Not-For-Profit's Patient Assistance Program Receives Favorable Advisory Opinion

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On August 23, 2024, the Department of Health and Human Services Office of Inspector General (OIG) issued Advisory Opinion No. 24-07, allowing a not-for-profit organization to establish a patient assistance program (PAP) to subsidize cost-sharing obligations for low-income diabetic Medicare enrollees.

The requestor sought to pay the cost-sharing obligations for diabetes drugs for Medicare Part D enrollees who reside in the community it serves. To qualify, Part D enrollees must have no secondary insurance coverage, a household income below 400% of the Federal Poverty Level (FPL) and submit an enrollment application to the requestor. The requestor would allocate funding on a first-come first-serve basis. Under the proposed arrangement, participants can use any pharmacy. However, if participants use a "Preferred Pharmacy," the requestor would pay the cost-sharing up front. Otherwise, participants would pay their cost-share to the pharmacy and receive reimbursement from the requestor.

Although the cost-sharing subsidies and the use of a "Preferred Pharmacy" would each generate remuneration, the OIG issued a favorable opinion, stating that the risk of fraud and abuse is "sufficiently low" for the reasons set forth below.

Cost-Sharing Subsidies:

1. The subsidies would not function as a "conduit for payments by a pharmaceutical manufacturer" because the requestor is independent of pharmaceutical influence and does not solicit or receive donations from or on behalf of a pharmaceutical entity.

2. There is a low likelihood that the subsidy would steer Medicare beneficiaries to a particular drug because the subsidy would

apply to all FDA-approved diabetes medications that are covered by Part D.

3. The subsidy would not induce participants to purchase drugs because eligibility is based on strict need-based criteria and is subject to annual re-enrollment and funding limitations.

Enabling Participants to Avoid Out-of-Pocket Expenses by Using a Preferred Pharmacy:

1. The risk of steering patients to a Preferred Pharmacy is low because participants use other factors when selecting a pharmacy, such as location and drug availability, and the dollar value of the subsidy does not differ based on the pharmacy used.

2. The use of a Preferred Pharmacy is unlikely to interfere with clinical decision-making or otherwise induce a participant to purchase a prescription drug.

3. The arrangement is unlikely to increase costs to Federal health care programs because Federal health care programs will pay the same amount, regardless of the pharmacy used.

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For more information, contact:
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Edward J. Yun | 973.364.5229 | eyun@bracheichler.com
Rebecca Falk | 973.364.8393 | rfalk@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

Rebecca T. Falk

Associate
Healthcare Law

973-364-8393 · 973-618-5923 Fax

rfalk@bracheichler.com