



**CMS Perspective
on
Pharmaceutical Company Patient Assistance Programs
January 25, 2006**

- The decision to keep a patient assistance program is up to the pharmaceutical company, not the US government. The terms of the programs are determined by the company, without any government involvement.
- There is nothing in the law that prohibits a pharmaceutical company patient assistance program from providing drug assistance to Medicare beneficiaries, even those enrolled in a Medicare prescription drug plan, but that help has to be *outside* the Medicare coverage – just as it has been until now.
- No company needs to end its patient assistance program on account of the drug benefit starting. Lawful avenues exist for pharmaceutical companies and others to help Part D beneficiaries with their drug costs. Pharmaceutical company patient assistance programs may elect to provide free drugs to financially needy Medicare Part D enrollees outside the Part D benefit. In these circumstances, the beneficiary obtains the patient assistance program drugs without using his or her Part D insurance benefit.
- Specifically, pharmaceutical company patient assistance programs **can** provide coverage for particular drugs that are included in the Medicare drug benefit. This assistance would remain independent of the Medicare drug coverage, as it was before 2006. Any assistance a pharmaceutical patient assistance program provides to a Part D enrollee for prescription drugs that would have been covered under his or her Part D plan would not count as an incurred cost that would be applied toward the enrollee's true out-of-pocket costs (known as "TrOOP") balance or total drug expenditures. In other words, beginning when a beneficiary's assistance under a patient assistance program became effective, no claims for payment for any covered outpatient prescription drug provided outside of the Part D benefit may be filed with a Part D plan or the beneficiary, and the assistance must not count toward the beneficiary's TrOOP or total Part D spending for any purpose.
- In fact, a company can continue its patient assistance program at a much lower cost than in the past, because most of the seniors eligible for pharmaceutical company patient assistance programs now have access to very comprehensive coverage through the Medicare program's Limited Income Subsidy.
- Nothing in any Office of the Inspector General (OIG) laws, regulations, or guidance prevents pharmaceutical company patient assistance programs from providing free or reduced price outpatient prescription drugs to uninsured patients and Medicare beneficiaries who have not enrolled in Part D.

- In addition, as outlined more fully in the OIG guidance, lawful avenues exist for pharmaceutical company patient assistance programs to assist financially needy Part D enrollees. The OIG has issued a Special Advisory Bulletin addressing the application of the fraud and abuse laws to pharmaceutical company patient assistance programs (see <http://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/PAPAdvisoryBulletinFinal-Final.pdf>).
 - The Bulletin explains that pharmaceutical companies face a heightened risk of liability under the fraud and abuse laws if they assist Part D enrollees by paying all or a portion of the Part D cost-sharing amounts owed by the Part D enrollees for the company's products. For reasons explained more fully in the OIG's Bulletin, these types of cost-sharing subsidies pose all the usual risks of fraud and abuse associated with kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries' incentives to locate and use less expensive, equally effective drugs.
 - The Bulletin also makes clear that pharmaceutical companies may choose to provide free or reduced price drugs to financially needy Part D beneficiaries, so long as the assistance program is properly structured and the free or reduced price drugs are provided entirely outside the Part D benefit. They may also choose to make cash donations to bona fide, independent charities that assist Medicare beneficiaries with drug expenses.
- For example, suppose Ms. Smith has qualified for a patient assistance program for a particular, costly cancer drug. She signs up for Part D for her other medications, but her income and assets are too high to qualify for the Part D low-income subsidy. The pharmaceutical company could continue to provide her cancer drug through their patient assistance program, so that Ms. Smith continues to face the same out-of-pocket costs for the cancer drug as she did before. Ms. Smith would not get coverage from her Part D plan for the cancer drug. Because the pharmaceutical company would only need to provide such coverage for Medicare beneficiaries with incomes that are limited but too high to qualify for the low-income subsidy, the company could continue the assistance program for people like Ms. Smith at a significantly lower cost than before Part D began.
- If a company chooses to do so, it can have a "win-win": significantly lowering the cost of its patient assistance program compared to before the drug benefit, so that it can help more people getting drugs they need, and at the same time they can make sure that all people who have depended on the pharmaceutical company's patient assistance program in the past can get the same or more help.
- OIG guidance states that companies may enter into data sharing agreements with CMS to facilitate plan tracking of beneficiary drug utilization. CMS will work with companies interested in pursuing a data sharing agreement in accordance to the OIG guidance.