DOJ PROBE OF PHARMACEUTICAL COMPANIES IMPLICATES PATIENT ASSISTANCE PROGRAMS

Recently, the U.S. Department of Justice ("DOJ") announced that 3 charities will pay a total of $10 million to settle claims that the charities operated as conduits for illegal kickbacks to pharmaceutical companies. The industry-wide probe also implicated several pharmaceutical companies that, according to the DOJ, improperly used charitable foundations as a way to assist Medicare patients with copayments, effectively paying patients to use the companies' drugs. This development comes as health care providers strive to find ways to provide care for larger numbers of uninsured and underinsured individuals and as lawmakers urge greater scrutiny over the practices of pharmaceutical manufacturers.

DOJ SETTLEMENTS

The 3 charities involved in the DOJ settlements, Good Days, the Patient Access Network Foundation ("PANF) and The Assistance Fund ("TAF") help patients obtain medications by operating patient assistance programs ("PAPs"). PAPs typically provide financial support to uninsured or underinsured individuals, often through health insurance premium payments or copayment assistance. When operated in strict compliance with existing federal guidance, PAPs operate independent of the entities that contribute financially to their funds and have structural guardrails to protect against violations of the federal Anti-Kickback Statute and Civil Monetary Penalties Law.[1] However, the DOJ alleged that Good Days, PANF and TAF conspired with pharmaceutical companies to violate federal law by:

- Directing donations from a single company to funds wherein only patients taking that company's drug would receive financial assistance from the donations;
- Adopting policies that inappropriately benefitted certain companies, including refusing to maintain patient wait lists and timing assistance awards to ensure that patients receiving a certain company's drug received a disproportionate share of the funds donated by that specific company;
- Discriminating against patients using a certain company's drug after the company gave notice that it would stop donating to the PAP;
- Providing data and financial reports to correlate the PAP's assistance to patients taking a company's drug with that company's donations; and
- Creating a specific fund purportedly to cover health care-related travel expenses for patients in need of a general class of drugs, but which in fact functioned primarily to cover only the travel expenses for patients taking a specific donor company's drug.

The DOJ asserted that Good Days, PANF, TAF and the pharmaceutical companies used funds ostensibly donated to help financially needy patients to induce patient purchases, drive up utilization, increase drug sales and increase costs to insurance programs such as Medicare and Medicaid. As part of the settlement, Good Days agreed to pay $2 million, PANF agreed to pay $4 million and TAF agreed to pay $4 million. Each of the PAPs also agreed to enter into integrity agreements with the Department of Health & Human Services ("DHHS") Office of the Inspector General ("OIG") for the next 3 years to ensure that their relationships with pharmaceutical companies comply with federal law. For their alleged involvement in the scheme to increase drug purchases by providing donations to charities, the DOJ filed charges against, or settled with, several pharmaceutical companies earlier this year. Among them, Amgen settled for $24.75 million, Astellas settled for $100 million, and Pfizer settled for $23.85 million.

EXECUTIVE AND LEGISLATIVE BRANCH CALLS FOR INCREASED SCRUTINY

The DOJ settlements come amidst calls from both the federal executive and legislative branches to increase scrutiny of pharmaceutical manufacturers' pricing and other practices. For example, in a December 4, 2019 letter to the OIG ("December 4 Letter"), Senators Elizabeth Warren (D-MA) and Sheldon Whitehouse (D-RI) urged the OIG to update a 2014 Special Advisory Bulletin to PAPs to:

- Require independent charity PAPs to publicly disclose which treatments they cover, and to provide written justifications for any deviations from the U.S. Food and Drug Administration's full list of approved treatments for any specific disease or condition;

- Require all PAPs to cover generic alternatives to brand-name treatments whenever available;
- Prohibit independent charity PAPs from excluding potential beneficiaries on the basis of their insurance status;
- Prohibit pharmaceutical company donors from earmarking their donations for disease-specific funds; and
- Require annual public reports from each PAP about their applicant characteristics, approval rates, insurance status and type for both applicants and participants, distribution of spending and data shared with donors.

PRACTICAL TAKEAWAYS

As evidenced by the DOJ settlements and the December 4 Letter, hospitals, health systems, charitable foundations, drug and medical device manufacturers and other entities involved in the health care industry should weigh the risks of participating in PAPs and should ensure that any PAPs in which they participate are structured carefully. Still, the increasing number of patients without health coverage,[2] asymmetric information in the health care market and rising health care costs make PAPs an attractive option and a powerful tool to make health care more affordable.

PAPs can fill a gap in the health care industry and open the door to necessary care for financially needy individuals if they are properly structured. Current available guidance suggests that PAPs should involve funds that are independent of their donors without earmarks for certain treatments, provide for patient choice and use uniform financial eligibility determination criteria when evaluating assistance applications. Health care providers interested in making donations to a charity operating a PAP or establishing a charitable foundation to operate a PAP should consult their compliance and legal counsel to ensure adherence to applicable laws and regulatory guidance.

If you have any questions or would like additional information about this topic, please contact:

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Please visit the Hall Render Blog at http://blogs.hallrender.com/ or click here to sign up to receive Hall Render alerts on topics related to health care law.

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[1] We previously discussed proper PAP safeguards based on Advisory Opinions issued by the DHHS OIG and also highlighted the on-going debate over PAPs, located here and here.

[2] According to the U.S. Census Bureau, the number of uninsured individuals rose from 25.6 million people in 2017 to 27.5 million people in 2018.

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