Key Takeaways: Non-Traditional Arrangements and Related Compliance Considerations in Payments to Third Parties

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The healthcare industry continues to face significant scrutiny regarding fraud and abuse, particularly in the realm of third-party arrangements. In a recent webinar, attorneys Noah Goldstein, Todd Roth, and Sara Simon from Porzio's Life Sciences Legal, Regulatory, and Compliance Team discussed government enforcement trends related to non-traditional financial arrangements for life sciences companies and offered suggestions for companies navigating third-party payment structures to help manage associated compliance risks.

There has been a noticeable shift in the types of remuneration offered in quid pro quo schemes by drug and device manufacturers and healthcare providers. Recent enforcement actions and settlements have highlighted that kickbacks are not always in the form of traditional cash payments to doctors or patients but can involve more complex third-party arrangements. As technologies and arrangements evolve, new opportunities for fraud have emerged, particularly in areas with small patient populations, such as rare diseases.

Two areas receiving increased scrutiny are manufacturer-sponsored testing and electronic health record (EHR) systems. Genetic testing, for example, has seen a significant increase in spending, nearly quadrupling in the past decade, and the Office of Inspector General (OIG) has identified genetic testing as an avenue for potential fraud and abuse. Similarly, Electronic Health Record (EHR) arrangements have received heightened focus due to the growing role of health technology in managing and directing patient care. The involvement of manufacturers in EHR systems, including advertising on platforms or providing payments for the systems, presents potential legal and compliance risks. Recent advisory opinions and settlements provide insight into how the government views these third-party arrangements.

Manufacturer-Sponsored Testing Arrangements

In an April 2022 Advisory Opinion, the OIG reviewed an arrangement where a pharmaceutical company covered the cost of genetic testing and counseling for a hereditary disease. While the arrangement implicated the anti-kickback statute and the beneficiary inducements civil monetary penalty law provision (CMP), the OIG found it posed a low risk of fraud and abuse because it included clear patient criteria, attestations from healthcare providers, and restrictions on using the arrangement as a marketing tool.

In December 2023, Ultragenyx Pharmaceutical agreed to a $6 million settlement with the government to resolve anti-kickback statute and false claims allegations related to free genetic testing for a rare genetic disorder that allegedly induced prescriptions for the company's drug. Unlike the 2022 Advisory Opinion, Ultragenyx's arrangement involved commercial teams using de-identified test results and healthcare provider information to target sales efforts. This settlement highlighted the importance of maintaining appropriate boundaries between testing programs and sales activities.

In November 2024, QOL Medical and its CEO agreed to a $47 million settlement and entered into a Corporate Integrity Agreement (CIA) with the OIG. The company provided free Carbon-13 testing services to healthcare providers that allegedly induced prescriptions for its drug. QOL's commercial team used de-identified test results and provider information to target sales calls and track prescription conversions. They also made unsubstantiated claims about the test's efficacy.

Shortly after the QOL settlement, the OIG released another advisory opinion suggesting compliant ways to offer no-cost testing services. This opinion, similar to the 2022 Advisory Opinion, involved a pharmaceutical company providing unbranded disease awareness information about an ultra-rare condition on two websites—one for the public and patients and another for healthcare providers. Testing had to be ordered by a physician who attested to its clinical appropriateness for patients meeting specific eligibility criteria. The company also sponsored genetic counseling for eligible patients, with counselors prohibited from discussing therapeutic options. The testing lab provided limited de-identified information to the company, ensuring no identifiable patient data or information about the ordering healthcare providers (HCPs) was shared. The OIG found that while the arrangement implicated the anti-kickback statute and beneficiary inducement CMP, it posed a low risk of fraud and abuse due to specific eligibility criteria, the likelihood of ruling out conditions rather than diagnosing the company's drug-related condition, and safeguards preventing the use of the arrangement for marketing purposes.

EHR Arrangements

In January 2020, EHR company Practice Fusion agreed to a $145 million settlement to resolve allegations of engaging in a kickback scheme with a pharmaceutical manufacturer to increase prescriptions of the manufacturer's opioid drug. The settlement revealed that Practice Fusion allowed the manufacturer to participate in designing and developing clinical decision support (CDS) alerts that were not based on objective medical standards, setting criteria for when healthcare providers received the alerts, and, in some instances, drafting the alert language. Practice Fusion integrated these alerts into their EHR software, which was widely used by healthcare providers. When physicians using the software were treating patients, these alerts would appear, encouraging them to prescribe more extended-release opioids. This effectively allowed the opioid company to influence prescribing decisions at the point of care. The arrangement was allegedly marketed to the opioid company as a way to achieve a favorable return on investment through increased opioid prescriptions. The arrangement compromised the integrity of the doctor-patient relationship and U.S. Attorney Christina Nolan stated in a press release that Practice Fusion "took a million-dollar kickback to allow an opioid company to inject itself in the sacred doctor-patient relationship," emphasizing the government's view on the importance of maintaining the integrity of medical decision-making.

In November 2022, EHR company Modernizing Medicine (ModMed) agreed to a $45 million settlement to resolve kickback and false claims allegations involving a scheme with Miraca Life Sciences, where ModMed allegedly solicited and received kickbacks in exchange for recommending Miraca's pathology lab services to its users. The companies had allegedly established a "strategic partnership" that included co-marketing efforts, joint press releases, and the development of shared marketing materials. This arrangement purportedly allowed both companies to benefit financially and strategically from their alignment.

The DOJ further alleged that ModMed and Miraca conspired to improperly donate ModMed's EHR platform to HCPs to increase lab orders for Miraca and expand ModMed's customer base. The complaint highlighted the inappropriate exchange of sales data between the two companies, which was used to target new customers and maximize returns on Miraca's EHR platform donations. Additionally, ModMed was accused of paying kickbacks to its current HCP customers and other influential sources to promote its platform and refer potential customers. Internal emails reportedly showed ModMed employees acknowledging that their referral program was intended to drive sales, with compensation for these influential sources based on the amount of business generated rather than fair market value. This settlement resolved these allegations without ModMed admitting to any wrongdoing.

These settlements and other government activity underscore the government's commitment to scrutinizing arrangements around the development and use of EHR systems and sponsored testing programs. As technologies and the healthcare industry as a whole continue to evolve, companies must carefully navigate the complex landscape of third-party arrangements. The recent enforcement actions and advisory opinions demonstrate that while there are compliant ways to offer valuable services to patients and providers, the line between acceptable practices and potentially fraudulent activities can be narrow. Life Sciences companies should ensure they are implementing robust compliance programs and carefully structuring their third-party arrangements to minimize risks, and seeking appropriate legal counsel when necessary. As noted by a government official in the Ultragenyx settlement, law enforcement agencies remain vigilant in investigating allegations of healthcare fraud, and companies engaging in similar conduct may face significant consequences.

The Porzio panelists concluded by offering some practical guidance for the audience to help evaluate third-party arrangements and activities at their companies. First, understand and evaluate whether there is a legitimate business objective for a certain activity while being sensitive to new types of technologies. Next, although data from third-party arrangements may be of interest, especially for rare disease companies, consideration must be given to how the data will be used or shared and to patient privacy and data access. Finally, arrangements involving government healthcare program dollars should be thoughtfully structured to avoid commercial influence over clinical matters. This means including all of the necessary fraud and abuse provisions in contracts with third parties and allowing for transparency and monitoring of the arrangements to mitigate risks and help facilitate compliance.

In conclusion, life sciences companies must remain vigilant and structure third-party arrangements to comply with anti-kickback laws and other regulations. By learning from recent enforcement actions and guidance, companies can work towards providing value to patients while maintaining the integrity of the healthcare system.

Porzio's team of Life Sciences attorneys can provide legal and compliance counsel to assist life sciences companies with analyzing activities and arrangements, including third-party arrangements.