Midyear Update on Recent OIG Activity for Life Sciences Legal and Compliance Professionals (Part 1)

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Nearly 30 years ago, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) was signed into law. While perhaps best known for protecting consumers' rights to obtain health insurance in spite of pre-existing conditions as well as laying the foundation for privacy and security protections related to protected health information, the law also contains lesser-known provisions designed to curb fraud and abuse in the healthcare system, including providing a framework for the Department of Health and Human Services (DHHS) to issue advisory opinions.

Midway through 2025, DHHS Office of Inspector General (OIG) has issued several advisory opinions, including a flurry issued in June and July alone, which include two unfavorable opinions. While life sciences legal and compliance professionals often look to Department of Justice (DOJ) settlements and Corporate Integrity Agreements to inform compliance program development and help them evaluate potentially high-risk activities, OIG Advisory Opinions can serve as a valuable tool as well. While limited in scope to the requesting entity, known as the Requestor, the facts of the proposed arrangement and the applicable statutory provisions that are addressed in the Advisory Opinions can provide valuable insight into the government's views on various business arrangements. This is especially important given the Trump Administration's stated commitment to root out fraud, waste, and abuse in the federal government, and the announcement this month of a DOJ-HHS False Claims Act Working Group, which will include, the Office of Counsel to the OIG. The Working Group identified priority enforcement areas, including those related to "[d]rug, device or biologics pricing, including arrangements for discounts, rebates, service fees, and formulary placement and price reporting," "[k]ickbacks related to drugs, medical devices, durable medical equipment, and other products paid for by federal healthcare programs," and "[m]anipulation of Electronic Health Records systems to drive inappropriate utilization of Medicare covered products and services."

What follows in this first of a two-part series is a summary of recent Advisory Opinions (two favorable and one unfavorable). Again, it is important to note that these Advisory Opinions, as with all Advisory Opinions, are only binding with respect to the Requestor and should not be relied upon by others.

Advisory Opinion 25-04 (Unfavorable)

The Requestor, a medical device company, sells products and services used in procedures to its customers—hospitals, health systems, and ambulatory surgery centers (Customers). Under the proposed arrangement, Customers would ask, or at times require, the Requestor to pay for a third-party entity (Company) to screen and monitor Requestor for exclusion from federal health care programs and to ensure compliance with other legal requirements (Arrangement). This would be done initially as a condition of doing business with Customer and monitored on an ongoing basis. Under the Arrangement,

the Company would bill the Requestor annual subscription fees for each Customer that received screening and monitoring reports on the Requestor (Fees). The Fees were estimated to be approximately $450,000 annually.

OIG opined that the Arrangement implicated the Federal Anti-Kickback Statute because the Fees would otherwise be incurred by its referral sources (Customers) and such payments could induce Customers to purchase items or services from Requestor that may be reimbursable by federal health care programs, which in turn could "inappropriately steer Customers to Requestor over Requestor's competitors that are not able or willing to pay the Fees." OIG also acknowledged that "… there may be different fact patterns that would result in OIG reaching a favorable conclusion in an advisory opinion …" but said there appeared to be a risk under the Arrangement that the Company would be a "gatekeeper" of referrals between Customers and Requestor as Customers potentially would be conditioning their business on Requestor's payment of the Fees.

Although this Advisory Opinion seemed to be more about the importance of carefully evaluating and structuring business arrangements with customers and third parties and associated fraud and abuse risks, rather than about exclusion checking, it also brings attention to conducting screening(s), which can include debarment, exclusion, and other compliance screenings. In a footnote, with citation to an OIG Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (May 2013) (Bulletin) and 42 U.S.C. § 1320a-7a(a)(6), OIG stated that screening employees and contractors monthly minimizes potential overpayment and civil monetary penalty (CMP) liability because if a health care provider (HCP)[1] arranges or contracts with a person that the provider knows or should know is excluded by OIG, the provider may be subject to CMP liability if the excluded person provides items or services payable directly or indirectly by a federal health care program. The Bulletin defines the term "provider" broadly to include "providers, suppliers, **manufacturers**, and any other individual or entity, including a drug plan sponsor or managed care entity, that directly or indirectly furnishes, arranges, or pays for items or services" (emphasis added).

Advisory Opinion 25-05 (Favorable)

Requestor, a medical device manufacturer, proposed an arrangement that would allow it to offer up to $2,500 in reimbursement to cover actual costs incurred by purchasers (such as hospitals, clinics, or labs) if a needle stick injury occurred due to a device failure (Arrangement).

The Requestor manufactures a device used by HCPs to administer immunizations and other drugs to patients via injections. The device includes a one-year warranty against a needle stick injury if used in accordance with its instructions for use and for its intended purposes, and not as a result of user error. However, when an accidental needle stick injury occurs, the HCP's employer (the purchasers of the device) often covers the costs associated with the injury. According to the Requestor, reimbursable costs may include counseling for the injured party, re-training staff and/or staff replacements, and other obligations, including legal fees, costs, payment of damages or settlement, and increased insurance premiums.

In the Advisory Opinion, OIG determined that, while the Arrangement implicates the Federal Anti-Kickback Statute because it would offer something of value to purchasers which could induce them to purchase the device, the Arrangement, as proposed, would be protected by a safe harbor to the Anti-Kickback Statute. Specifically, the Warranties Safe Harbor defines "warranty" as a written affirmation or promise made in connection with the sale of an item that affirms or promises that the quality or workmanship of such item is defect free/will meet a certain level of performance for a specified period of time, *see* 42 C.F.R. §1001.952(g)(7)(i).

In addition to the terms of the warranty meeting this definition, to fall within the safe harbor, a proposed arrangement must comply with various elements and standards to be protected. Specifically, the buyer must report any price reduction on an item under warranty, and the manufacturer must comply with four standards including: (i) adhering to certain requirements for reporting price reductions; (ii) not paying remuneration for any medical, surgical, or hospital expenses incurred by a federal health care program enrollee except for the cost of the item under warranty; (iii) adhering to

reimbursement requirements where multiple items are under warranty; and (iv) not conditioning a warranty on the exclusive use or minimum purchase of the item. In its analysis of the Arrangement, OIG concluded that the Arrangement's terms were either not applicable or satisfied the elements for protection under the safe harbor and, therefore, would not run afoul of the Federal Anti-Kickback Statute.

Advisory Opinion 25-07 (Favorable)

Requestor, a drug manufacturer, proposed paying for the cost of a laboratory test to determine if certain eligible patients were positive for an enzyme deficiency (Test), which would inform an HCP if a patient is a candidate for Requestor's drug (Arrangement). In ruling favorably, OIG relied on certain factors surrounding the Arrangement, specifically with regard to the data (i.e., Test results), such as (i) whether it was de-identified (it was), what the data was used for (it should be limited), and (iii) the limitations put into place on its use. Ultimately, although OIG opined that the arrangement constituted prohibited remuneration under the Federal Anti-Kickback Statute, for the reasons set forth in the Advisory Opinion and explained in more detail below, OIG said it would not impose administrative sanctions, nor did it find that it generated prohibited remuneration under the Beneficiary Inducements CMP.

The Arrangement involved field personnel undertaking certain passive, non-promotional disease-awareness activities in connection with the Arrangement, such as:

- Sales representatives making providers aware of the Arrangement by leaving behind a pamphlet with pre-approved information about the Arrangement. The pamphlet does not contain any branding for or reference to the Requestor's drug nor was it distributed in a manner that takes into account a provider's participation in the Arrangement or prescribing of Requestor's products.
- Non-sales personnel with expertise in diagnostic testing making certain pathologists aware of the Arrangement by distributing materials with pre-approved information about the Arrangement. These materials also contain no branding for or reference to the Requestor's drug.
- Requestor contracting with online search vendors to return results related to the Arrangement when individuals search disease state-related information (e.g., testing for the enzyme deficiency). An online search for the drug will not return results related to the Arrangement.

In addition, Requestor's personnel were prohibited from discussing the drug during any disease-awareness communications that included a discussion of the Arrangement. The lab is also prohibited from promoting the Arrangement.

In evaluating this Arrangement, although OIG found that the Arrangement implicated the Federal Anti-Kickback Statute, it also found that the risk (of over-utilization) was "sufficiently low." Specifically, Requestor did not and will not receive any provider-identifiable or patient-identifiable information or data from the lab as part of the Arrangement but instead will receive (from the lab) certain *limited, aggregated, de-identified data* regarding the Test via monthly data reports. In addition, only certain, limited individuals at Requestor's headquarters receive and review this information, and field personnel do not have access to this information.[2]

Importantly, all of Requestor's personnel, including field personnel, were explicitly prohibited from using data related to the Arrangement to target patients or providers. The data could not be used by Requestor to direct any field activities, and Requestor implemented internal rules and controls to prohibit the use of this data to re-identify any provider or patient. The lab was also prohibited from using data from the Arrangement to promote the Arrangement or any other lab product or service to patients or providers identified through the Arrangement. Finally, Requestor paid no remuneration to providers, either directly or indirectly through the lab, in connection with the Arrangement.

In rendering a favorable decision about this Arrangement, OIG stated that it is "unlikely to result in overutilization or inappropriate utilization, skew clinical decision-making[,] or result in unfair competition." OIG found it persuasive that determining whether a patient has the enzyme was necessary prior to the drug being prescribed. It was also germane, according to OIG, that Requestor did not require or incentivize providers in any way to recommend, prescribe, or administer Requestor's drug. OIG opined that there was no risk of skewed clinical decision-making or steering because the drug is not discussed by field personnel, and providers receive no remuneration from Requestor in connection with the Arrangement. Finally, because there were numerous safeguards in place to prevent the use of the Arrangement as a "sales or marketing tool to steer providers to order items or services," OIG will not impose Administrative Sanctions in connection with the Arrangement, nor did it find that it generated "prohibited remuneration" under the Beneficiary Inducements CMP.[3]

It is clear from the OIG Advisory Opinions discussed in this client alert that there are many concerns that arise when entering into various business arrangements beyond the provision of "prohibited remuneration" in the more traditional sense. In part two of this series, we will summarize additional recent OIG Advisory Opinions and provide important takeaways. Porzio's team of Life Sciences attorneys can provide legal and compliance assistance to companies, including related to the development and commercialization of their products, evaluation of potentially high-risk activities, and other activities and interactions.

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[1] For purposes of this Client Alert, the terms "health care provider," "HCP," and "provider" may be used interchangeably as OIG uses all of these terms to refer to health care practitioners.

[2] The receipt of such data may also raise various data privacy concerns and subject companies to potential liability under various state or federal law. [3] In 2024, we published a Client Alert, followed by a 2025 webinar (summarized here) that discussed DOJ settlements and OIG Advisory Opinions related to similar manufacturer-sponsored testing arrangements which pointed out that while the facts and circumstances of each arrangement are important in evaluating fraud and abuse risks, advisory opinions can provide a window into how OIG might assess an issue. In fact, according to the Ultragenyx Pharmaceutical Inc. Settlement Agreement, after the release of OIG Advisory Opinion 22-06, Ultragenyx allegedly stopped providing results reports to its sales force and using such reports for marketing purposes so as to structure an arrangement consistent with OIG's thinking.