



CLIENT ADVISORY

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Mokena: 19065 Hickory Creek Drive, Suite 220, Mokena, IL 60448 (708) 479-3230
Bloomington: 1003 Martin Luther King Drive Bloomington, IL 61701 (309) 820-6026

Pharmaceutical Manufacturer Patient Assistance Programs

The Office of Inspector General (“OIG”) recently issued an opinion regarding a non-profit corporation’s program, which arranges for pharmaceutical manufacturer patient assistance programs to provide donated drugs to free clinics and Federally qualified health centers (“FQHCs”) for use by financially-needy patients who do not have outpatient prescription drug insurance coverage (the “Arrangement”). This opinion answered the question “Would this Arrangement constitute grounds for the imposition of sanctions under the Social Security Act (“Act”) or the civil monetary penalty provision of the Act.”

Based on the facts presented to the OIG, the OIG concluded it would not impose administrative sanctions and the Arrangement would not constitute grounds for the imposition of civil monetary penalties under the Act.

The entity requesting the opinion is a non-profit, tax exempt organization that serves as a liaison between the pharmaceutical industry and free clinics and FQHCs. This entity entered into a written agreement with a pharmaceutical company in which affiliated free clinics and FQHCs receive free drugs from the pharmaceutical company’s bulk replacement patient assistance programs (“PAP”).

Under the agreement, the donated drugs may only be distributed to patients whose incomes are less than 200% of the Federal Poverty Level and who do not have any form of outpatient prescription drug insurance. PAP drugs may not be dispensed to Medicare Part D enrollees or Medicaid patients. Patients are not enrolled under this Arrangement and the affiliated free clinic and FQHCs are responsible for documenting patient eligibility before dispensing the drugs. In addition, the agreement between the entity and the pharmaceutical company prohibits the sale of any of the donated PAP drugs and the transferring of any PAP drug to any third party other than the qualifying patients.

The free clinics and FQHCs must meet the following

criteria: i.) Must operate its own licensed pharmacy that complies with applicable Federal and state laws; ii.) Must be a 501(c)(3) tax-exempt organization organized for the purpose of providing health services to low-income patients; iii.) Must agree to screen for patients whose income is at or below 200% of the Federal Poverty Level and who do not have any form of outpatient prescription drug insurance; and iv.) Must agree to cooperate with compliance monitoring of program requirements by the entity.

This opinion is limited to the requestor of the opinion. No other individual or entity may rely upon this opinion.

For more information please contact Popovits & Robinson at 708/479-3230.

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