

OIG RESCISSION OF 2006 ADVISORY OPINION: AN IMPORTANT COMPLIANCE REMINDER

On November 28, 2017, the Department of Health and Human Services, Office of Inspector General ("OIG") rescinded Advisory Opinion 06-04, which had been issued in 2006 to Caring Voice Coalition ("Requestor"), a nonprofit, tax-exempt, charitable organization.

Requestor operated a patient assistance program ("PAP") that provided financially needy Medicare beneficiaries with Medicare premium and cost-sharing assistance. OIG rescinded the favorable opinion regarding Requestor's PAP after determining that Requestor failed to accurately disclose all relevant and material facts to OIG. More specifically, OIG determined that Requestor failed to comply with factual certifications OIG relied on in issuing the original opinion by: (i) providing patient-specific data to one or more donors, thus enabling donors to correlate the amount and frequency of their donations with the number of subsidized orders for the donors' products; and (ii) allowing donors to directly or indirectly influence the disease categories covered by the PAP. Because the misrepresentations made by Requestor were determinative factors in OIG's original conclusion that the PAP was low risk, OIG rescinded its initial favorable opinion.

ORIGINAL ADVISORY OPINION

In the original Advisory Opinion, OIG considered a proposed arrangement ("Proposed Arrangement") under which Medicare premium and cost-sharing obligations for financially needy beneficiaries would be provided on a first-come, first-served basis. Under the Proposed Arrangement, Requestor would use objective criteria, such as the applicant's medical condition and financial need, to determine eligibility. Requestor would not take into account the interests of any donors, the patient's choice of product, provider, practitioner or supplier, or the identity of the referring entity (i.e., donor versus non-donor) in determining which patients to assist. Patient freedom of choice regarding physicians, providers, suppliers and treatment regimens would be maintained at all times. In addition, Requestor would permit donors to provide unrestricted donations or to designate donations for a specific disease category or program.

OIG analyzed two aspects of the Proposed Arrangement: (i) the donor contributions to Requestor; and (ii) Requestor's grants to beneficiaries. With respect to donor contributions, OIG supported the Proposed Arrangement because an independent, bona fide charitable organization would be interposed between donors and patients, effectively insulating beneficiary decision-making from information attributing funding of the benefit to any donor. Thus, the Proposed Arrangement's design made it unlikely that donor contributions would influence any Medicare beneficiary's selection of a particular provider, practitioner, supplier or product. The favorable opinion outlined the following specific factors and safeguards related to the donor contribution analysis.

1. Donors would have no direct or indirect control over Requestor or its programs.
2. Requestor would award assistance in an independent manner using its own criteria, considering applications on a first-come, first-served basis and only to the extent of available funding.
3. Requestor would award assistance without regard to any donor's interests and without regard to the beneficiary's choice of provider, supplier or product.
4. Requestor would provide assistance based upon a reasonable, verifiable and consistently applied measure of financial need.
5. Requestor would not provide donors with any data that would allow correlation of the amount or frequency of donations with the amount or frequency of use of the donor's products or services.
6. Requestor would not allow donors to directly or indirectly influence selection of disease categories covered by the PAP.

OIG outlined the following specific factors and safeguards in the analysis of Requestor's grants to beneficiaries.

1. Requestor would assist all eligible, financially needy patients on a first-come, first-served basis to the extent funding was available; would refrain from making referrals or recommendations of providers, suppliers or products; and would not inform patients of the identity of donors.

2. Patient financial qualification for assistance would be based solely on the patient's financial need, without considering the identity of any of the patient's health care providers, suppliers or products; the identity of any referring party; or the identity of any donor that may have contributed to support of the patient's specific disease category.
3. Requestor's subsidies would expand beneficiary freedom of choice by financially supporting access to the beneficiary's previously selected provider or supplier.

SPECIAL ADVISORY BULLETIN AND MODIFICATION OF ADVISORY OPINION

In 2014, OIG released a Supplemental Special Advisory Bulletin ("SAB") regarding PAPs operated by independent charities.^[1] The SAB included new limitations to address anti-kickback related concerns in three areas: disease funds, eligible recipients and the conduct of donors.^[2] Specifically, OIG clarified that independent charities could not define disease funds so narrowly that earmarking of funds would effectively result in a donor's subsidization of its own products. Further, the SAB stated that charities may not operate disease funds in a way that limits assistance to only a subset of available products rather than all FDA-approved treatments. OIG also indicated that independent charity PAPs must determine eligibility according to reasonable, verifiable and consistently applied measures of financial need, which may not include the cost of a particular drug. Finally, OIG affirmed that charity certifications of donor independence serve as critical factors on which OIG relies in providing its opinions. Accordingly, in 2015, OIG modified Requestor's favorable opinion based on certified compliance with the additional requirements outlined in the SAB.

RESCISSION OF OPINION 06-04

OIG's rescission of Advisory Opinion 06-04 was based on Requestor's failure to comply with specific factual certifications and safeguards upon which OIG had relied in approving the Proposed Arrangement. Specifically, OIG determined that Requestor did not adhere to two factual certifications material to OIG's conclusion that the arrangement placed an independent, bona fide charitable organization between donors and patients. First, Requestor provided patient-specific data to donors, thus linking donations to the number of subsidized prescriptions and products ordered. Second, Requestor allowed donors to influence the disease categories covered by the PAP, which materially increased the risk that the PAP served merely as a conduit for financial assistance from a pharmaceutical manufacturer donor to a patient and would steer patients to drugs sold by the donor. These misrepresentations of material fact resulted in the retroactive revocation of any legal protections the Advisory Opinion conferred back to the original date of issuance in 2006.

PRACTICAL TAKEAWAYS

It is important to note that OIG's rescission of Advisory Opinion 06-04 does not represent a change in OIG's stance on PAPs in general or on the factors that OIG considers important safeguards to protect against fraud and abuse in such programs. Instead, OIG's rescission of Advisory Opinion 06-04 emphasizes that favorable Advisory Opinions where all relevant and material facts were not fully, completely and accurately presented, or where the arrangement in effect fails to comport with the material facts or certifications OIG relied upon in approving the proposed arrangement, are subject to additional review and rescission. Moreover, failure to comply with material facts and certifications, or making material misrepresentations to the government, could trigger additional enforcement actions based on violations of any relevant laws or regulations that continue to apply, including making a false statement to the government.

With respect to pharmaceutical PAPs, OIG's action on Advisory Opinion 06-04 signals heightened scrutiny for PAPs that fail to maintain sufficient independence from pharmaceutical manufacturer donors. However, PAPs that incorporate the safeguards outlined in Advisory Opinion 06-04 (as well as other similar Advisory Opinions) in both design and practice should continue to represent low risk of being viewed as violating fraud and abuse laws.

OIG's rescission of Advisory Opinion 06-04 serves as an important reminder to health care providers that any information provided to the government, whether in the advisory opinion process, self-disclosure process or any other exchange, must be complete, accurate and truthful. Providers who have previously implemented similar programs based on advisory opinions should ensure such arrangements continue to comport with the appropriate safeguards outlined in the advisory opinions and related guidance.

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

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[1] Department of Health and Human Services, Office of Inspector General, Supplemental Special Advisory Bulletin: Independent Requestor Patient Assistance Programs (79 Fed. Reg. 31120, May 30, 2014).

[2] The 2014 SAB supplemented the OIG's 2005 SAB. Department of Health and Human Services, Office of Inspector General, Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (70 Fed. Reg. 70623, Nov. 22, 2005).