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CLIENT ALERT

OIG's Latest Advisory Opinion Raises Questions About Patient Assistance Programs

By Jennifer E. Michael

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On September 18, 2020, the U.S. Department of Health and Human Services' Office of Inspector General ("OIG") issued Advisory Opinion 20-05. In this unfavorable Advisory Opinion, OIG declined to approve a pharmaceutical manufacturer's proposal to provide cost-sharing assistance directly to Medicare beneficiaries who are prescribed the manufacturer's drugs.

Recent Government Enforcement Activity

OIG Advisory Opinion 20-05 represents another shot across the bow from the government to pharmaceutical manufacturers that attempt to subsidize federal health care program beneficiaries' cost-sharing obligations for the manufacturers' own drug products. This Advisory Opinion comes on the heels of recent federal enforcement activity surrounding pharmaceutical manufacturers' involvement in patient assistance programs run by purportedly independent foundations. In those enforcement actions, the U.S. Department of Justice alleged that a number of pharmaceutical manufacturers violated the federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, by unlawfully paying the Medicare copayments for their own products through purportedly independent nonprofit charitable foundations that the manufacturers used as conduits.[1] The Department of Justice's position on financial assistance provided directly to Medicare beneficiaries by pharmaceutical manufacturers is clear: such conduct not only violates the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), but also undermines the Medicare program's copayment structure, which Congress intended to serve as a check against the prices manufacturers can charge for their drugs.

[1] *See, e.g.,* Department of Justice, Two Pharmaceutical Companies Agree to Pay a Total of Nearly $125 Million to Resolve Allegations That They Paid Kickbacks Through Copay Assistance Foundations, Apr. 25, 2019, available at https://www.justice.gov/opa/pr/two-pharmaceutical-companies-agree-pay-total-nearly-125-million-resolve-allegations-they-paid.

Highlights from OIG Advisory Opinion 20-05 and the Uncertainty Surrounding Patient Financial Assistance

Although OIG Advisory Opinions are not binding on any individual or entity other than the requestor, they provide valuable insights into OIG's interpretation of the law. Health care providers that provide financial assistance directly to federal health care program beneficiaries for the providers' own items or services may wish to re-evaluate the fraud and abuse risks associated with such assistance in light of unfavorable Advisory Opinion 20-05 and the current enforcement environment. Consequently, the principles discussed in this Advisory Opinion may have ramifications well beyond the pharmaceutical industry.

Advisory Opinion 20-05 is unusually long and highlights OIG's concerns regarding how remuneration offered to federal health care program beneficiaries may impact physicians' ordering and prescribing decisions. OIG began its analysis of the requestor's proposed subsidies by noting that OIG has been and remains "extremely mindful" of the importance of ensuring that federal health care program beneficiaries have access to medically necessary drugs, and that manufacturers have other lawful avenues for ensuring that beneficiaries have access to such drugs. OIG also provided publicly available background information as additional context for its analysis, including a reference to a study that found that treating all eligible patients with the medications that were the subject of Advisory Opinion 20-05 would increase health care spending by $32.3 billion per year.

OIG then went on to characterize the requesting manufacturer's proposal to subsidize Medicare beneficiaries' cost-sharing obligations as "a quid pro quo," pursuant to which the manufacturer would offer remuneration (in the form of a subsidy card) to beneficiaries in return for the beneficiaries' purchase of the manufacturer's medication. OIG recognized that the proposed arrangement could help individual beneficiaries access needed medications but stated that this potential benefit did not change the fact that the proposed arrangement "plainly would involve remuneration to an individual to induce that individual to purchase an item for which payment may be made under a Federal health care program." OIG concluded that the subsidy would present many of the traditional risks of fraud and abuse that the federal Anti-kickback Statute is designed to prevent, including increased costs to federal health care programs, beneficiary steering and anti-competitive effects, and interference with or skewing of clinical decision-making. This is because the subsidy was contingent on the beneficiary's purchase of the manufacturer's product. OIG's concern that the manufacturer's subsidy program could affect physicians' clinical decision-making is particularly noteworthy. OIG did acknowledge that the manufacturer's proposed arrangement would not involve remuneration to prescribers, and that a critical prerequisite to a beneficiary's purchase of the medication is the treating physician's decision to prescribe (or not prescribe) the medication. Nevertheless, OIG stated its belief that physicians generally consider a patient's out-of-pocket costs when deciding whether to prescribe the medications and that "it is reasonable to anticipate that physicians would learn of the [s]ubsidy [p]rogram soon after its implementation." OIG went on to explain that, "once a physician is aware of the program, every subsequent prescribing decision would be made with the

knowledge that the [s]ubsidy [p]rogram is available to minimize out-of-pocket costs for Medicare beneficiaries" and that the program therefore could affect the prescriber's decision as to whether to order the medications.

While expressing no opinion as to the appropriateness of the medications' list price, OIG stated that it could not ignore the fact that the requesting manufacturer's proposal would drive up costs to the Medicare program by shielding Medicare beneficiaries from the list price's economic impacts, thereby influencing the beneficiaries' decisions to purchase the medications. OIG cited to its historic concern regarding the profitability of cost-sharing subsidies and stated that OIG believed the risk that the proposed arrangement could be used to support future increases in list price is significant.

Conclusion

While the financial assistance in Advisory Opinion 20-05 would have been provided by a pharmaceutical manufacturer, and therefore can be distinguished from financial assistance offered by other types of health care providers in several important ways, the government could take the position that the principles OIG discussed in this Advisory Opinion might apply similarly in other contexts. Consequently, health care providers that provide financial assistance directly to federal health care program beneficiaries for the providers' own items or services may wish to re-evaluate their financial assistance policies with the principles discussed in Advisory Opinion 20-05 in mind.

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This Client Alert was authored by **Jennifer E. Michael.** *For additional information about the issues discussed in this Client Alert, please contact the author or the Epstein Becker Green attorney who regularly handles your legal matters.*