PUBLICATION

OIG Nixes Pharmaceutical Cost-Sharing Subsidy Program Under AKS

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In Advisory Opinion No. 20-05, posted September 23, 2020, OIG was unwilling to approve a pharmaceutical company's proposed cost-sharing subsidy program for beneficiaries seeking to use its expensive new drug for treatment of a rare cardiovascular disease. While OIG stated it was not in a position to reach a definitive conclusion regarding whether a violation of the federal Anti-Kickback Statute (AKS) existed, OIG was unwilling to issue a favorable advisory opinion. In particular, OIG was concerned that the arrangement would make beneficiaries less sensitive to the costs of their treatment, thereby risking an increase in the costs to the federal health care programs, and influencing clinical and beneficiary decision-making. Notably, OIG highlighted its use of publicly available information in reaching its conclusion under the AKS. With respect to the beneficiary inducement statute, OIG found the proposed arrangement did not implicate the statute because the pharmaceutical company is not a "provider, practitioner, or supplier."

Overview of the Facts and the Proposed Arrangement

A. The Proposed Arrangement: A Cost-Sharing Subsidy Program

The pharmaceutical company (Company) certified that it has developed a new drug treatment for a rare, progressive, cardiovascular disease that affects approximately 100,000 to 150,000 Americans and that can lead to heart failure and death. The majority of patients who have the disease and may be prescribed the new drug are Medicare beneficiaries. The Company's drug is the only FDA-approved treatment for the disease, although there are non-pharmacological and pharmacological treatment alternatives, including organ transplants and off-label use of two other drugs. There is also a competitor therapy in the pipeline, but it is not expected to receive FDA approval until 2021 or later.

The Company set the drug's list price at $225,000 for each one-year course of treatment. Based on the cost-sharing requirements of the standard Medicare Part D benefit, a Medicare beneficiary enrolled in the standard benefit would pay approximately $13,000 annually in out-of-pocket expenditures for the drug. Many beneficiaries filling their first order of the drug would be charged $5,100 in out-of-pocket costs, thereby meeting the catastrophic phase of the Part D benefit with their first prescription. Additionally, a beneficiary's coinsurance in the catastrophic phase would be five percent of the cost of the drug. The Company certified that these cost-sharing amounts would likely be prohibitive to many beneficiaries.

The Company proposed a subsidy program to address the out-of-pocket costs associated with purchasing the drug, which the Company describes as a "financial impediment for a substantial portion of the Medicare population." Under the proposed arrangement, the Company would pay all but $35 of a beneficiary's monthly cost-sharing obligations for the drug for United States residents who are prescribed the drug, are enrolled in a Part D or Medicare Advantage-Part D plan (collectively, "Part D programs") that covers the drug, and have a household income between 500 percent and 800 percent of the federal poverty level. Beneficiaries with household incomes below 500 percent of the federal poverty level would obtain financial assistance for the cost of the drug through either the Company's existing free drug program or other funding sources, including the Medicare Low-Income Subsidy.

The Company's subsidy program would be administered by a third-party vendor who would enroll eligible beneficiaries and provide each with a physical subsidy card and/or a personal identification number through its patient support hub. The beneficiary could present the card and/or number at the point of sale at any pharmacy of his or her choosing that is authorized to dispense the drug, and the beneficiary would be entitled to pay only a monthly copay of up to $35 each time he or she fills a prescription. The Company would pay 100 percent of the beneficiary's remaining cost-sharing obligations through its vendor. The Company would not provide financial support for beneficiaries prescribed other FDA-approved treatments for the disease or for other pharmacological therapies prescribed to treat beneficiaries' co-morbidities.

B. Publicly Available Information Influences the OIG's Legal Analysis

In an unusual move by OIG, the agency highlighted its use of publicly available information that it found through independent research and that was not provided by the Company. This demonstrated that under the implementation of the proposed subsidy program, the Company's existing free drug program, and the Medicare Low-Income Subsidy, all but nine percent of Medicare beneficiaries would be eligible to receive cost-sharing assistance for the drug. OIG also cited a study published in 2020 which asserted that treating all eligible patients with the disease with the Company's drug would increase health spending in the United states by at least $32.3 billion per year.

Legal Analysis

OIG reviewed the proposed arrangement for compliance with the AKS and the Beneficiary Inducements civil money penalty (CMP).

1. The Anti-Kickback Statute

A. The Plain Language of the AKS

OIG determined that the proposed arrangement "plainly would" implicate the AKS, and even went so far as to say that the subsidy program might "operate as a quid pro quo," depending on the party's intent when implementing the program.

In deciding that the subsidy program could implicate the AKS, OIG first discussed the plain language of the statute. Given the expensive cost-sharing obligations for the drug, beneficiaries may not purchase the drug without the subsidy program, which is precisely the issue the Company sought to address in designing the program. OIG noted that the subsidy card that the Company would provide to allow beneficiaries to receive the discounted drug price at the point of sale had no value outside of its use to purchase the Company's specific drug because the subsidy program could only be used to pay for cost-sharing obligations for this drug. Using the plain language of the AKS statute, OIG surmised that the Company "proposes to provide remuneration (the Subsidy Card) to a person (the Medicare beneficiary) to induce that person to purchase an item (the Medications) reimbursable under a Federal health care program (Medicare)." As such, one purpose − and perhaps the primary purpose − of the subsidy program would be to induce beneficiaries to buy the Company's federally reimbursable drug, making the proposed arrangement "highly suspect" under the AKS.

B. Economic Safeguards That Keep the Costs of the Medicare Program in Check

OIG explained in detail that the proposed arrangement would abrogate key safeguards that the AKS put in place and that were designed to protect against the risk of improper increased costs to the federal health care programs, anti-competitive effects, and inappropriate influences on clinical decision-making.

(i). The Importance of Cost-Sharing Obligations

In its discussion of the increased costs to the federal health care programs that could result from the proposed arrangement, OIG highlighted the relevance of publicly available information that it had found regarding the drug's pricing. OIG noted that the Company's list price of $225,000 for each one-year course of treatment makes the drug "the most expensive cardiovascular drug ever launched in history." Additional public information explained that if all eligible patients with the disease were treated with the drug, the cost would increase total prescription drug spending in the United States by 9.3 percent, with the potential to be more expensive in the future. Without expressing an opinion on the appropriateness of the drug's price, OIG noted that the implementation of the subsidy program would be "critical" to the Company's ability to maintain its list price. Many beneficiaries would simply not be able to afford the drug without the cost-sharing subsidy. As such, the list price necessitates cost-sharing assistance to beneficiaries because without the assistance, the Company would either be forced to lower the list price or suffer fewer sales of the drug.

OIG also emphasized the importance of having beneficiaries fulfill their own cost-sharing obligations, both as a key pricing control for the Part D program and as a method to constrain beneficiaries' progress toward reaching the catastrophic phase of coverage in the Part D program. The agency explained that Congress deliberately structured the Part D program so that the market could moderate drug costs by pressuring pharmaceutical companies to lower the prices of drugs that beneficiaries could not afford. OIG further noted that inflated drug prices could have a "spillover" effect by increasing the costs of direct subsidies, reinsurance payments, and risk corridor payments by the Medicare program. Congressional design also ensures that beneficiaries are exposed to the economic effects of drug pricing so that they remain sensitive to the costs of their prescription coverage. Both structures protect the federal health care programs from excessive spending.

(ii). Subsidy Program May Decrease Fair Competition

OIG reiterates in this Opinion, as it has stated in prior publications, that one of the goals of the AKS is to ensure fair competition in the health care marketplace. OIG also reiterates its "longstanding concerns" that a pharmaceutical manufacturer's cost-sharing subsidy program could steer beneficiaries to, and lock them into, the manufacturer's product and could lead to anti-competitive effects. The agency's trepidation regarding these arrangements is evident in its analysis. OIG calls attention to the likelihood that both the treating physician and the beneficiary will consider the costs and availability of the subsidy program in determining a preferred treatment for the beneficiary. The lack of cost-sharing obligations that most beneficiaries would benefit from under the subsidy program would present a more than minimal risk that a beneficiary would choose the Company's drug over any others. Additionally, even though no other FDA-approved pharmacological therapy currently exists, there is another drug that could be used to treat this disease in the pipeline for approval as soon as 2021. OIG expressed the concern that because the subsidy program would virtually eliminate beneficiaries' out-of-pocket costs for the drug, a beneficiary may choose to continue to use the Company's drug, regardless of whether other treatments are equally or more effective, to save money. As such, the Company's subsidy program would give it a financial edge over its competitors.

(iii). Subsidy Program Could Potentially Impact Clinical Decision-Making

Similar to its concerns regarding the impact that the remuneration offered under the subsidy program could have on beneficiaries' decisions to purchase the Company's drug, OIG also articulated its unease regarding the impact the program could have on physicians' decision-making in recommending a patient's course of treatment. Under the subsidy program, physicians would be alerted as to the program's existence by the Company's third-party vendor soon after the program's implementation. OIG opined that once a physician is made aware of the program, the physician would know with every prescription thereafter that there would be a significant financial benefit for the patient in prescribing the Company's drug, a benefit that the patient would not receive with other treatments. OIG noted its concern that the physician's knowledge of this benefit for his patient could influence the physician to recommend the Company's drug, even over a treatment that is equally

or more effective, or that may have a lower overall cost. As such, the Company's subsidy program could prompt the physician to prescribe the drug to a beneficiary instead of pursuing other, possibly more suitable, clinical alternatives.

2. Beneficiary Inducement

Although the Beneficiary Inducement CMP and AKS are frequently interpreted in the same way, this advisory opinion highlights the fact that there are key differences. The Beneficiary Inducements CMP focuses on remuneration that the offeror knows or should know is likely to influence a beneficiary's selection of a particular provider, practitioner, or supplier for items or services reimbursable by Medicare or a state health care program. As such, only remuneration that would influence a beneficiary's selection of a particular provider, practitioner, or supplier is within the scope of the Beneficiary Inducements CMP. Pharmaceutical manufacturers are not "providers, practitioners, or suppliers." Therefore, while OIG found that the arrangement could influence a beneficiary to purchase the Company's drug, the Beneficiary Inducements CMP was not implicated because the arrangement did not influence the pharmacy from which the beneficiary would receive the drug.

Notable Takeaways

OIG's analysis of Advisory Opinion 20-05 is notable for two reasons. First, OIG made references in the Opinion to its recent enforcement history involving arrangements between pharmaceutical companies and foundations that operate cost-sharing assistance programs. The United States has settled enforcement actions against ten pharmaceutical manufacturers and four foundations in amounts totaling more than $900 million for allegations that pharmaceutical companies were using the foundations to direct payments to patients, in violation of the AKS. OIG drew parallels between the subsidy program proposed by the Company and the arrangements in these recent enforcement actions. OIG seems to be trying to draw a line in the sand regarding the types of arrangements it considers acceptable.

Second, we note the important role that public information played in OIG's conclusions regarding the structure of the subsidy program and its implication under the AKS. Some of OIG's weightiest concerns seem to stem from the public information and studies detailing the potential costs of the drug to the federal health care programs and the nominal number of beneficiaries who would be subject to any cost-sharing under the subsidy program. This is an important reminder that OIG's conclusions are supported by many sources, not just certified information.

For more information please contact any member of Baker Donelson's Health Law Group.