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OIG Supplemental Special Advisory Bulletin Raises New Concerns About Independent Charity Patient Assistance Programs [Ober|Kaler]

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In an effort to address new concerns about the independence of charity patient assistance programs (PAPs), the Office of Inspector General (OIG) released its Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs (Supplemental SAB) on May 21, 2014. The Supplemental SAB expands upon previous guidance issued in the OIG's November 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (2005 SAB). In light of this new guidance, industry stakeholders will have to reexamine their PAP arrangements.

PAPs were established by pharmaceutical companies and independent organizations to help patients meet their out-of-pocket drug treatment expenses. They have grown in size and prominence in recent decades due to increases in prescription drug costs. While PAPs have been praised for providing important patient benefits, critics counter that they can also promote overutilization and drug price inflation. Regulators have also raised concerns about conflicts of interest, as pharmaceutical manufacturers increasingly seek to fund narrowly defined PAPs—which may be limited to a small number of drugs—to promote sales of their own drugs.

In the 2005 SAB, which was released before the implementation of the Medicare Part D prescription drug program, the OIG analyzed various types of PAPs under the federal antikickback statute (AKS) and concluded that "lawful avenues" exist for pharmaceutical manufacturers to facilitate patients' access to medically necessary drugs. Among other things, the 2005 SAB addressed PAPs operated by independent charities and set forth a list of factors that may be used to assess their propriety. Informed by several years of experience with the Medicare Part D program, the OIG's Supplemental SAB provides additional guidance on fraud and abuse concerns related to independent charity PAPs. Specifically, the new guidance addresses: (1) disease funds, (2) eligible recipients, and (3) conduct of donors.

Disease Funds

The OIG recognized in the 2005 SAB that bona fide independent charities may reasonably focus upon particular diseases, and confirmed that pharmaceutical manufacturers may donate to such disease funds when they have a broad focus. Donations to narrowly defined disease funds raise concerns, however. The OIG stated in the Supplemental SAB that PAPs “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 identified several areas of concern with disease funds in the 2005 SAB:

- Pharmaceutical manufacturers and their affiliates exert direct or indirect influence or control over the fund.
- Donors influence the identification of the diseases covered by the fund.
- The fund is defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs.

The OIG said at the time that these were examples, not an exclusive list. Through its experience over the past several years, including consideration of advisory opinion requests, the OIG has identified additional areas of concern with disease funds. The Supplemental SAB expresses growing concerns in the following scenarios:

- The fund is defined by the stages of a particular disease, the type of drug treatment, or in any other way that serves to narrow the treatment of widely recognized disease states.
- The fund is so narrowly defined that it funds exclusively or primarily the products of donors.
- Facts and circumstances suggest the fund is operated to induce the purchase of donors' products.
- The fund is limited to a subset of available products—by covering copayments only for expensive or specialty drugs—rather than all products approved by the FDA for treatment of the disease states covered by the fund or all products covered by the relevant federal health care program when prescribed for the treatment of the disease state(s).

The OIG warned that funds focused on expensive products are subject to greater scrutiny out of concern that they may steer patients away from more beneficial products, increase drug prices, and generate added costs for federal health care programs. In the end, the OIG advised that “disease funds should be defined in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of products….”

Eligible Recipients

The OIG reaffirmed its view that the risk is not necessarily increased if a PAP fund serves only federal health care program beneficiaries. Far more critical, according to the OIG, is that the PAP "must determine [patient] eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner." The OIG acknowledged that PAPs may consider relevant variables beyond income, but warned that the cost of a particular requested drug should not be the sole factor in determining individual financial need. Finally, the OIG noted that generous financial need criteria, especially in the case of narrowly defined funds, could be evidence that the fund is intended to impermissibly induce the use of one or more drugs.

Conduct of Donors

According to the Supplemental SAB, PAPs should be configured to ensure that they operate independently from their donors. The OIG recognizes that donors should not be given "any information that would enable a donor to correlate the amount or frequency of its donations with the number of aid recipients who use its products or services or the volume of those products supported by the PAP." The OIG noted that in prior advisory opinions it had cited various steps taken by the PAP to control the conduct of donors. While acknowledging that these safeguards were critical to the advisory opinions, the OIG recognized that the actions of the donors would be considered in determining whether the donor's intent is to channel its financial support to copayments of its own products, thereby implicating the AKS.

Looking Ahead: PAP Compliance in a Stricter Regulatory Environment

While recognizing the benefits of properly structured PAPs, the Supplemental SAB warns that PAP arrangements, such as narrowly focused disease funds, raise serious fraud, waste, and abuse risks. The OIG also indicated that it would be contacting organizations that have received favorable advisory opinions to ensure the approved arrangements are consistent with this new guidance. Where necessary, the OIG would seek to modify existing PAPs. Not wanting to disrupt the important work being done by existing PAPs, the OIG

has stated that favorable advisory opinions "will continue to protect the arrangements described in the opinions until we issue any final notice of modification or termination to the requestors of those opinions."

It remains to be seen how industry stakeholders will react to the new concerns expressed by the OIG in the Supplemental SAB. Drug companies, charities, and donors will have to carefully reassess their involvement in PAP arrangements in light of the new OIG guidance. The key will be to implement sufficient safeguards into PAPs to satisfy the concerns expressed by the OIG, without having a chilling effect on PAPs' important contributions to our social safety net.