The More Things Change, the More They Stay the Same: Government Scrutiny of Financial Arrangements Continues

January 18, 2024

By: Sara Simon, Noah Goldstein

Although 2024 is sure to bring new areas of focus for the government, at the end of 2023 we were reminded that some of the tried and true areas of enforcement still loom large, with the government providing a warning for companies as they look for new and creative ways to reach patients and health care providers (HCPs).

On December 21, 2023, the U.S. Department of Justice (DOJ) announced a $6 Million settlement with Ultragenyx Pharmaceutical Inc. (Ultragenyx) to resolve allegations that the company caused the submission of false claims to both Medicare and Medicaid related to the marketing of its drug Crysvita (the Settlement). The complaint, originally filed by an Ultragenyx sales force employee under the whistleblower (or *qui tam*) provision of the federal False Claims Act (FCA), concerned the company's payments for genetic testing for patients to identify a rare genetic disorder, X-linked hypophosphatemia (XLH) and to provide the company the test results to identify potential Crysvita patients and their HCPs (the Complaint). As described below, the DOJ contended that the genetic testing arrangement was in essence a "payment-for-referral" scheme to induce prescriptions for Crysvita by identifying HCPs and patients, in violation of the federal anti-kickback statute (AKS), resulting in the submission of false claims to government payers.

Ultragenyx manufactures Crysvita, approved by FDA in 2018, to treat XLH. In 2020, Crysvita was approved to treat tumor-induced osteomalacia (TIO), a disease similar to XLH, with an even smaller patient population. The affected patient population for both conditions is extremely small, with XLH occurring in 1 in 20-25,000 live births. Even rarer, it is estimated that only between 500 and 1,000 individuals in the US are affected by TIO each year. The annual cost of Crysvita is approximately $200,000.

Facing what appears to be the conundrum of many rare disease companies, the "major focus" of Ultragenyx, according to the Complaint, was identifying the population of patients who would benefit from Crysvita. Notably, this necessary task was described in a company presentation as "finding a needle in the haystack" because a positive genetic test was required to definitively diagnose XLH and prescribe Crysvita. The company allegedly knew that insurers, including Medicare and Medicaid, would require a positive genetic test result for XLH to pay for treatment.

As a result, in early 2019, Ultragenyx entered into an agreement with a genetic testing laboratory (the lab) whereby, upon an HCP order, Ultragenyx would pay for the cost of genetic testing to identify the mutation that causes XLH or provide confirmation of an XLH diagnosis, at no additional cost to patients. In addition, Ultragenyx paid the lab for the test results and then shared the de-identified results with sales and marketing, as well as the HCPs who ordered the tests, referring to this program as its "sponsored" XLH testing program (the Program). To get the word out, sales personnel were, according to the Complaint, expected to inform HCPs about the Program and provide them with order forms for the test.

In 2021, the arrangement was brought to the attention of the federal government by an employee of Ultragenyx who worked as a "Patient Diagnosis Liaison," or PDL. According to the Complaint, company emails and documents revealed that Ultragenyx PDLs were tasked with identifying HCPs that have XLH patients for which Crysvita would be indicated, i.e. those who tested positive for XLH. Once identified, the HCPs were contacted by various members of Ultragenyx's sales team to convince the HCP to prescribe Crysvita. At the same time, Ultragenyx allegedly worked with third-party payers to negotiate coverage for Crysvita and connected patients with foundations established to cover patient co-pays for Crysvita.

In 2022, the Department of Health and Human Services, Office of Inspector General (OIG) rendered Advisory Opinion No. 22-06 (the Advisory Opinion) regarding an arrangement with similar facts, but which also had important distinctions and mitigating factors.[1] Specifically, the Advisory Opinion involved a drug company that entered into an arrangement with a genetic testing laboratory to provide free genetic testing to identify a gene mutation associated with a certain disease. In contrast to the Ultragenyx arrangement, however, the use and exchange of testing data was limited, and the results were not provided to marketing or sales, thus eliminating the possibility of targeting specific patients for additional testing or encouraging the use of the company's product(s). The arrangement described in the Advisory Opinion even went as far as to protect any data that would allow the company to identify the HCPs that ordered the test by setting up a firewall so that no sales representatives would be able to access the lab results. In addition, according to the OIG, the proposed arrangement was unlikely to skew HCP clinical decision-making since a positive result did not, on its own, create a basis to prescribe the company's product(s). While the OIG stated that the arrangement would "generate prohibited remuneration" under the AKS, it opined that "the nexus between the remuneration offered and exchanged under the [a]rrangement and ordering or purchasing the … [drug company's] products" was "attenuated" and therefore posed a "sufficiently low risk of fraud and abuse" under the AKS.

According to the Settlement, Ultragenyx ceased providing the results to its sales force after it became aware of the Advisory Opinion in April 2022. Nevertheless, it was still alleged that between February 2019 and May 2022, because Ultragenyx caused the submission of fraudulent claims as a result of the prohibited remuneration (i.e. free genetic testing for patients) to induce referrals of Crysvita, Ultragenyx owed restitution to both the federal government and Medicaid participating states.

In the press release that announced the Settlement, both DOJ and OIG signified their continued efforts to root out behaviors that could "improperly influence medical decisions," vowing to "ferret out improper financial kickbacks of any permutation." OIG went as far as to reaffirm the fact that kickback arrangements that improperly influence medical decisions will always be an "investigative priority" for HHS. Taken together with the Advisory Opinion, it is clear that regulators continue to be focused on liability under the AKS and the FCA taking into account the new and emerging ways that companies may be identifying potential patients.

Life sciences companies, including those in the rare disease space, should thoughtfully structure any arrangements that involve remuneration to third parties. As companies consider novel ways to target patients and HCPs, careful analysis is recommended so that such arrangements and/or agreements do not provide a direct or indirect benefit that could be construed as an inducement to recommend, order, or prescribe a federally reimbursable product. The Settlement illustrates that while OIG Advisory Opinions can be a useful tool to understand the government's thinking about an issue (including ways to structure arrangements that do not run afoul of the federal fraud and abuse laws), it is crucial to carefully consider all of the facts and circumstances surrounding each arrangement and to implement compliance guardrails to mitigate fraud and abuse risks.

As you set your goals and priorities for the new year, this Settlement is a reminder that although the regulatory landscape is becoming more complex with the passage of new laws, holding companies accountable for improper financial arrangements remains a priority for the government. Porzio's team of Life Sciences attorneys can assist life sciences

companies of all sizes with structuring their arrangements, including with HCPs and other consultants, and establishing policies and procedures to help stay compliant.

---

[1]Although the drug company name was redacted for confidentiality, the Settlement states that the Advisory Opinion addressed a request by "another entity."