



MEDICARE REPORT



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Manufacturer Patient Assistance Programs—Inside or Outside Part D?

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Recent guidance from the Department of Health and Human Services Office of Inspector General (OIG) provides a solution for pharmaceutical manufacturers seeking to continue offering prescription drug assistance to certain financially needy Medicare patients now that Medicare Part D has commenced.¹ The Part D benefit creates a dilemma for Medicare beneficiaries who do not qualify for the low income subsidy but still cannot afford the cost sharing obligations required under Part D, particularly in the coverage gap known as the “donut hole” (\$2,250 – \$5,100 of drug costs).

Many of these patients—who often have income levels between 150 percent to 200 percent of the federal poverty level—have been relying on manufacturer patient assistance programs (“manufacturer PAPs”) to receive their prescription drugs. These patients will be seriously harmed if pharmaceutical manufacturers exclude them from participating in their PAPs now that Part D is in effect.

¹ “Patient Assistance Programs for Medicare Part D Enrollees,” available at <http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/2005/PAPAdvisoryBllletinFinal-Final.pdf>.

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Prior guidance from the Centers for Medicare & Medicaid Services (CMS) raised the specter of fraud and abuse enforcement action against pharmaceutical manufacturers that provide support to Part D enrollees.² More recently, however, the OIG outlined its views on the application of the federal anti-kickback statute to manufacturer PAPs providing assistance to Medicare Part D enrollees. This guidance was amplified in a CMS “Q&A” related to the Part D program.³ The result of these two pieces of guidance is a reasonably clear roadmap for pharmaceutical companies to follow in restructuring their current PAPs to fit the new Part D environment.

I. Background

The new Medicare Part D prescription drug benefit has generated questions about whether manufacturer PAPs can provide assistance to Part D enrollees without violating federal fraud and abuse laws. In the context of Medicare Part D, manufacturer PAPs can raise compliance risk because the assistance that the PAP provides to a Part D enrollee may constitute an illegal inducement for the enrollee to use a particular manufacturer's drug, in violation of the anti-kickback statute.⁴

² “Part D Coordination of Benefits Guidance” at 25, available at http://new.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CobGuidance_07.01.05.pdf

³ CMS Frequently Asked Questions, ID# 6153, last updated 12/14/05 and available at <http://questions.cms.hhs.gov>

⁴ 42 U.S.C. § 1320a-7b(b). The anti-kickback statute is a criminal law that prohibits the knowing and willful offer, payment, solicitation, or receipt of remuneration in any form as an inducement or reward for the referral of business or the purchase of items or services payable by a federal health care program. The statute applies equally to both the offering party and the recipient of an illegal inducement.

The OIG views subsidies from manufacturer PAPs that are tied to the use of a particular product as being squarely prohibited by the statute. The risks the OIG has identified are twofold: first, manufacturer PAPs potentially can increase Medicare costs by moving enrollees through the donut hole more quickly, thereby reaching catastrophic coverage, which is paid by Medicare substantially on a cost basis; and second, product-specific manufacturer PAPs can inappropriately steer patients to use particular branded drugs, even where cheaper generics or alternative treatments might be available.

A violation of the anti-kickback statute is a felony punishable by imprisonment. In addition, the OIG has administrative authority to impose civil monetary penalties and to exclude a party from participation in federal health care programs for violations of the anti-kickback statute.⁵ Because the statute requires proof of criminal intent to violate the law, the application of the statute in any particular case depends upon the facts and circumstances of the arrangement.

The OIG Bulletin emphasizes that manufacturer PAPs may provide free or reduced price outpatient prescription drugs to Medicare beneficiaries who do not enroll in Part D.⁶ However, pharmaceutical manufacturers are reluctant to accept these patients into their PAPs for several reasons:

- First, manufacturers view their PAPs as a source of drugs for patients with no insurance and limited financial resources. Because Part D is a form of prescription drug insurance, they generally want to see patients take advantage of the Part D benefit before accessing a PAP.

- Second, most manufacturer PAPs are drug-specific and are unlikely to cover all of a patient's drug needs. Thus, patients may be better off enrolling in Part D if they have multiple prescriptions.

- Third, the decision not to enroll in Part D has long-term financial consequences for the beneficiary due to the late enrollment penalty.⁷ While a decision not to enroll in Part D might be beneficial in the short term because of the availability of a PAP, the patient will be faced with a substantial penalty if the patient's drug needs change or the PAP is terminated by the manufacturer. Manufacturers will not want to encourage patients to take these risks.

Consequently, the significance of the Bulletin lies in its description of other alternatives that manufacturers can follow to provide assistance to Medicare beneficiaries through PAPs without incurring compliance risk.

II. Impact of the OIG Bulletin and CMS Guidance

There are numerous ways that pharmaceutical companies provide assistance to low income patients who cannot afford to pay for their prescription drugs. One model—sometimes referred to as a charity or foundation PAP—involves cash contributions by manufacturers to independent charities, which then provide financial support to patients in meeting their out-of-pocket expense requirements.

⁵ 42 U.S.C. § 1320a-7a(a)(7) and 7(b)(7).; 42 C.F.R. § § 1003.102 and .105.

⁶ OIG Bulletin at 3.

⁷ The penalty for 2006 and 2007 is set at 1% of the base beneficiary premium for each uncovered month. 42 C.F.R. § 423.286(d)(3).

Another common model involves the donation of free drugs to patients directly. The OIG Bulletin, combined with the CMS guidance, indicates that the first model can be operated “inside” the Part D benefit, while the second model must be operated exclusively on the “outside.” The meaning of these different approaches is discussed below.

A. The Inside the Part D Benefit Model

The Bulletin makes clear that the OIG would prefer for manufacturers to support financially needy Part D enrollees by making charitable contributions to independent charities.

Assistance provided by a charity that is unaffiliated with a pharmaceutical manufacturer will not normally implicate the anti-kickback statute.⁸ Moreover, the support provided by these charities to Part D enrollees will count towards each recipient's out-of-pocket requirement for reaching catastrophic coverage, referred to as “true out-of-pocket expense” or “TrOOP;” in other words, these programs can operate “inside” the Part D benefit. The charity must be *bona fide*, however, meaning that it may not be controlled directly or indirectly by any pharmaceutical manufacturer. Consequently, a *bona fide* charity PAP may not be formed, funded, or controlled by a manufacturer or its affiliates, employees, or other agents, such as its wholesalers, distributors, or pharmacy benefit managers.⁹

A charity PAP must sever any links between manufacturer funding and patient support. For example, the charity cannot steer patients toward any particular manufacturer's products or attribute assistance to any particular manufacturer. Also, the charity may not focus on such a narrow category of disease or illness that it might act as a conduit for manufacturers to provide funds to patients using their specific drugs.¹⁰

Lastly, the OIG is critical of manufacturers making product donations to charities because they “have the effect of creating a direct correlation between the donation and use of a particular donor's product.”¹¹ In essence, the OIG's position is that a manufacturer may only make anonymous, cash donations to independent charities over which the manufacturer exerts no direct or indirect control.

The CMS guidance also emphasizes that the charity must make an independent determination of patient financial need, and the patient may not be required to use any particular product or supplies to qualify for support.

Unfortunately, the inside the Part D benefit model is not likely to replace the existing support framework provided by manufacturer PAPs to financially needy

⁸ OIG Bulletin at 9.

⁹ OIG Bulletin at 2, n.3.

¹⁰ A recent Wall Street Journal article illustrates the potential abuse that can result when charities establish funds to help patients with specific diseases that are treated with a narrow range of drugs. The charities solicit contributions from the manufacturers of those drugs, which enable the supported patients to continue insurance coverage for the drug treatment, and result in additional purchases of the drugs from the manufacturers contributing to the fund. Critics maintain that these arrangements enable drug companies to protect the prices of their most expensive drugs. Geeta Anand, *Through Charities, Drug Makers Help People – And Themselves*, Wall Street Journal, December 1, 2005, at A-1.

¹¹ OIG Bulletin at 9.

Medicare beneficiaries. The charitable foundation model provides supporting manufacturers with the least amount of recognition and good will for their charitable work. It is also much more expensive, as it requires cash rather than product donations, and the development and oversight of a foundation bureaucracy to administer the programs.

Industry sources point out that few foundation model PAPs exist today and those that do exist lack the capacity to assume the volume of free drugs being processed by company-run programs. In 2004, traditional and institutional PAPs reportedly filled approximately 22 million prescriptions with free drugs having a wholesale value of \$4.1 billion.¹² Therefore, notwithstanding the OIG's clear preference for the inside the Part D benefit model, it seems unlikely that it will be successful on a large scale.

B. The Outside the Part D Benefit Model

In the traditional PAP model, an individual applies for assistance by submitting an application to the sponsoring manufacturer and, if the application is accepted, the manufacturer donates free product to the individual. Use of this model with Medicare beneficiaries enrolled in Part D raises concerns under the federal anti-kickback law, according to the OIG Bulletin.

As a starting point, the OIG emphasizes that a manufacturer may not make cash payments or product donations to subsidize cost-sharing obligations of Part D enrollees for the manufacturer's product. The OIG views these types of subsidies as squarely prohibited by the anti-kickback statute. The OIG also believes that a traditional PAP runs a "heightened risk" of violating the anti-kickback statute if the PAP provides coverage (*i.e.*, free drugs) only during the Part D coverage gap.

In the Bulletin, however, the OIG suggests a model that manufacturers can adopt for their traditional, individual-application model PAPs to assist Medicare Part D enrollees without violating the anti-kickback statute. A manufacturer PAP may provide free drugs to financially needy Medicare Part D enrollees if it is done **entirely outside** the Part D benefit and if safeguards are implemented to protect against the support counting towards a patient's cost-sharing obligations.

The safeguards that the OIG recommends for manufacturers are as follows:

1. Notify Part D plans that particular drugs are being provided to an enrollee outside of the Part D benefit, thereby ensuring that no payment is made by the Part D plan for the drug and no part of the cost of the subsidized drug is counted toward the enrollee's cost-sharing obligation;
2. Make the assistance available to the patient for the whole Part D coverage year (or the remainder of the coverage year after the enrollee first begins receiving PAP assistance);
3. Cover periodic use of the drugs throughout the remainder of the coverage year (in cases where the enrollee's need for the drug is not continuous);
4. Maintain accurate and contemporaneous records of subsidized drugs;
5. Award assistance to enrollees based on reasonable, uniform, and consistent measures of financial need, and

¹² Pharmaceutical Research and Manufacturers of America (PhRMA), Partnership for Patient Assistance, Fact Sheet; available at https://www.pparx.org/help_uninsured.php.

without regard to the providers, practitioners, or suppliers used by the enrollee or the enrollee's Part D plan; and

6. Comply with any applicable CMS guidance.

PAP assistance provided by manufacturers under this "outside Part D" model would not help an enrollee meet his or her TrOOP requirement for reaching catastrophic coverage because it would not count as a patient incurred cost. Thus, enrollees receiving PAP assistance under this model would only be able to count qualified expenses arising from their non-PAP drugs as TrOOP.

The CMS Q&A clarifies that it will allow PAPs the option of providing assistance outside the Part D benefit. The PAP will remain responsible for establishing eligibility criteria, and CMS recommends (but does not require) that a PAP provide assistance to a patient through the end of the year once a patient has been accepted into the program. Alternatively, a PAP may limit the amount of assistance it will provide to a patient in the program, but the cap must apply uniformly to all enrollees, not just those participating in Part D. Further, CMS emphasizes that the cap cannot be triggered by the patient's becoming eligible for catastrophic coverage under the Part D benefit based on the purchase of other drugs.

Finally, CMS strongly recommends that manufacturer PAPs seeking to offer assistance outside the Part D benefit enter into voluntary data sharing agreements with CMS. These agreements would establish the PAPs as a type of third party payer for purposes of calculating TrOOP. Through a voluntary data sharing agreement, a PAP would exchange eligibility files with CMS at the time a Part D enrollee becomes a participant in the PAP, much like any other third party payer. The information would be used to exclude PAP support from the participant's TrOOP calculation. CMS' Coordination of Benefits (COB) Contractor would transmit this information to the Medicare Beneficiary Data Base and to the TrOOP Facilitator and Part D plans.

The TrOOP tracking system would alert Part D plans to implement system edits to protect them from making any payments for the type of drug provided by the PAP. CMS also notes that the data sharing agreements will enable a Part D plan to identify drugs that an enrollee is receiving outside the Part D benefit for the Part D plan's utilization review and medication therapy management programs.

This piece of advice is perhaps the most helpful item in the CMS Q&A. The OIG Bulletin requires manufacturer PAPs to notify Part D plans when providing drugs outside the Part D benefit, but does not specify a mechanism for assuring compliance. CMS' suggestion for voluntary data sharing agreements appears to be the solution. Manufacturer PAPs that enter into these agreements, and perform the "front end data exchanges" suggested by CMS, should be deemed to have met the notification requirements imposed by the OIG on the outside the Part D benefit model.

Thus, the CMS Q&A answers one of the significant questions left open by the OIG Bulletin.

III. The Remaining Gap In Guidance

Unfortunately, the combined guidance from OIG and CMS still leaves a significant question mark for a common type of PAP known as "institutional PAPs" or "bulk replacement programs." These manufacturer-

sponsored programs have proven to be very effective for assisting the uninsured poor because they deliver needed drugs to patients at the time of service and avoid significant waste caused under other PAP models when patient treatment changes occur before the drugs are dispensed.

Institutional PAPs provide free drugs in bulk volumes—typically on a monthly or quarterly basis—to hospitals, pharmacies, health centers, clinics, and other institutions to replace drugs dispensed to patients who meet established PAP criteria. Because the free drugs are donated to replace stock dispensed from the institutions' own inventory, these programs are also sometimes called "bulk replacement PAPs."

Institutional PAPs have proven to be a very cost-effective way for pharmaceutical manufacturers and safety net providers to help meet the prescription drug needs of the uninsured poor. Their chief advantages over the traditional PAP model are that institutional PAPs make drugs immediately available to patients in need; eliminate waste that results in the traditional PAP model when a patient fails to pick up his or her prescription, or the prescription or dosage changes before the drugs arrive (these drugs are frequently discarded); reduce paperwork and shipping costs; and improve documentation and tracking capabilities.

As a means of helping Medicare Part D enrollees meet their cost-sharing obligations, however, institutional PAPs are problematic. The OIG believes that institutional PAPs create the same heightened risk of violating the anti-kickback statute as traditional PAPs because they create an incentive for a safety net provider to steer Part D enrollees towards the sponsoring manufacturer's products.

In addition, institutional PAPs can create a compliance risk if participation in the PAP is either offered as an inducement for a safety net provider (typically a DSH hospital) to include a manufacturer's products in the provider's formulary or a safety net provider solicits a manufacturer to offer an institutional PAP in return for listing the manufacturer's drug(s) in the provider's formulary.

In evaluating a bulk replacement PAP, the OIG states that it will look to whether the PAP has safeguards to prevent (1) improper patient steering based on financial incentives, (2) increased cost to federal health care programs, and (3) improper charges to federal health care programs (e.g., by allowing free drugs to be credited toward a patient's TrOOP). Hospitals must also protect against the appearance that the inclusion of a manufacturer's products on the hospital's formulary is conditioned on the manufacturer's offering of an institutional PAP.

Assuming that appropriate safeguards are in place with respect to formulary decision-making, institutional PAPs are unlikely to encounter a compliance risk when serving uninsured patients and other individuals who are not beneficiaries of a federal health care program because the anti-kickback statute applies only with respect to federal health care program business.

Institutional PAPs may not, however, take advantage of the "outside of Part D" model suggested by the OIG

because it appears that they cannot meet criterion (5) of that model, which requires, in part, that the manufacturer award assistance without regard to the providers or suppliers used by the enrollee. Institutional PAPs are designed for pharmaceutical manufacturers to work collaboratively with designated safety net providers to assist their uninsured patients.

Thus, absent a favorable advisory opinion by the OIG, or unless the OIG issues a clarification of its position, it would not be prudent for institutional PAPs to provide assistance to Part D enrollees, even outside the Part D benefit.

Nevertheless, it is important to note that criterion (5) is designed to protect against inappropriate patient steering. Many hospitals participating in institutional PAPs have adopted safeguards to protect against the PAP becoming an inducement for a patient to select the particular hospital for care.

These safeguards include:

- A ban on advertising the availability of the institutional PAP;
- Informing the patient of the availability of the PAP only after he or she has visited an attending physician and been prescribed the drug;
- Nondiscrimination in accepting patients into the PAP (except for appropriate financial need criteria); and
- Advising the patient that participation in the PAP is not conditioned upon the use of the hospital for any other service.

A safety net provider participating in an institutional PAP that has adopted these types of safeguards may wish to seek an advisory opinion from the OIG authorizing it to extend support to Medicare Part D enrollees outside the Part D benefit. Institutional PAPs remain perhaps the most efficient model for manufacturers and safety net providers jointly to support financially needy Part D enrollees who do not qualify for the Part D subsidy.

IV. Conclusion

In summary, the OIG Bulletin clarifies the ground rules for manufacturer PAPs with respect to Medicare Part D. Manufacturer PAPs may provide support to Part D enrollees who reach the donut hole either through an inside the Part D benefit model—which requires support in the form of cash contributions to truly independent charities—or by serving patients entirely outside of the Part D program, where none of the manufacturer-provided support can count towards TrOOP.

In the outside the Part D model, the OIG requires the PAP to notify affected Part D Plans to insure that no additional payment is made by a Part D Plan for any drugs provided through a PAP. The CMS guidance indicates, however, that a PAP can satisfy this obligation by entering into a voluntary data sharing agreement with CMS to provide "front end" data exchanges to ensure that the PAP operates wholly outside Part D.

This approach should provide drug manufacturers with the regulatory compliance comfort they need to continue serving financially needy Medicare beneficiaries through their patient assistance programs.