

HHS-OIG RESCINDS ADVISORY OPINION ON PHARMA FUNDING OF PATIENT CHARITIES

On November 28, 2017, the Office of Inspector General of the US Department of Health and Human Services (HHS-OIG) rescinded an earlier advisory opinion that permitted a pharmaceutical manufacturer to fund patient charities that defrayed the costs of certain patient co-payments in connection with drugs paid by the Medicare program. This decision could have significant implications going forward for pharmaceutical companies that contribute to such patient assistance programs. As DOJ and state governments continue to investigate the funding arrangements between pharmaceutical manufacturers and patient assistance foundations, it is more important than ever for pharmaceutical companies that donate to such foundations to examine closely their funding arrangements to ensure compliance with federal health care laws and regulations.

BACKGROUND ON ADVISORY OPINION 06-04

In 2006, Caring Voice Coalition requested an advisory opinion from HHS-OIG. Caring Voice is one of the largest patient assistance charities in the US. It is funded almost entirely by pharmaceutical manufacturers and helps certain Medicare-eligible patients afford expensive medications by funding the co-payments that patients must contribute under Medicare or private health insurance. Caring Voice asked for the 2006 advisory opinion from HHS-OIG to provide protection against the possibility that its funding arrangement might violate the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, which prohibits the exchange (or offer to exchange) of anything of value in an effort to induce or reward the referral federal health care program business.

In Advisory Opinion 06-04, HHS-OIG opined that Caring Voice's proposed arrangement would not run afoul of the Anti-Kickback Statute. Importantly, however, HHS-OIG emphasized that its opinion was based in part on Caring Voice's assurance that "[n]o individual patient data information will be conveyed to

donors," nor would donors receive "any information that would enable [them] to correlate the amount or frequency of [their] donations with the number or subsidized prescriptions or orders for its products or the volume or medical condition of patients choosing its services."

GOVERNMENT INVESTIGATIONS

In recent years, pharmaceutical companies have increased their contributions to charities such as Caring Voice. While those companies cannot, consistent with the Anti-Kickback Statute, directly fund patients' co-payments in connection with their Medicare drugs, they have instead contributed to independent foundations that provide such financial assistance. However, in recent years, allegations have surfaced that some patient assistance foundations have steered patients toward the drugs manufactured by the foundations' donors rather than competitor drugs of non-donors. For example, in 2016, several former employees of Caring Voice disclosed that it sometimes steered patients to drug companies that were its donors over those that were not. In particular, those employees stated that Caring Voice steered patients to Jazz Pharmaceuticals' narcolepsy drug Xyrem over non-donors' competitor drugs. Since those disclosures, Jazz Pharmaceuticals announced it would not continue its contributions to Caring Voice's narcolepsy fund.

In response to these allegations, both federal and state governments have brought investigations in recent years in connection with the funding of these patient foundations. In 2016, three pharmaceutical manufacturers—Gilead Sciences, Jazz Pharmaceuticals, and Biogen—disclosed that they had received subpoenas in connection with their funding of co-pay assistance programs. Valent pharmaceuticals also disclosed that the Department of Justice (DOJ) had issued it a subpoena about its contributions to such programs. Several other pharmaceutical companies have received similar subpoenas in recent months. Earlier this year, United Therapeutics announced it had set aside \$210 million for a potential settlement with DOJ over its contributions to patient foundations, and Jazz has disclosed that it might be subject similar penalties. Likewise, when similar donations and activities have occurred overseas, they have received additional scrutiny under the Foreign Corrupt Practices Act (FCPA), which prohibits providing items of value to public officials for the purpose of obtaining or retaining business.

HHS-OIG RESCISSION OF ADVISORY OPINION 06-04

On November 29, 2017, HHS-OIG sent Caring Voice a letter formally rescinding Advisory Opinion 06-04, the first time it has rescinded a favorable advisory opinion for a patient assistance foundation. HHS-OIG stated that the reason it rescinded its prior opinion was that it determined that Caring Voice provided patient-specific data to one or more donors that allowed them to "correlate the amount and frequency of their donations with the number of subsidized prescriptions or orders for their products," as well as allowing donors "to directly or indirectly influence the identification or delineation of [Caring Voice's] disease categories." HHS-OIG stated that Caring Voice's information-sharing with its pharmaceutical donors "increased the risk that [it] served as a conduit for financial assistance from a pharmaceutical manufacturer donor to a patient, and thus increased the risk that the patients who sought assistance from [Caring Voice] would be steered to federally reimbursable drugs that the manufacturer sold."

Of particular concern to HHS-OIG was the risk of steering patients to a more expensive drug if co-payment assistance was available for that drug but not less expensive alternatives, and the compounding of that risk when those donor companies "raise the price of their drugs while insulating patients from the immediate out-of-pocket effects of price increases, leaving Federal health care programs like Medicare (and the taxpayers who fund those programs) to bear the cost." OIG made its rescission decision notwithstanding Caring Voice's representation that were OIG to rescind or terminate 06-04, it "likely would cease operations and no longer provide copayment assistance to patients."

HHS-OIG noted that its rescission of 06-04 did not require that Caring Voice cease operations, notwithstanding its stated intention to do so. HHS-OIG further made clear that because Caring Voice had, in HHS-OIG's view, misrepresented material facts, Advisory Opinion 06-04 had "no force or effect," and nothing in its rescission letter "limits the investigational or prosecutorial authority of OIG, the Department of Justice, or any other agency of the government."

KEY TAKEAWAYS

While HHS-OIG's rescission of Advisory Opinion 06-04 seems based in part on the specific circumstances at issue with respect to Caring Voice's sharing of information with its donors and the deviations from the certifications it provided in its initial request for the opinion, it is also clear that both HHS-OIG and DOJ are increasing oversight and enforcement of possible violations of the Anti-Kickback statute in connection with pharmaceutical manufacturers' donations to patient assistance charities. Pharmaceutical companies that receive information from patient assistance foundations must be particularly careful in light of the concerns raised by HHS-OIG's rescission letter. In light of the HHS-OIG rescission of Advisory Opinion 06-04, coupled with the current enforcement climate, every pharmaceutical company that contributes to patient assistance foundations should undertake a careful review to ensure that the foundation provides assistance without favoring the donors' products or patients on those products.

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