OIG Issues Favorable Opinion of an Arrangement Involving a Patient Assistance Program



5/31/2024

On April 11, 2024, the Department of Health and Human Services, Office of Inspector General (OIG) issued a favorable advisory opinion regarding an arrangement where a not-for-profit organization would provide financial assistance to needy patients with rare diseases (Disease Funds) that would be funded by drug manufacturers (Donors) that produce drugs to combat these diseases. The OIG concluded that under the current Medicare Part D cost-sharing structure, this arrangement would not warrant sanctions, although the arrangement would generate prohibited remuneration under the Federal Anti-Kickback Statute if the requisite intent were present.

The OIG identified two reasons why sanctions are unwarranted for this arrangement:

1. Despite raising Federal Anti-Kickback Statute concerns and potentially being a conduit for payment by a Donor to a patient, the arrangement incorporates features that mitigate fraud and abuse risks. These features include defining Disease Funds based on established disease states, awarding assistance irrespective of specific treatment regimens, limiting information sharing with Donors, and implementing a stringent financial eligibility process.

2. The Disease Funds offer potentially impactful support amid rising prescription drug costs. Notably, over two-thirds of the funds are allocated to various forms of assistance besides the purchase of Donors' drugs. These include cost-sharing for non-drug items and services, medical aid, premium support, and emergency relief, underscoring the comprehensive nature of the support provided by the arrangement beyond solely pharmaceutical assistance.

The OIG notes that its opinion is effective until January 1, 2027 and will be subject to future modifications to the Medicare Part D program.

Click Here to read the entire May 2024 Healthcare Law Update now!

For more information, contact:
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Edward J. Yun | 973.364.5229 | eyun@bracheichler.com
Vanessa Coleman | 973.364.5208 | vcoleman@bracheichler.com

Authors

The following attorneys contributed to this insight.



Carol Grelecki

Member
Healthcare Law

973.403.3140 · 973.618.5540 Fax

cgrelecki@bracheichler.com



Edward J. Yun

Member
Healthcare Law

973.364.5229 · 973.618.5589 Fax

eyun@bracheichler.com



Vanessa Coleman

Associate
Healthcare Law

973.364.5208 · 973.618.5566 Fax

vcoleman@bracheichler.com