



OIG Advisory Opinion 08-01

Approves Bulk Replacement PAP Arrangement for FQHCs and Free Clinics

In its first advisory opinion of 2008, the OIG approved an arrangement involving the participation of Federally Qualified Health Centers (FQHCs) and free clinics in certain “bulk replacement” patient assistance programs. This opinion represents the first time that the OIG has specifically ruled on the application of the anti-kickback statute to bulk replacement PAPs.

Bulk replacement PAPs provide free drugs in bulk quantities—typically on a monthly or quarterly basis—to hospitals, clinics and other safety net providers to replace drugs dispensed to patients who meet established PAP criteria. They are often more efficient than individual application model PAPs because, among other advantages, they provide needy patients with immediate access to the medications and are easier to monitor against diversion.

The opinion reviews an arrangement developed by the Rx Drug Access Partnership of Virginia (Rx Partnership), a tax-exempt organization formed to promote access to prescription drugs for uninsured patients. The Rx Partnership seeks to make it easier for drug manufacturers to offer their bulk replacement PAPs to free clinics and FQHCs affiliated with the Rx Partnership by imposing uniform PAP operating standards on the affiliates, including requirements that they:

- Maintain separate, auditable records for all PAP drugs;
- Maintain systems for separating PAP inventory from other purchased product;
- Implement a computerized dispensing system that will generate electronic reports for monitoring compliance with The Rx Partnership requirements; and
- Agree to submit to annual on-site compliance audits.

The OIG analyzed whether the Rx Partnership’s model would potentially violate the anti-kickback statute (41 U.S.C. § 1320a-7b(b)), or the prohibition on inducements to Medicare beneficiaries contained in the civil monetary penalties statute (42 U.S.C. § 1320a-7a(a)(5)). Although the Rx Partnership limits utilization of the PAP drugs to uninsured patients with income below 200% of the federal poverty limit (including Medicare beneficiaries who are not enrolled in Part D), the arrangement raised potential compliance risk as a possible inducement for the affiliates to purchase other products from the sponsors that are payable by a federal health care program, or as an improper influence on the prescribing patterns of physicians working at the affiliates. The OIG concluded that the arrangement could potentially implicate these laws, but nevertheless approved the arrangement, citing the following safeguards:

1. The inventory replenishment model developed by the Rx Partnership protects against clinics and FQHCs receiving excess stock that could be diverted to other uses.
2. The arrangement is documented, monitored, and auditable, which assures transparency.
3. Manufacturers are not able to “cherry pick” clinics or FQHCs for participation based on their use of other program-reimbursable products.
4. The program protects the independent judgment of prescribing physicians.
5. In its liaison capacity, the Rx Partnership insulates the FQHCs from potentially inappropriate influence on their formulary decision-making process.

Importantly, the OIG also noted that the arrangement provides substantial community benefit by serving financially needy patients who lack outpatient prescription drug coverage, and by helping FQHCs continue to serve as a vital part of the health care safety net.

The advisory opinion is available at
<http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-01C.pdf>