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Insights

OIG Signals Potential Approval of Prescription Drug Assistance Programs

February 12, 2025

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Non-profit healthcare entities may soon have greater flexibility when it comes to patient assistance programs that subsidize the cost of prescription drugs for their patients residing in rural areas. Generally, such programs risk violating the patient remuneration prohibition under the federal Anti-Kickback Statute ("AKS"). However, a recent Office of Inspector General ("OIG") Advisory Opinion—OIG Advisory Opinion 24-07—signaled a potential change in the way that the OIG sanctions these programs.

OIG Advisory Opinion 24-07, released in August 2024, advised a non-profit grant-making organization on its patient assistance program ("PAP") that paid for 100% of patient cost-sharing obligations for all diabetes prescription drugs for low-income Medicare enrollees who did not qualify for Medicaid and resided in rural areas.

While the OIG did conclude that the PAP created a prohibited remuneration under the AKS, it stated that it would forgo administrative sanctions, finding the arrangement's potential for fraud and abuse to be sufficiently low. The OIG based this conclusion on the following factors:

- The non-profit organization was not funded by a pharmaceutical entity, so there was no risk that the PAP could function as a conduit for payments by a pharmaceutical manufacturer (or other pharmaceutical entity) to patients.
- The design of the PAP did not steer Medicare enrollees to a particular product based upon the availability of a subsidy.
- Eligibility for the PAP was based on a good-faith determination of need.
- There was no impact on swaying patient choice of pharmacy.
- There was no clinical impact.
- The PAP was unlikely to increase healthcare costs overall.

It is important to note that OIG's conclusion above is limited in scope to the non-profit organization that was advised. However, this Advisory Opinion does signal a potential future move by the OIG to withhold AKS enforcement for PAPs that fall in line with the above factors.

If you have questions regarding Advisory Opinion 24-07 or other Anti-Kickback Statute-related issues, please contact Stephanie T. Eckerle, Brandon W. Shirley, or Madison Hartman Harada.

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