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HEALTH LAW

A SHIPMAN & GOODWIN® ALERT

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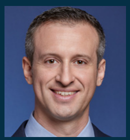

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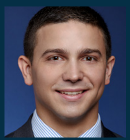

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OIG Scrutiny of Patient Assistance Programs

Last week, one of the largest charity patient assistance programs in the country, Caring Voice Coalition, announced that it would not be offering financial assistance for any of its disease funds in 2018. This announcement follows an unprecedented November 2017 decision by the Department of Health and Human Services Office of Inspector General to rescind an advisory opinion it had previously issued to the charity in 2006, Advisory Opinion 06-04.

The Office of Inspector General's (OIG) advisory opinion protected Caring Voice Coalition from liability under the Anti-Kickback Statute for its work providing financially needy Medicare patients with premium and cost-sharing assistance. Drug companies are the primary donors to almost all charity patient assistance programs (PAPs), including Caring Voice Coalition, while some drug companies also create their own charity PAPs. The OIG's 2006 opinion issued to Caring Voice Coalition was fact-specific, as are all advisory opinions, and in this case was predicated on commitments the charity made to implement certain safeguards regarding contributions from donors and grants to beneficiaries.

In its rescission, OIG found that Caring Voice Coalition violated two commitments in particular:

(1) by providing data to one or more drug company donors that was patient-specific, thereby enabling the donors to "correlate the amount and frequency of their donations with the number of subsidized prescriptions or orders of their products"; and

(2) by giving drug company donors influence over the charity's outlining of disease categories.

According to the OIG, the alleged violations "materially increased the risk that [the charity] served as a conduit for financial assistance from a [drug company] donor to a patient," and thus increased the risk that the charity's Medicare patients would be steered to that company's federally reimbursable drugs. The OIG further stated, "this type of steering can harm patients and the Federal health care programs, because, for example, patients may be urged to seek, and physicians may be more likely to prescribe, a more expensive drug if copayment assistance is available for that drug but not for less expensive but therapeutically equivalent alternatives."

Furthermore, the OIG stated that such arrangements could allow drug companies to raise drug prices while providing patient assistance to insulate patients from immediate out-of-pocket costs, leaving federal health care programs to bear the cost. Finally, OIG said that its rescission would be retroactive to 2006, when it issued the advisory opinion, although it said determining whether there were violations of the Anti-Kickback Statute during that time was beyond the scope of the advisory opinion process.

Given the reasons for the OIG's rescission of its advisory opinion to Caring Voice Coalition, it is not surprising that, a few weeks later, the OIG announced a Corporate Integrity Agreement (CIA) with one of the charity's drug company donors, United Therapeutics. The CIA was dated December 18, 2017, and required United Therapeutics to alter its interactions, including donations, with charity PAPs.

Not only does the December 2017 CIA require United Therapeutics to craft policies and procedures regarding these interactions, it also requires it to completely separate its "Independent Charity Interaction Team" from its commercial organization. This team will have sole authority and responsibility for communicating with charity PAPs regarding donations, for establishing a budgeting process and proposing an annual budget for donations to charity PAPs, which United Therapeutics must approve at a level "above the commercial organization." In addition, the team will have sole responsibility for distributing the assigned budget through donations to charity PAPs, after which United Therapeutics' legal and compliance department must "review all proposed donations and arrangements between" it and any charity PAP. The CIA also outlines criteria United Therapeutics must satisfy in its donations to charity PAPs.[1]

The December 2017 OIG CIA was announced as part of a settlement between United Therapeutics and the Department of Justice (DOJ), which alleged that United Therapeutics induced patients to purchase its drugs by donating to charity PAPs over which it exerted some control. The settlement reiterates DOJ's position that charity PAPs must function with appropriate independence from the drug companies from which they receive donations, or both entities may be violating the Anti-Kickback Statute. In addition to this and another settlement agreement with a drug company in 2017,[2] DOJ has issued subpoenas dating back to 2015 to several other drug companies, which have yet to be resolved.

Subsequent to entering the CIA with United Therapeutics, and on the same day Caring Voice Coalition announced it would not offer financial assistance in 2018, OIG released a letter it sent to a drug company trade group, dated January 4, 2018. The letter states that the OIG "will not pursue administrative sanctions against any Drug Company for providing free drugs during 2018 to Federal health care program beneficiaries who were receiving cost sharing support from [Caring Voice Coalition]" as of the date of the advisory opinion rescission, provided certain conditions are met.

The conditions imposed by the OIG for drug companies to avoid administrative sanctions in 2018 include:

(1) The free drugs must be provided in a uniform and consistent manner to Federal health care program beneficiaries who were both receiving cost sharing assistance from Caring Voice Coalition as of November 28, 2017 and have been impacted by its decision to not offer assistance in 2018;

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1 OIG's December 2017 CIA followed a September 22, 2017 CIA it entered with Aegerion Pharmaceuticals, Inc., which contained nearly identical requirements for that manufacturer. Together, these CIAs articulate the policies and safeguards OIG expects from drug companies that interact with and donate to charity PAPs, and speak to the structure that should be in place if a drug company is running its own PAPs.

2 DOJ's December 2017 settlement agreement followed a September 2017 settlement agreement it entered with Aegerion Pharmaceuticals, Inc., covering alleged conduct similar to that of United Therapeutics.

(2) The free drugs are given without regard to the beneficiary's choice of provider, practitioner, health plan, or supplier;

(3) The free drugs are not billed to any Federal health care program, counted toward the beneficiary's Medicare Part D true out-of-pocket costs, resold, or otherwise billed to any third-party payor; and

(4) The provision of the free drugs is not contingent on any future purchases from or orders to the drug company of the drugs or any other item or service.

OIG and DOJ were not the only Federal agencies pursuing oversight of drug company donations to PAPs in 2017, however, as the Internal Revenue Service (IRS) has also shown an interest in identifying potential violations by charity PAPs which would threaten their tax-exempt status. Specifically, the IRS issued subpoenas to at least six drug companies to probe whether a specific charity PAP to which they donated returned a benefit to the companies which is not allowed pursuant to the relevant tax laws.

Overall, scrutiny of PAPs was intense in 2017, with regulators examining the PAPs themselves as well as their donors from the perspective of the Anti-Kickback Statute and other Federal law violations. Needless to say, PAPs will remain on the radar of the OIG, the DOJ, the IRS, state legislatures and regulators moving into 2018. Despite the enforcement, however, OIG guidance is robust in this space, and the scrutiny only helps to further refine the rules by which PAPs and their donors must play.

Questions or Assistance

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