



CMA Weekly Alert – May 4, 2006

PRESCRIPTION DRUG PATIENT ASSISTANCE PROGRAMS (PAPS) MAY WORK FOR SOME MEDICARE PART D ENROLLEES

Many large pharmaceutical companies offer Patient Assistance Programs (PAPs) to assist qualifying individuals receive high-cost medications at reduced- or no-cost. Without these programs, many individuals would not be able to afford medically necessary drugs.

PAPs operating outside of Medicare Part D that offer free or reduced-cost prescription drugs - mostly to persons with low incomes and no insurance - may still be able to offer assistance to Medicare beneficiaries, according to an advisory opinion released April 18 by the Office of the Inspector General (OIG) [OIG Advisory Opinion No. 06-03]. The opinion warns that its approval applies only to programs offered by the company that requested the opinion (Schering-Plough), and urges each individual PAP to seek an approval, rather than use this advisory opinion as guidance.

The continued existence of PAP assistance for Medicare beneficiaries was put into question recently with the strict rules governing pharmaceutical companies' ability to contribute to beneficiary's drug costs without violating the anti-kickback statute. That statute prohibits offering or receiving payment to increase the use of products or services (in this case, to steer prescription drug use) at the cost of federal health care programs. The latest opinion offers qualified confirmation that PAPs are permissible provided they function within certain parameters, while pointing out that that PAP drugs will not count toward an individual's Medicare Part D true out-of-pocket (TrOOP) costs and cannot be billed to any third party, including Medicare.

The advisory opinion, which was requested by Schering-Plough for its two PAPs, has quelled many fears that arose after the OIG published a special advisory bulletin November 22, 2005 [70 Fed.Reg. 70623] which evaluated how four different types of PAPs might violate the anti-kickback statute. The 2005 bulletin resulted in many companies choosing to discontinue their PAPs for Medicare beneficiaries. Since then, PAPs have sought more definitive guidance from the OIG. The new advisory opinion, though it applies only to the Schering-Plough programs, seems to confirm that PAPs that adhere to the guidance from the November 2005 bulletin, and more specifically, that operate completely outside of Medicare Part D, will not be in violation of the anti-kickback statute.

As described in the November 2005 bulletin, "PAPs Operating Outside Part D" would be at a "reduced risk" of violating federal anti-kickback rules, provided that:

- The PAP includes safeguards to ensure that Part D plans are notified that the drug is being provided outside the Part D benefit so that no payment is made for the subsidized drug by any Part D plan and no part of the costs of the subsidized drug is counted toward any beneficiary's Part D true out-of-pocket costs (TrOOP) when calculating whether the beneficiary is eligible for Part D's catastrophic coverage;
- The PAP provides assistance for the whole Part D coverage year (or the portion of the coverage year remaining after the beneficiary first begins receiving the PAP assistance);
- The PAP assistance remains available even if the beneficiary's use of the subsidized drug is periodic during the coverage year;
- The PAP maintains accurate and contemporaneous records of the subsidized drugs to permit the Government to verify the provision of drugs outside the Part D benefit;
- Assistance is awarded based on reasonable, uniform, and consistent measures of financial need and without regard to the specific providers, practitioners, or suppliers used by the patient or the Part D plan in which the patient is enrolled; and
- The arrangement complies with any then-existing guidance from CMS.

The 2005 bulletin also encourages PAPs to coordinate with Part D plans so that those Part D plans can operate their own drug utilization review and medication therapy management programs.

The latest advisory opinion assesses Schering-Plough's programs based on these criteria. Though the OIG agrees that Schering-Plough has taken appropriate safeguards to avoid violations of the anti-kickback statute, it concludes that "the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute...but that the OIG would not impose administrative sanctions...in connection with the Arrangement."

Schering-Plough has two patient assistance programs. The first, Commitment to Care, offers free outpatient prescription drugs for cancer and hepatitis. It provides assistance to those with incomes below 325% of Federal poverty (or 340% in some areas). Medicare beneficiaries must meet an additional test requiring that their prescription drug expenses exceed 3% of their annual household income. The second program, SP-Cares, offers allergy, asthma, dermatology and cardiovascular prescription drugs. It has an income limit of 250% of Federal poverty, and as with Commitment to Care, there is also a 3% test for Medicare participants. Applicants for either program are required to apply for all other assistance, such as Medicaid and Medicare, before they can be accepted by the PAP. Beneficiaries who have not enrolled in Part D are required to apply to, and be rejected by, the low-income subsidy. They must also attest that they cannot find an affordable Part D plan, in order to be eligible to participate in the PAP.

Merck and AstraZeneca will also continue to allow Medicare beneficiaries to enroll in their PAPs. These drug companies, however, did not receive advisory opinions from the OIG.

Patient Assistance Programs have been a vital source of drug coverage for many low-income beneficiaries, and may continue to help those for whom Part D remains too costly. As many PAPs are predicated on income, but not asset limitations, they may be particularly useful for

beneficiaries who were rejected from the Part D low-income subsidy because their assets were too high. An enrollee who needs a drug that is on their plan's highest cost-sharing tier may also benefit from receiving those drugs through a PAP.

For more information about Patient Assistance Programs available to Medicare beneficiaries, see:

Schering-Plough

PAPs http://www.schering-plough.com/schering_plough/pc/patient_programs.jsp

Part D http://www.schering-plough.com/schering_plough/news/release.jsp?releaseID=844149

Merck

PAP <http://www.merckhelps.com/patientassistance/>

Part D http://www.merck.com/newsroom/press_releases/corporate/2006_0302.html

AstraZeneca

<http://www.astrazeneca-us.com/pap/>

OIG Advisory Opinion

<http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-03F.pdf>

OIG Special Advisory Bulletin

<http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-23038.pdf>

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