

## New OIG Advice on Patient Assistance Programs

The Office of Inspector General (“OIG”) of the Department of Health and Human Services has issued a Special Advisory Bulletin on patient assistance programs (“PAPs”) for Medicare Part D enrollees. The principal points of the OIG Bulletin are as follows:

### Pharmaceutical Company PAPs Cannot Provide Assistance to Patients in the Part D Coverage Gap

In previous issuances, the OIG had stated that pharmaceutical companies could provide free drug to patients needing assistance but could not pay their Medicare coinsurance obligations. The OIG has now ruled that a company PAP that provides financial assistance to patients in the Part D coverage gap (the “donut hole”) would raise substantial concerns under the anti-kickback statute.

### Company PAPs Can Provide Free Drug Outside Part D

The OIG Bulletin indicates that company PAPs can provide free drug to patients if they operate wholly outside Part D. This means that the free drug cannot count toward satisfaction of the patient’s true out-of-pocket cost (“TrOOP”) requirement to qualify for Part D catastrophic coverage, and the PAP must provide free drug to the patient for the entire calendar year (or for whatever portion remains after the patient qualifies for the PAP). Even in that situation, the OIG Bulletin identifies a number of conditions that the PAP should meet to ensure that there is no violation of the anti-kickback statute.

### Independent Charity PAPs Are Permissible

In the Bulletin the OIG reaffirms its previous advice that pharmaceutical companies may make contributions to independent charities that provide financial assistance to patients unable to pay their Medicare coinsurance (and now also their obligations under Part D) provided that the charities furnish assistance to qualifying patients without regard to the particular drug they are taking and in an otherwise neutral manner. The OIG had previously said that these charities could limit their activity to particular diseases. In this Bulletin the OIG expresses concern that some charities may be defining disease categories too narrowly and advises that, to avoid risk, categories should be defined in accordance with “widely recognized clinical standards and in a manner that covers a broad spectrum of available products.”

### One-Year Transition Period

The Bulletin expresses the OIG’s concern that there may not be enough independent charity PAPs in operation when Part D goes into effect on January 1, 2006. Therefore, the OIG indicates that it will exercise its enforcement discretion in taking action in 2006 against pre-existing manufacturer PAPs provided that they are taking steps to transition their enrollees to independent charities or other arrangements. The Bulletin also outlines other steps that PAPs should take to reduce their legal risk during the transition year.

### **“Coalition Model” PAPs**

The OIG notes the development of some early efforts to offer discounts to Part D beneficiaries by multiple pharmaceutical companies jointly offering a discount card or similar mechanism. The Bulletin states a number of criteria that such a program should meet to reduce the risk of illegal inducement.

### **Bulk Replacement Models**

The Bulletin briefly addresses programs in which pharmaceutical companies provide free drug in bulk to clinics and other entities for dispensing to needy patients and identifies various factors that the OIG would consider in evaluating such a program.

The OIG Bulletin is available by clicking [here](#).

