LEGAL CORNER

Patient Assistance Programs Revisited

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Last fall, the U.S. Department of Health and Human Services' Office of Inspector General (OIG) issued two advisory opinions, OIG Advisory Opinion No. 06-14 (Sept. 26, 2006) and No. 06-21 (Nov. 9, 2006) that describe the safeguards necessary for patient assistance programs to prevent fraud and abuse and to preserve the integrity of the Part D program. These advisory opinions conclude that "properly structured" patient assistance programs that operate outside the Medicare Part D benefit may not risk enforcement under the federal Anti-Kickback statute. This is promising news for patients and providers, as many patient assistance programs continue to provide crucial, often costly medications to qualified financially needy patients who are enrolled in Medicare Part D but who do not qualify for the low-income subsidy and cannot afford the Part D cost-sharing obligations.

Specifically, these two advisory opinions address the issue of whether fixed cost-sharing obligations or fees paid by Medicare Part D enrollees for prescription drugs provided by a patient assistance program, but outside the Part D benefit, should count toward the enrollee's true-out-of-pocket expenditures for the Part D benefit. (Providing drugs "outside" the Part D benefit means, in effect, to ensure that no payment is made by the Part D plan and no cost of the subsidized drug counts toward the enrollee's cost sharing.)

In both advisory opinions, the OIG concluded that sufficient safeguards were in place to mitigate the risk that patient assistance program benefits would be used to tie Part D enrollees to a particular prescription drug, and that patient assistance program drugs would not be used to increase Medicare expenditures through, for example, increasing the number of enrollees eligible for Part D catastrophic coverage.

In general, a Part D enrollee's pharmaceutical expenses only count toward true-out-of-pocket costs if paid for by:

- The Part D enrollee directly, or through a flexible spending or health savings account
- Another person on behalf of the Part D enrollee, such as a friend, charity patient assistance program, or family member
- CMS' federal low-income subsidy program
- A federally qualified state patient assistance program.

In addition, any other costs *not* paid for by a patient assistance program, annual Part D cost-sharing program, or a similar third-party arrangement. In other words, nearly all funds paid by or on behalf of the Part D enrollee to cover costs for Part D drugs count toward the enrollee's true-out-of-pocket costs.

Additionally, nominal co-payments submitted by a patient are also "incurred costs" aggregated toward true-out-of-pocket expenditures. As CMS explained in an Oct. 4, 2006 memorandum to Part D sponsors, patient assistance programs may require Part D enrollees to pay a nominal co-payment for a prescription drug provided by the program. CMS advises, however, that a patient assistance program operating outside the Part D benefit should never submit such claims for an enrollee to the Part D plan. Rather, enrollees are responsible for submitting claims for co-payments to the Part D plan sponsor, which will then calculate the enrollee's total true-out-of-pocket costs.

The patient assistance program structures outlined in AO 06-14 and AO 06-21, in effect, separate the particular patient assistance program prescription drug from the Part D benefit and ensure that the Medicare program, the Part D plan, and the enrollee do *not* pay for the balance of the cost of the drug. Neither patient assistance program provides free prescription medication. Rather, the patient assistance program in AO 06-14 requires qualified participants to pay a $25 fee for each month's supply of the drug, which is dispensed by a mail order pharmacy. Similarly, the patient assistance program in AO 06-21 requires participants to pay a fixed cost-share based on the patient's income and the supply of the drug dispensed.

In both cases, participants must demonstrate financial need to receive patient assistance program-sponsored prescription drugs. Moreover, once a participant enrolls in the patient assistance program for a given year, assistance continues for the remainder of the year regardless of whether the use is periodic during the coverage year.

Communication is the key to ensuring that the patient assistance program bears the cost, rather than Medicare, the PDP, or the enrollee. In these two advisory opinions, the patient assistance programs envision a data-sharing arrangement with CMS to notify Part D plans of a Part D enrollee's participation in the patient assistance program, and to safeguard against Part D plan payment for the drug. This data-sharing mechanism ensures appropriate and continued drug use and medical therapy management.

Given the high costs of many cancer drugs, oncologists should determine whether their Part D patients who demonstrate sufficient financial need, but who do not qualify for Medicare's low-income subsidy, can take advantage of prescription medications provided through patient assistance programs.

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