How Life Sciences Firms Can Reduce DOJ Enforcement Risks

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The Anti-Kickback Statute has long been a driver of enforcement actions against the life sciences industry. Sidley Austin health-care attorneys explore areas that are most likely to draw enforcement scrutiny and how compliance programs can be updated to control risk going forward.

Scrutiny of life sciences companies, from their relationships with physicians to their promotional practices, has become one of the few constants in the evolving government enforcement landscape. But life sciences companies can mitigate this risk by making targeted updates to their compliance programs to address areas of particular interest to the Department of Justice.

Manufacturer Speaker Programs

The Anti-Kickback Statute (AKS) has become perhaps the single biggest driver of investigations and settlements under the False Claims Act (FCA), with financial relationships between industry and physicians a significant area of focus. After scores of enforcement actions focused on promotional speaker programs in the 2000s, many life sciences companies took steps to bring their programs into compliance with guidance from the Department of Health and Human Services Office of Inspector General (HHS OIG) and industry trade associations.

But recently, the HHS OIG issued a special fraud alert on manufacturer-sponsored speaker programs—in which physicians are reimbursed by drug companies for speaking on relevant educational topics—articulating a harsher stance than in the past on the lawfulness of these programs.

The HHS OIG acknowledged that many companies decreased in-person speaker programs during the pandemic and warned that post-pandemic, companies "should assess the need for in-person programs given the risks associated with offering or paying related remuneration and consider alternative less-risky means for conveying information to" health-care providers.

As vaccination rates increase and in-person educational events once again become possible, life sciences companies are assessing whether and to what extent their speaker programs must change.

Among other things, companies should review how they evaluate and document the need for in-person programs, whether pandemic-era programs adequately addressed legitimate educational needs, the environment of future in-person events, and whether compliance controls around the selection of speakers and attendees are adequate.

More Rigorous Sunshine Act Reporting

Also in connection with its focus on financial relationships between industry and providers, the DOJ recently expressed interest in parallel settlements that resolve both alleged AKS violations under the FCA and failures to report to the Centers for Medicare & Medicaid Services (CMS) transfers of value as part of the Sunshine Act's Open Payments program (Sunshine Act reporting).

Since reporting obligations began in 2013, CMS has not engaged in any public-facing enforcement actions, despite having authority to impose civil monetary penalties.

But in October 2020, the DOJ and CMS announced a settlement with a device manufacturer over alleged violations of the AKS and the FCA—in the form of unreported purchases at a restaurant owned by a physician—and a corresponding violation of Sunshine Act reporting.

This settlement portends a change in Sunshine Act enforcement, particularly in light of this database's untapped potential as an enforcement tool and the DOJ's recent embrace of data analytics to drive the selection of targets for investigations.

The risk of more rigorous Sunshine Act reporting is heightened by the leadership of HHS Secretary Xavier Becerra, who was an aggressive health-care enforcer during his prior tenure as the California Attorney General.

Life sciences companies should consider performing a gap assessment of their Sunshine Act reporting and address areas of potential oversight. For example, companies may work to understand whether any of their consultants or other contractors are triggering additional reporting obligations, such as by hiring health-care providers as sub-contractors.

Existing processes must also be updated to reflect recently expanded reporting requirements from the calendar year 2020 physician fee schedule rule.

To mitigate the broader threat of AKS enforcement, life sciences companies should also consider conducting their own data analytics to understand any outliers in their Sunshine Act reporting data and whether there may be actual or perceived correlations between payments and purchasing or prescribing decisions that could generate enforcement scrutiny, mindful that HHS-OIG and DOJ may be running their own, similar data analytics.

Off-Label Promotion

Although it is true that, for various reasons, the era of colossal settlements focused on pure "off-label" promotion may have passed, manufacturers still face significant risks if they are perceived to be promoting products in ways that are false or misleading, including by overstating efficacy or cost effectiveness or minimizing risk.

The manner in which promotional review committees (PRCs) evaluate materials may be due for a reassessment to ensure they are keeping pace with the DOJ's evolving approach to building an off-label promotion case.

Life sciences companies should ensure that their PRCs are functioning as designed to control for risk arising under the Federal Food, Drug, and Cosmetic Act; have appropriate representation from key internal stakeholders, including medical and regulatory functions; and that participants are experienced and comfortable voicing objections and addressing concerns.

Companies should consider the extent to which not just field sales materials, but also materials and statements used in interactions with payors, pharmacy benefit managers, and pharmacy and therapeutics committees, go through an appropriate review process. Field-based monitoring and auditing, informed by data analytics, can guard against risk from sales representatives departing from approved messaging.

Given how some companies' field medical personnel engage with prescribers regarding off- and out-of-label information, and as the role of field medical personnel has evolved in recent years, companies could confirm there is a consistent understanding in the organization of the appropriate role of the field medical function and consider benchmarking how their structures and policies compare to those of their peers.

Where off-label promotion cases have a kickback component, the DOJ is more likely to get involved. Corporate compliance programs should consider whether the business has access to any data that could reflect off-label use of a product and compare such data to the company's data on financial arrangements with prescribers.

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