LEGAL CORNER

OIG Clarifies Role of Patient Assistance Programs under Medicare Part D

by Stephen R. Bentfield, Esq., and Tara E. Swenson

Implementation of the Medicare Part D program concerned some patient assistance programs, in particular, those sponsored by pharmaceutical manufacturers.

The problem began last year when the Office of Inspector General (OIG) for the Department of Health and Human Services issued a ***Special Advisory Bulletin*** (Nov. 7, 2005) warning of potential fraud and abuse issues related to patient assistance programs and Medicare Part D enrollees. Specifically, the OIG found that manufacturer patient assistance programs present the usual fraud and abuse risks associated with kickbacks:

- Potentially steering enrollees to particular drugs
- Increasing Medicare costs
- Potentially providing financial advantages over competing drugs
- Reducing enrollee incentives to locate and use less expensive, equally effective drugs.

Manufacturer response quickly followed. Some pharmaceutical companies reported that they would eliminate their patient assistance programs for Medicare beneficiaries. Others said they would provide Medicare beneficiaries with the option of enrolling in the Part D program or continuing to receive medications through the patient assistance program. Because these programs are often the only option for low-income oncology patients placed on expensive anticancer regimens, these reports alarmed the oncology community.

Two subsequent OIG Advisory Opinions have since clarified this issue. While they provide insight into the OIG's current position, keep in mind that Advisory Opinions are issued only to the requestor and cannot be relied upon by any other individual or entity.

In ***OIG Advisory Opinion No. 06-03*** (April 18, 2006) the agency explained that while manufacturer-sponsored patient assistance programs generally pose significant kickback risks, those risks could be minimized if the manufacturer used proper safeguards.

In this specific instance, the manufacturer sponsored two patient assistance programs. Program A covered medications used to treat cancer and hepatitis, while Program B covered a broader range of medications. Both programs accepted Part D enrollees. To be eligible for Program A, patients must: 1) take drugs covered under Program A, 2) fall below 325 percent of the Federal poverty level, 3) have spent at least 3 percent of their household income on outpatient prescription drugs during that coverage year. Program B required enrollees to meet lower income standards, and required that drugs are shipped to the patient's physician.

The OIG found these patient assistance programs did *not* pose a high kickback risk because they:

1. Operated entirely outside of Part D. (Enrollees received their drugs without using Part D insurance benefits and the assistance did not count towards the enrollee's true out-of-pocket spending.)
2. Based eligibility upon financial need, not an enrollee's provider, supplier, Part D plan, or benefit spectrum.
3. Covered eligible individuals for the entire coverage period and required eligibility to be reassessed each year.

Additionally, the OIG supported the programs' commitment to maintaining accurate records of all medications provided to Part D enrollees and their efforts in working with the Centers for Medicare & Medicaid Services to ensure that no free drug provided to an enrollee is billed to Medicare or any Part D plan.

OIG Advisory Opinion No. 06-08 (June 27, 2006) concluded that a free clinic dispensing free prescription medications to eligible individuals also did not create prohibited kickbacks. In this situation, the clinic only treated uninsured individuals; it did not provide services for Medicare or Medicaid enrollees. In limited circumstances the clinic filled Medicare enrollees' prescriptions *if* the filling price was prohibitive; however, the clinic did not provide services to Medicare enrollees. Therefore, no prescription filled for a Medicare enrollee was generated from care received at the clinic.

While the clinic received 99 percent of its medication from manufacturer-sponsored patient assistance programs, the OIG found no prohibited remuneration, as the free clinic was not a Medicare or Medicaid provider. The OIG noted that the clinic never billed any insurer for services or prescriptions filled at the clinic; and the clinic received no compensation from any patient assistance program or program sponsor. Any benefits the clinic received inured to the public good by increasing availability of healthcare to underserved populations.

Bottom line: following OIG recommendations, manufacturers may be able to craft their patient assistance programs in such a way as to avoid potential fraud and abuse issues. In fact, OIG Advisory Opinion No. 06-08 states: "It should not be difficult for pharmaceutical manufacturers to structure PAPs [patient assistance programs] to provide drugs to Part D enrollees entirely outside the Part D benefit in a manner that poses little, if any, risk under the fraud and abuse laws."

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