Advisory Opinion Demonstrates OIG's Enhanced Scrutiny of "Improperly Narrow" Industry-Funded Patient Assistance Programs

On January 5, 2015, the Office of Inspector General ("OIG") of the U.S. Department of Health and Human Services issued an advisory opinion approving a charitable Patient Assistance Program ("PAP"), funded in part by donations from pharmaceutical manufacturers, that helps low-income patients meet their copayment obligations for drugs treating Crohn's disease and ulcerative colitis. The opinion—the first to be issued on the topic since the agency's May 2014 Supplemental Special Advisory Bulletin ("SSAB")—is consistent with OIG's long-standing guidance and pre-SSAB advisory opinions, but also reflects the enhanced scrutiny suggested in the SSAB of "improperly narrow" PAPs that can serve as conduits for drug manufacturers to induce the prescription of their own products.

Like its predecessor Special Advisory Bulletin of 2005, the SSAB cautioned that industry-funded PAPs could be used by manufacturers to subsidize the purchase of their own products, improperly influencing drug choices and potentially raising Medicare costs in the process. Even PAPs operated by bona fide, independent charities can be problematic if, for example, a PAP provides assistance for only a narrowly defined disease or only a subset of available drug products. Recognizing both the potential for abuse and the important benefits at stake for patients in need, the 2005 and 2014 Bulletins outline several factors that OIG believes are "fundamental to a properly structured PAP" that complies with both the Anti-Kickback Statute and the beneficiary inducement provision of the Civil Monetary Penalties Law. The 2005 Bulletin listed the following factors:

- Neither the pharmaceutical manufacturer nor any affiliate of the manufacturer can exert direct or indirect influence or control over the PAP;
- The PAP must award assistance in a truly independent manner that severs any link between the manufacturer's donation and the patient (i.e., the assistance provided to the patient cannot be attributed to the donating manufacturer);
- The PAP must award assistance without regard to the manufacturer's interests and without regard to the patient's choice of product, provider, practitioner, supplier, or drug plan;
- The eligibility criteria used by the PAP must consist of reasonable, verifiable, and uniform measures of financial need, and must be applied in a consistent manner; and
- The manufacturer must not solicit or receive data from the PAP that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products.

After the 2005 Bulletin was published, OIG observed a shift away from "broad disease funds" to more narrowly defined PAPs that present heightened risks of abuse. Thus, in the SSAB the agency announced that certain PAPs will be subject to enhanced scrutiny. In particular, the SSAB warned against: (i) disease-specific PAPs with an "improperly narrow approach" to defining the disease; and (ii) PAPs that "limit assistance to a subset of available products." The 2005 bulletin provided some examples of such improperly narrow approaches to defining a disease—namely, those in which a disease is limited by reference to specific symptoms, severity of symptoms, or the method of administration of drugs—but the SSAP explained that

these were only examples, and not an exclusive list. "For example," the OIG elaborated, "we are also concerned about disease funds defined by reference to the stages of a particular disease, the type of drug treatment, and any other ways of narrowing the definition of widely recognized disease states."

Unlike a comparable opinion issued in 2010 (OIG Advisory Opinion No. 10-06), the 2015 advisory opinion specifically considered, as part of its comprehensive analysis of the factors listed above, these two additional ways of narrowing the definition of widely recognized disease states: reference to the stages of a particular disease or the type of drug treatment (in addition to "any other way" of narrowing the definition). In all other respects, however, the opinions are analytically identical. Thus, the opinion confirms that the SSAB did not represent a sea change in OIG's approach to industry-funded PAPs. However, OIG's fine-tuning of the factors it will apply in deciding whether industry contributions to a PAP should be treated as kickbacks to induce the use of the donor's drug suggests that OIG intends to apply more exacting scrutiny to such arrangements going forward.

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