DRUG & PHARMACY ALERT

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Department of Health and Human Services Issues Special Advisory Bulletin on Independent Charity Patient Assistance Programs

By **Brian E. Dickerson**

The Department of Health and Human Services (HHS) Office of Inspector General (OIG) recently issued a Supplemental Special Advisory Bulletin concerning Independent Charity Patient Assistance Programs (PAPs). The Supplemental Bulletin updates the OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees that published in the Federal Register on November 22, 2005 and expands upon the guidance issued in the 2005 Special Advisory.

PAPs have long assisted many patients who cannot afford their cost-sharing obligations for prescription drugs. The OIG notice recognizes that independent charities can help financially needy beneficiaries with their health care expenses, and notes that pharmaceutical manufacturers can donate to these charities. However, charities that are not sufficiently independent from drug manufacturer donors may operate PAPs that harm patients and Federal health care programs and may, depending on the facts, violate fraud and abuse laws. The Supplemental Bulletin expands upon the previous guidance, focusing particularly on disease funds and legitimate co-pay waivers for prescribed medications from such funds.

The 2005 Special Advisory recognized that bona fide independent charities might reasonably focus their efforts on patients with particular diseases and that, in general, a pharmaceutical manufacturer's donations to an independent charity "are earmarked for one or more broad disease funds should not significantly raise the risk of abuse." However, the OIG finds that since the 2005 Advisory, it has become aware that some PAPs are, in fact, establishing narrowly defined disease funds and covering a limited number of drugs within those funds. To address this concern, the OIG states in the Supplemental Bulletin that a charity with narrowly defined disease funds may be subject to enhanced scrutiny if the disease 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 donors' products."

The OIG Supplemental Bulletin goes further and notes that a fund will also be subject to more scrutiny if it is "limited to a subset of available products, rather than all products approved by the Food and Drug Administration (FDA) for treatment of a disease state(s) covered by the fund or all products covered by the relevant Federal health care program when prescribed for the treatment of the disease states (**including generic or bioequivalent drugs**)." [Emphasis added]

The Supplemental Bulletin concludes by stating that, in short, disease funds should be defined in accord with widely recognized clinical standards and in such a manner that it covers a broad range of drug products. Those that are narrowly defined or limited in coverage raise serious questions of fraud, waste and abuse if they are not sufficiently independent from donors.

Roetzel's health care, drug and pharmacy attorneys are available to assist you with any questions regarding the interpretation or implementation of the recently issued Supplemental Bulletin or the 2005 Special Advisory Bulletin that it updates and expands. It is imperative to properly analyze the PAP

before engaging in any co-pay assistance program. Please contact the following Roetzel attorneys for further information:

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