DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR BENEFICIARY CHOICES

October 4, 2006

Memorandum To: All Part D Sponsors

Subject: HPMS Q & A - Patient Assistance Programs

From: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

The following question and answer on patient assistance programs operating outside the Part D benefit has been revised and updated in the Frequently Asked Questions Database on the CMS website at http://questions.cms.hhs.gov.

Q: Can patient assistance programs (PAPs) provide assistance with Part D drug costs to Part D enrollees outside of the Part D benefit and without counting towards TrOOP?

A: We have previously advised that drug payments made by PAPs on behalf of Part D enrollees could count toward TrOOP, unless these organizations qualify as group health plans, insurance or otherwise, or other similar third-party payment arrangements. However, we clarify that we will allow PAPs the option of providing assistance for covered Part D drugs on behalf of Part D enrollees outside the Part D benefit. Under this option, a PAP would operate outside of the Part D benefit, and any assistance it provides to a Part D enrollee for 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 TrOOP balance or total drug spend. In other words, when operating outside the Part D benefit (and beginning at the point at which a beneficiary's assistance under a PAP is effective), a claim for the drug for which a PAP had provided assistance would never be submitted to a beneficiary's Part D plan.

Operating outside the Part D benefit does not preclude a PAP sponsor from requiring its enrollees – including those enrolled in a Part D plan – from paying a nominal copayment when they fill a prescription for a covered Part D drug for which they provide assistance. We believe that any copayments assessed by PAPs operating outside the Part D benefit should be nominal, since only nominal beneficiary cost-sharing is consistent with the concept of operating outside Part D. Moreover, given that copayments are typically assessed for purposes of minimizing drug overutilization, the assessment of anything but nominal cost-sharing by PAPs is seemingly inconsistent with the mission of a charitable organization structured to provide assistance with prescription drug costs to low-income patients.

Although PAP payments made for those covered Part D drugs outside the benefit may never count toward enrollees' TrOOP or total drug spend balances, we clarify that any nominal

PAP copayment amounts paid by Part D enrollees will be aggregated to their TrOOP and total drug spend balances, provided the enrollees take responsibility for submitting the appropriate documentation to their plan. It will not be permissible, however, for beneficiary payments structured as administrative fees or premiums to be aggregated to Part D TrOOP and total drug spend balances, as these types of beneficiary out-of-pocket expenditures do not meet the definition of "incurred costs" at 42 CFR 423.100.

Enrollee submission of this documentation is necessary because a PAP operating outside the Part D benefit should never submit a claim for assistance provided for a covered Part D drug to a Part D enrollee's Part D plan. Consistent with our guidance on claims processing, plans should process these enrollee-submitted claims in the order in which they are received, not based on date of service.

As noted elsewhere, in order to facilitate implementation of this policy, plans should establish processes and clear instructions for enrollee paper claim submissions such that they can distinguish between claims submitted for : (1) out-of-network coverage; (2) adjustment to TrOOP balances based on wraparound payments by supplemental payers not previously submitted to the plan; (3) documentation submitted for a purchase made via a discount card or other special cash discount outside the Part D benefit in any applicable deductible or coverage gap phase of the benefit; and (4) documentation submitted for a copayment assessed by a PAP sponsor operating outside the Part D benefit for assistance provided with covered Part D drug costs. We plan to develop and share with plans model paper claims submission forms they can use or revise for these purposes.

The choice of whether to operate inside or outside the Part D benefit would be entirely at each individual PAP's discretion, although the PAP would still need to comply with the Federal fraud and abuse statutes. We note that the issue of establishing criteria for applicability of PAP assistance remains up to each individual PAP. PAPs have discretion to decide at what point financial burden triggers PAP assistance – for example, a set income level or an asset test or a ratio of drug cost to income or assets. [We note, however, that a criterion of being uninsured would be problematic because we do not consider a Part D enrollee in the benefit's coverage gap to be "uninsured" for purposes of a PAP's determination of financial need. Although a Part D enrollee may be required to pay 100 percent cost-sharing until he or she has accrued $3,600 in TrOOP expenditures, that individual continues to have coverage under the Part D plan given his or her access to negotiated prices and continued payment of premiums.]

Once a beneficiary satisfies a PAP's eligibility criteria, however, we believe the PAP should provide assistance through the end of the year. If, for budgetary reasons, a PAP declines to commit to providing assistance through the year, the PAP may decide to limit the amount of drug it will provide to any PAP enrollee. If a PAP decides to set such a cap, such cap should apply uniformly to all PAP enrollees - and not just to Medicare beneficiaries - and should be determined in a manner that is not directly or indirectly related to other drug expenditures by Part D enrollees. PAPs must not employ a cap to terminate PAP assistance in a manner designed to correlate with when the beneficiary's other drug expenditures might suffice to trigger catastrophic coverage under Part D or otherwise as a proxy for when Federal reimbursement would be available for the beneficiary's drugs. (Please refer to Appendix A

for some examples of how TrOOP and total Part D drug spend are affected depending on when enrollment in a capped program takes place and whether an enrollee surpasses the cap in a given coverage year).

The option of operating outside the Part D benefit, with or without the assessment of nominal enrollee copayments for assistance provided, will allow PAP sponsors to continue providing needed assistance to financially needy beneficiaries – those whose incomes are too high to qualify for the low-income subsidy, but whose incomes are low enough that out-of-pocket costs on drugs are still burdensome – while allowing the individual PAPs flexibility to determine the form of their donations and, if operated with sufficient safeguards, to use existing PAP programs to assist needy beneficiaries. We note, however, that we will be monitoring the impact of this guidance and reserve the right to revise it for future plan contract years..

We also emphasize that the most effective – and, ultimately, for the beneficiary, the safest – way for PAPs to operate outside the Part D benefit would involve front-end data exchanges with CMS through the use of PAP-specific trading partner agreements, which we will provide further information about in forthcoming guidance. General information about eligibility file exchange with supplemental payers and other entities is provided in our coordination of benefits guidance. To the extent that a PAP exchanges eligibility files with us, we will be able to flag it as a non-TrOOP eligible payer for the particular Part D drugs it provides Part D enrollees at no cost. This information would therefore be available to plans through the TrOOP facilitation process, and plans would be alerted to the fact that they must follow up with the PAP to identify the prescription drug provided outside the benefit. This, in turn, would allow plans to set their systems to recognize that drug as part of a patient's profile, while setting systems edits to prevent any payment for that prescription. As a result, a beneficiary will be able to obtain free product through the PAP without affecting either TrOOP or total drug spend amounts on plan PDE records. As a result of the data exchange process, the PAP will also receive information regarding its enrollees' Part D enrollment status.

To address safety concerns associated with prescription drugs provided outside the Part D benefits, the front-end data exchange process will enable, as described above, plans to follow-up with PAPs to identify those Part D drugs an enrollee is receiving outside the Part D benefit. This will facilitate plans' provision of required drug utilization review and, if applicable, medication therapy management program activities. If a PAP did not exchange information with CMS in the manner outlined above, such information would remain unknown to the plan, which could potentially lead to quality of care issues. For these reasons, we strongly encourage PAPs wishing to operate outside the Part D benefit participate in this process. Alternatively, a PAP could provide its enrollees with a notice they could provide to their Part D plans indicating that they are receiving one or more drug products from that PAP.

PAP sponsors, whether operating inside or outside the Part D benefit, remain responsible for complying with relevant fraud and abuse laws, including the anti-kickback statute. Liability under the anti-kickback statute requires a case-by-case analysis of the particular facts and circumstances, including the intent of the parties. However, to the extent that PAPs choose to operate within the Part D benefit, generally, the least problematic way of providing

assistance with the costs of covered Part D drugs to Part D enrollees is through support of independent PAPs operated by bona fide public charities without regard to donor interests. Properly structured, these programs can offer an alternative that reduces the risk of fraud or abuse. Among other things, the charity must make an independent determination of patient need, and the patient's receipt of assistance may not depend directly or indirectly on the patient's use of any particular product or supplier of drugs.

We have also received inquiries about the ability of PAPs to pay Part D premiums on behalf of enrollees or to provide free or discounted product through a coalition of manufacturers. Nothing in CMS rules and regulations prohibit such arrangements. We also note that organizations or entities offering patient assistance programs must comply with all relevant fraud and abuse laws, including, when applicable, the Federal anti-kickback statute and the civil monetary penalty prohibiting inducements to beneficiaries. The HHS Office of the Inspector General (OIG) enforces Federal fraud and abuse statutes, and all questions regarding the compliance of specific arrangements with these statutes should be referred to the OIG.

Examples of Impact on TrOOP and Total Part D Drug Expenditures in Capped Patient Assistance Programs

Scenario 1: Mrs. Jones enrolls in a PDP with a defined standard benefit with an effective coverage date of January 1, 2007. Mrs. Jones applies for assistance with her drug costs with PAP X. PAP X does not impose any nominal beneficiary cost-sharing, but finds that she meets the financial need criteria to receive $5,000 worth of free Drug ABC beginning January 1, 2007. Mrs. Jones uses $2,500 worth of free Drug ABC in 2007.

Donated Product	Dollar Value of Donated Product	Dollar Value of Donated Product Utilized	Impact on Total Drug Spend	Impact on TrOOP
ABC	$5000	$2500	$0	$0

Scenario 2: Mrs. Jones enrolls in a PDP with a defined standard benefit with an effective coverage date of January 1, 2007. Mrs. Jones applies for assistance with her drug costs with PAP X. PAP X does not impose any nominal beneficiary cost-sharing, but finds that she meets the financial need criteria to receive $5,000 worth of free Drug ABC beginning March 1, 2007. Mrs. Jones purchases $1,265 worth of Drug ABC between January 1 and March 1, 2007 and purchases no additional covered Part drugs. She then uses $2,500 worth of free Drug ABC between March 1 and December 31, 2007.

Donated Product	Dollar Value of Donated Product	Dollar Value of Donated Product Utilized	Impact on Total Drug Spend	Impact on TrOOP
ABC	$5000	$2500	$1265	$515 ($265 deductible plus 25% coinsurance on $1000)

Scenario 3: Mrs. Jones enrolls in a PDP with a defined standard benefit with an effective coverage date of January 1, 2007. Mrs. Jones applies for assistance with her drug costs with PAP Y. PAP Y imposes nominal cost-sharing of $5 for each prescription filled, and finds that she meets the financial need criteria to receive $5,000 worth of free Drug ABC beginning March 1, 2007. Mrs. Jones purchases $1,265 worth of Drug ABC between January 1 and March 1, 2007 and purchases no additional covered Part D drugs. She then uses $2,500 worth of free Drug ABC between March 1 and December 31, 2007. PAP Y imposes $50 of nominal beneficiary cost-sharing ($5 for each of 10 fills) between March 1 and December 31, 2007. Mrs. Jones submits the appropriate documentation to her PDP for all the nominal copayments assessed by the plan so that they may be aggregated to her TrOOP and total drug spend balances.

Donated Product	Dollar Value of Donated Product	Dollar Value of Donated Product Utilized	Impact on Total Drug Spend	Impact on TrOOP
ABC	$5000	$2500	$1315 ($1265 of total drug spend prior to March 1, 2007, plus $50 in nominal PAP copayments)	$565 ($265 deductible, plus 25% coinsurance on $1000, plus $50 in nominal PAP copayments)

Scenario 4: Mrs. Jones enrolls in a PDP with a defined standard benefit with an effective coverage date of January 1, 2007. Mrs. Jones applies for assistance with her drug costs with PAP X. PAP X does not impose any nominal beneficiary cost-sharing, but finds that she meets the financial need criteria to receive $5,000 worth of free Drug ABC beginning May 15, 2007. Mrs. Jones purchases $1,265 worth of Drug ABC between January 1 and May 15, 2007, and she purchases no additional covered Part D drugs. She then uses $5,000 worth of free Drug ABC between May 15 and November 1, 2007. Since she has reached PAP X's spending cap for Drug ABC, she begins to use her Part D benefit again for Drug ABC beginning November 1, 2007. She purchases $1,000 worth of Drug ABC between November 1 and December 31, 2007 (during this time period, she is in the coverage gap of the standard defined benefit given use of other covered Part D drugs throughout the year).

Donated Product	Dollar Value of Donated Product	Dollar Value of Donated Product Utilized	Impact on Total Drug Spend	Impact on TrOOP
ABC	$5000	$5000	$2265	$1515 ($265 deductible

				plus 25% coinsurance on 1st $1000 plus $1000 in coverage gap)

Please contact Alissa DeBoy at (410) 786-6041 if you have any questions about this guidance.