

OIG Supplemental Advisory Bulletin on Patient Assistance Programs Leaves Open Questions for High-Cost Breakthrough Drugs in Medicare Part D

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On May 21, 2014, the Office of the Inspector General (“OIG”) of the Department of Health and Human Services issued a Supplemental Special Advisory Bulletin (“Supplemental Bulletin”) addressing the risks that Independent Charity Patient Assistance Programs (“PAPs”) raise under the Anti-Kickback Statute and beneficiary inducement civil monetary penalties of the Social Security Act.¹ In a PAP, pharmaceutical manufacturers and others can contribute to independent, bona fide charities that assist beneficiaries enrolled in federal health care programs in meeting cost-sharing obligations for prescription drugs. The Supplemental Bulletin adds new limitations to the 2005 Special Advisory Bulletin (“2005 Bulletin”) that the OIG issued regarding PAPs in advance of the 2006 implementation of the Medicare Part D outpatient prescription drug program (“Part D”).² The limitations reflect certain issues that the OIG has observed in the years since Part D was implemented and focus on three areas: disease funds, eligible recipients, and the conduct of donors. At the same time, the Supplemental Bulletin does not specifically address recent developments that can have important impacts on Part D beneficiary cost sharing and the development of PAPs. These recent developments include the phase-out of the Part D coverage gap by 2020 under the Affordable Care Act (“ACA”) and the emergence of breakthrough, high-cost drugs, such as Gilead’s sovaldi. This Client Alert summarizes the new limitations in the Supplemental Bulletin and the potential uncertainties that may remain given these recent Part D developments.

¹ OIG Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs (May 21, 2014), available at <https://oig.hhs.gov/compliance/alerts/bulletins/index.asp>.

² OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005), available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSpecialAdvisoryBulletin.pdf>.

If you would like to discuss how the Supplemental Bulletin impacts your organization, please contact one of the authors of this Client Alert or the Epstein Becker Green attorney who regularly handles your legal matters.

Disease Funds

As indicated in the 2005 Bulletin, the OIG recognizes that some bona fide independent charities may focus on particular disease states and that donors may earmark their contributions for support of patients suffering from these particular diseases. OIG also notes that, generally, the fact that a pharmaceutical manufacturer's donations are earmarked for such a purpose (broad disease states) should not significantly raise the risk of abuse. However, the Supplemental Bulletin discusses the OIG's concern related to charities' narrowing of disease funds. In particular, the OIG notes that, in recent years, some independent PAPs are narrowing their definition of disease funds to include a limited number of drugs within such funds. This, in turn, raises questions as to whether donor contributions to limited or narrowed disease funds result in the donor simply subsidizing its own products. In order to address this concern, the OIG expands on the previous safeguards discussed in the 2005 Bulletin. In doing so, the OIG "reiterate[s] here that an Independent Charity PAP must not function as a conduit for payments or other benefits from the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices."

The OIG discusses its concern with disease funds that are narrowed in ways, such as, but not limited to, particular stages of a disease and types of drug treatment. As such, a PAP with very narrowly defined disease funds may be scrutinized if the funds result in "funding exclusively or primarily the products of donors or if other facts and circumstances suggest that the disease fund is operated to induce the purchase of donor's products."

The Supplemental Bulletin acknowledges that, in the case of Medicare Part D, in rare circumstances, there may be only one drug covered for a disease in a particular PAP disease fund. In such a circumstance, the OIG states that "the fact that a disease fund includes only one drug or drugs made by one manufacturer would not, standing alone, be determinative of an [A]nti-[K]ickback [S]tatute violation." However, the Supplemental Bulletin does not explicitly address a scenario in which a particular disease fund covers all treatments for a disease but there is a new breakthrough drug that becomes, in effect, the standard of care for the disease. In such a scenario, the disease fund may, in practice, cover only one drug. Accordingly, it is not clear from the Supplemental Bulletin to what degree the OIG may raise concerns over a broadly defined disease fund that, in practice, covers only one drug that is the standard of care.

The OIG also addresses its concern related to PAPs establishing or operating disease funds that limit assistance to a certain subset of available products, such as expensive or specialty drugs. Limiting assistance in such a manner could be viewed as a way of steering patients to particular drugs, thus potentially increasing costs to federal health care programs. Limiting assistance may also be viewed as steering patients away from more beneficial or less costly alternatives. Thus, programs that limit assistance in this

way may be subject to scrutiny, as will funds that cover only a single product or products made or marketed by only a single manufacturer that is a significant donor to the fund.

The OIG is concerned with funds that “limit assistance” to “expensive or specialty drugs.” Yet, interesting policy questions are raised by the evolving prescription drug cost-sharing needs. The ACA established a phase-out by 2020 of the coverage gap in the Medicare Part D benefit, also known as the “donut hole.” Beneficiaries in the coverage gap have been responsible for 100 percent of drug costs before reaching the catastrophic portion of the benefit with reduced cost sharing. As the phase-out continues, Part D beneficiaries will have fewer cost-sharing obligations for lower- and moderately priced drugs, leaving significant demands on PAPs to assist with very expensive drugs. The Supplemental Bulletin does not make clear how the OIG may view a PAP that covers multiple products but, in practice, is providing assistance only for the most expensive drugs, where there is the greatest need for cost-sharing assistance.

Eligible Recipients

Next, the OIG addresses the concept of how recipients are deemed eligible by the PAP. The OIG acknowledges that a fund focused solely on federal health care program beneficiaries is not, in and of itself, suspect, because the safeguards related to disease funds and recipient eligibility described in both the 2005 Bulletin and the Supplemental Bulletin should adequately protect federal health care programs. However, the OIG stresses that eligibility criteria must be determined according to a “reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.” For example, eligibility criteria can consider the poverty guidelines, local costs of living, and the extent of the patient’s total medical bills. While the OIG does not proscribe a particular methodology for determining financial need, the Supplemental Bulletin emphasizes that the cost of a particular drug is not an appropriate “stand-alone” factor. In addition, the Supplemental Bulletin notes that financial criteria that is very generous (i.e., the financial need determination is too lax), especially when the fund is limited to a subset of available drugs or drugs of a major donor, could be evidence of an inducement.

Conduct of Donors

Although the majority of the Supplemental Bulletin focuses on the conduct of Independent Charity PAPs, the OIG seems to suggest that donors are not immune from liability under the law. Specifically, the OIG addresses how Advisory Opinions focus on the actions of the charities that requested the opinions—not the donors. When a charity requests an Advisory Opinion, the charity certifies to actions that it will take to ensure the PAPs’ financial independence from the donors. However, the charity is not in a position to certify to the actions of the donors. The OIG emphasizes that the procedures described in the certifications (e.g., the types of information that will be distributed to donors) are essential safeguards that the OIG relies upon when issuing favorable opinions. The OIG acknowledges that the favorable Advisory Opinions do not address

actions that donors may take to determine how their donations ultimately support their own product use. The OIG states, “Such actions may be indicative of a donor’s intent to channel its financial support to copayments of its own products, which would implicate the [A]nti-[K]ickback [S]tatute.”

What’s Next

The Supplemental Bulletin states that OIG will work with individuals who have received favorable Advisory Opinions to ensure that approved arrangements are consistent with the Supplemental Bulletin. The OIG expressly states that it anticipates needing to modify some Advisory Opinions. However, the OIG also clarifies that favorable Advisory Opinions will continue to protect the arrangement until a modification or termination is issued to the requestors of those opinions. Given the fact that the OIG is going to be reviewing all of the favorable Advisory Opinions that it has issued in this context, PAPs and, in some cases, donors may want to consider the impact of the Supplemental Bulletin on any legal analysis/opinions that they have previously received.

Apart from PAPs and prospective donors, pharmaceutical manufacturers, providers, and any other stakeholders concerned with patient access to prescription drugs should consider the likely impact of the new OIG policy. While it may be based upon experiences gained by the OIG since 2005, the Supplemental Bulletin will be in effect through future market developments and the evolution in prescription drug cost-sharing under federal health care programs.

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*This Client Alert was authored by **Mark Hamelburg, Thomas E. Hutchinson, Deepa B. Selvam, Philo D. Hall, and Anjali N.C. Downs**. For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

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