HEALTH CARE

Legal News Alert℠

FOLEY

FOLEY & LARDNER LLP

FEBRUARY 15, 2008

Legal News Alert is part of our ongoing commitment to providing up-to-the minute information about pressing concerns or industry issues affecting our health care clients and colleagues.

If you have any questions about this alert or would like to discuss this topic further, please contact your Foley attorney or any of the following individuals:

Jeannine Y. McGregor
Los Angeles, California
213.972.4680
jmcgregor@foley.com

Diane Ung
Los Angeles, California
213.972.4669
diane.ung@foley.com

Shirley P. Morrigan
Los Angeles, California
213.972.4668
smorrigan@foley.com

Lena Robins
Washington, D.C.
202.295.4790
lrobins@foley.com

Judith A. Waltz
San Francisco, California
415.438.6412
jwaltz@foley.com

OIG Advisory Opinion Approves Arrangement Involving Prescription Drug Donations to Free Clinics and Federally Qualified Health Centers

On February 1, 2008, the Department of Health and Human Services Office of Inspector General (OIG) issued Advisory Opinion No. 08-01, which approved an arrangement involving the participation of federally qualified health centers (FQHCs) and free clinics in "bulk replacement" patient assistance programs (PAPs). Since April 2006, the OIG has issued a series of Advisory Opinions approving PAPs but this is the first time the OIG has ruled on the application of the anti-kickback statute to bulk replacement PAPs. The request was submitted by a non-profit corporation, which arranged for FQHCs and free clinics to dispense drugs that were donated by PAP programs.

The OIG concluded that the proposed arrangement would not violate the anti-kickback statute or the prohibition on inducements to Medicare beneficiaries contained in the civil monetary penalties statute.

A bulk replacement PAP is an arrangement that allows pharmaceutical companies to donate drugs from the company's bulk replacement to FQHCs and free clinics. Bulk replacement PAPs provide a bulk volume of free drugs (typically on a monthly or quarterly basis) to hospitals, pharmacies, health centers, clinics, and other institutions to replace drugs dispensed to patients who meet established PAP criteria. Participating FQHCs and free clinics must agree to distribute the free drugs only to patients whose incomes are less than 200 percent of the federal poverty level and who do not have any form of outpatient prescription drug coverage. Accordingly, donated PAP drugs may not be dispensed to Medicare Part D enrollees or Medicaid patients. As the OIG recognized, PAPs provide important safety net assistance to these uninsured patients with limited means.

In rendering its opinion, the OIG raised concerns that the proposed arrangement may be: (i) a possible inducement for the FQHCs or free clinics to purchase other products from the pharmaceutical sponsors; or (ii) create an improper influence on the prescribing patterns of physicians working at the clinics. Although the OIG acknowledged these potential compliance issues, it concluded that there were sufficient safeguards in the arrangement between the nonprofit group and the drug companies to mitigate risks to the federal health programs. In analyzing the compliance risks associated with bulk replacement PAPs, the OIG reconsidered many of the safeguards applied in Advisory Opinion 06-03, which opined on PAPs operated for Part D enrollees.

FOLEY

FOLEY & LARDNER LLP

Of the safeguards discussed in this Advisory Opinion, the following summarizes those cited by the OIG as mitigating potential compliance risks:

- The pharmaceutical bulk replacement system is structured to protect against FQHCs and free clinics receiving any remuneration, including excess inventory that could be diverted to other uses
- The arrangement is appropriately documented, monitored, and audited to ensure transparency
- The arrangement is structured to prevent PAP sponsors from "cherry-picking" certain FQHCs or free clinics as recipients of the donated drugs
- The program ensures the independent judgment of the prescribing physicians because they do not receive compensation that takes into account their prescribing patterns for the provided drugs
- The arrangement protects the FQHCs and free clinics from the inappropriate influence of the PAP sponsors because of their formulary decision-making processes

A copy of the advisory opinion may be accessed here: http://www.healthlawyers.org/email/pg/080204ao/AO_08-01.pdf.

ABOUT FOLEY

Foley & Lardner LLP is a national law firm providing comprehensive legal services for innovative enterprises in the health care, pharmaceutical, biotechnology, and biomedical sectors. Our Health Care attorneys provide counsel on financial transactions, mergers, acquisitions, affiliations, joint ventures, regulatory and government compliance, and business operations. With offices throughout the United States and the backing of Foley's Health Care Industry Team — consistently ranked as one of the top health care law firms nationally and regionally by *Chambers USA* — Foley is well-positioned to serve the wide-ranging needs of health care entities across the country.

Foley.com