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HHS-OIG Issues Favorable Opinion on Drug Manufacturer's Free Genetic Testing, Counseling for Patients

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Highlights

HHS-OIG recently released Advisory Opinion No. 24-12, a favorable opinion involving a drug manufacturer's patient support program for individuals who suffer from genetic condition causing chronic kidney stones

The proposed arrangement is consistent with previous HHS-OIG guidance on patient assistance that promotes access to care involving rare health conditions

The HHS-OIG noted several factors that limited the possibility of fraud and abuse, even though the arrangement implicates the Anti-Kickback Statute and the civil monetary penalty provision prohibiting inducements to beneficiaries

The U.S. Department of Health and Human Services' Office of Inspector General (HHS-OIG) recently released Advisory Opinion No. 24-12, a favorable opinion regarding a drug manufacturer's program to sponsor genetic testing, related genetic counseling, and disease-state awareness education for certain hereditary conditions that may cause kidney stones. The manufacturer of a drug used to treat chronic kidney stones caused by a rare genetic condition requested the advisory opinion.

The manufacturer proposes the program be offered to certain patients that meet specified criteria. Eligible patients are those who: 1) have a family history of recurrent kidney stones, 2) received inconclusive results after testing for the genes responsible for the genetic condition, 3) have lab results indicating a potential monogenic disorder resulting in chronic kidney stones, 4) suffer from chronic kidney disease of unknown etiology, 5) suffer from nephrocalcinosis, 6) have a history of recurring kidney stones, or 7) are younger than two years old and failing to thrive with impaired renal function.

Under the program, no patient or payor would be billed for any of the tests or counseling services. The services would not be conditional on the use of the company's drug or any other items or services sold by the company or its affiliates. The company acknowledged that the arrangement could result in healthcare providers scheduling, conducting, and billing eligible patients and their payors for additional visits to review patient test results generated by the program. However, these visits are not required under the program and would be solely done at the provider's discretion in consultation with the patient.

The HHS-OIG concluded that the proposed arrangement implicated both the Anti-Kickback Statute and the civil monetary penalty provision prohibiting inducements to beneficiaries and would not fall directly within any exception or safe harbor. Nevertheless, the agency concluded the risk of fraud and abuse is sufficiently low and it would not impose sanctions on the proposed arrangement.

The HHS-OIG cited the following factors as limiting the possibility for fraud and abuse:

- The narrow eligibility requirements regarding how a patient obtains genetic tests and counseling reduce the risk of over-utilization and improper utilization
- The arrangement is unlikely to skew clinical decision-making or raise concerns regarding patient safety or quality of care because the manufacturer does not provide any sort of incentive to providers who order genetic testing or counseling
- The manufacturer does not receive any information that identifies the prescribers or the patients who receive free genetic testing and counseling under the arrangement, and therefore, the company cannot target any drug marketing materials specifically to those individuals
- Genetic counselors discuss genetic testing and hereditary diseases, but do not discuss treatment options therefore limiting any marketing of the drug

Notably, the HHS-OIG warned that it would likely reach a different conclusion if patient or provider data was shared with the drug manufacturer that would allow it to perform target marketing of the drug based on the arrangement. The HHS-OIG also noted its conclusion would likely be different if there was a more direct nexus between the free genetic testing, counseling, and education and ordering or purchasing the manufacturer's drug.

Takeaways

This advisory opinion continues to demonstrate HHS-OIG's leniency toward targeted patient support programs for rare diseases and genetic conditions. It also shows HHS-OIG's tolerance for arrangements that increase the standard of care while limiting costs to federal healthcare programs, especially when patient data under the arrangement cannot be used for marketing purposes or other financial gain.

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