufacturer CIAs, as well as the corresponding DOJ news releases, settlement agreements, and underlying complaints detailing the actions at issue (to the extent publicly available), reveal certain trends that may be of interest to compliance personnel. Our analysis provides insights into potential risks arising from (i) remuneration provided to referral sources, (ii) remuneration provided to patients, (iii) arrangements with other manufacturers pertaining to drug pricing and market share, and (iv) product marketing. The specific allegations underlying these Manufacturer CIAs, and the associated compliance obligations imposed through them, can be leveraged as valuable informational tools for pharmaceutical companies and medical device manufacturers when developing risk management and compliance strategies.

Alleged kickbacks to referral sources

Ten of the 11 Manufacturer CIAs arose, in whole or in part, from alleged violations of the federal healthcare program Anti-Kickback Statute. For the remaining Manufacturer CIA, at least one of the underlying relator complaints included alleged violations of the Anti-Kickback Statute, but those allegations do not appear to be covered under the DOJ settlement.[5] Five of these Manufacturer CIAs, discussed in this section, involved allegations of improper remuneration provided by the manufacturer to a referral source (i.e., physicians or other healthcare providers in a position to prescribe or order the manufacturer's products).

Intellectual property

For two Manufacturer CIAs, the remuneration at issue included royalties and other intellectual property (IP) payments made by the manufacturer to referral sources.[6] In one instance, a manufacturer of spinal implants, devices, and equipment entered into the following types of agreements with surgeons (i.e., users of the manufacturer's products): (i) product development agreements, pursuant to which the surgeons would advise on the manufacturer's products in the development stage, and (ii) IP purchase agreements, pursuant to which the manufacturer would purchase or license surgeons' patents or patent applications. The manufacturer also entered into consulting arrangements with surgeons.[7]

The government found the following aspects of these arrangements to be problematic:[8]

- For the product development agreements, the surgeons typically were paid not only $500 per hour for time spent advising on the manufacturer's products, but also royalties on future sales of the products once they went to market in exchange for any IP rights of the developing surgeon in the product (excluding any sales attributable to the surgeon's own usage of the products or the usage of other physicians in the surgeon's practice). The manufacturer retained up to eight surgeons per new product development project and frequently retained the same surgeon to consult on several different projects at the same time.
- For the IP purchase agreements, the manufacturer frequently paid up-front acquisition fees, some of which were hundreds of thousands of dollars. The manufacturer also provided surgeons with royalties on sales of any products developed based on the patents, some of which were 5%–7% of net sales (excluding any sales attributable to the surgeon's own usage of the products or the usage of other physicians in the surgeon's practice).

- Many of the surgeons who received the royalties and IP acquisition payments described earlier (as well as consulting fees) were "high-volume users" of the manufacturer's products.
- The manufacturer "closely tracked" the usage of its products by surgeons who received the payments. For example, the manufacturer generated reports for management that reflected both the payments made to surgeons and the surgeons' usage of the manufacturer's products. In one instance, the report included a "ROI" column that calculated the manufacturer's return on investment by dividing the sales revenue associated with each surgeon's usage of the manufacturer's products by the total amount paid to the surgeon in consulting fees and royalties during the same period.

A second Manufacturer CIA arose from allegedly improper royalty payments made by a medical device manufacturer specializing in orthopedic products to an orthopedic surgeon. The government claimed that these royalty payments were kickbacks because, allegedly, the manufacturer had previously denied the surgeon's request for royalties for the two product lines at issue, but when the surgeon threatened to switch to a competitor's products several years later, the manufacturer not only agreed to the surgeon's royalty request but also (i) agreed to pay royalties retroactively and, (ii) for future sales, agreed to pay royalties at double the rate that it typically used in its royalty arrangements (specifically, 4% of revenue, instead of its standard 2%).[9]

Consulting arrangements

For two of the Manufacturer CIAs (including one discussed in the prior section), the remuneration at issue included payments for consulting services that the government considered to be sham arrangements.[10]

In addition to providing remuneration to surgeons in the form of royalties and other IP payments, the spinal implant manufacturer discussed earlier also entered into consulting arrangements with surgeons, pursuant to which the surgeons were paid $500 per hour to provide training and education services. The scope of these services was "fairly broad" and could include, among other things, speaking about the manufacturer's products, demonstrating procedures at cadaver labs, preparing research papers related to the manufacturer's products, presenting at trade shows or conferences, participating in clinical studies of the manufacturer's products, and training the manufacturer's staff. As previously noted, many of the surgeons who received consulting fees (in addition to the royalties and IP acquisition payments described earlier) were "high-volume users" of the manufacturer's products, and the manufacturer "closely tracked" the usage of its products by surgeons who received these payments.[11]

Another Manufacturer CIA arose from allegations that a manufacturer of an endovascular laser system paid kickbacks to physicians disguised as payments for training events and consulting services. The government contended that the manufacturer maintained an internal document tracking the product use of high-volume physician customers, which allegedly was used to identify physicians that the manufacturer would target with offers of improper remuneration.[12]

Speaker programs

Another Manufacturer CIA involved purportedly improper remuneration pertaining to a pharmaceutical manufacturer's speaker events, roundtables, speaker training meetings, and lunch-and-learns.[13] The government found the following aspects of these speaker programs to be problematic:[14]

- The manufacturer's sales representatives were provided with budgets specifically for promotional programs, including speaker programs and roundtables. Many of these sales representatives were directed

by their sales managers to spend all of their budgets on promotional programs. Moreover, many sales representatives were specifically evaluated in their annual reviews as to how much of their budget for promotional programs they had used; a sales representative's failure to use their entire budget could be treated as a negative factor in their review.

- The manufacturer's sales representatives and their managers had "broad discretion" to decide which local physician to nominate to become company-approved speakers. Some sales representatives selected physicians with high prescribing volumes to become speakers, and these high-prescribing physicians were paid tens of thousands or hundreds of thousands of dollars in honoraria over a nearly 10-year period.
- Some of the manufacturer's sales representatives hosted speaker programs or roundtables at "some of the most expensive restaurants in the United States" or "at venues where the focus was on entertainment." The amount spent on meals was significantly in excess of the $125 per person limit set by the manufacturer's compliance policies, and typically the manufacturer also paid for alcohol. Moreover, guests who were not healthcare professionals were often invited or allowed to attend such events in contravention of the manufacturer's policy.
- At many speaker events and roundtables, there was "little to no medical discussion." Often, the speaker (who was being paid an honorarium) was not required to deliver a presentation or was allowed to complete the presentation in only a few minutes by clicking through the presentation slides.
- In several instances, doctors were paid honoraria for purportedly speaking at events that never took place.
- Many sales representatives would repeatedly invite the same doctors to attend promotional programs for the same drugs and presentations with the same title. In thousands of instances, the manufacturer paid for the same group of doctors, often colleagues or friends, to have dinners together repeatedly. Doctors in these groups would sometimes rotate being the speaker and receiving the honorarium payment.

A few months after the OIG imposed this Manufacturer CIA, the OIG issued a special fraud alert on speaker programs sponsored by pharmaceutical and medical device companies. In the alert, many of the practices described in this section were listed as "suspect characteristics" that, "taken separately or together," could potentially indicate a speaker program arrangement that could violate the Anti-Kickback Statute.[15]

Subsidized advertising

A fifth Manufacturer CIA involved payments for advertising.[16] The government contended that a manufacturer of embolotherapeutic devices paid kickbacks to various healthcare providers in the form of "free advertising assistance, practice development, practice support, and purported unrestricted 'educational' grants."[17] As alleged by the government, the advertising sponsored by the manufacturer typically promoted the healthcare providers by name, provided contact information for those healthcare providers, and did not mention the manufacturer or its products. Before selecting healthcare providers to receive advertising support, the manufacturer allegedly often estimated the "projected revenue" that it expected to receive from the healthcare provider's product purchases. The manufacturer also purportedly measured its "return on investment" by tracking the healthcare provider's product purchases after the advertising payments were made.[18]