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Center for Beneficiary Choices
Medicare Plan Payment Group

Date: June 22, 2006

To: All Part D Plan Sponsors

From: Abby L. Block, Director
Center for Beneficiary Choices

Subject: Q&A Addressing Drug Costs Reported On Prescription Drug Events (PDEs)

On May 19th, CMS released a Q&A in response to questions concerning the reporting of drug costs on Prescription Drug Events (PDEs). The Q&A reflected the instructions CMS has consistently provided for reporting of prescription drug event data. Despite consistent guidance since April of 2005 for reporting prescription drug event data, CMS received concerns about the May 19th Q&A from various parties. Due to the June 5th Bid Submission deadline and possible misunderstandings as to CMS's consistent guidance, CMS released a memo on June 2nd instructing Part D sponsors to submit their bid information as planned prior to the distribution of the Q&A. CMS indicated that if the bids reflected a misunderstanding of CMS's instructions, then bidders would be permitted to amend their bids to reflect the May 19th articulation of CMS's consistent policy. Bidders would need to demonstrate how adopting the policy of the May 19th Q&A would alter the assumptions in their original bids.

Upon final review, CMS continues to believe that the May 19th Q&A merely restated CMS's consistent policy and reflected PDE instructions for both contract years 2006 and 2007. Any organization that misunderstood CMS's consistent policy and that believes the May 19th Q&A conflicted with the assumptions underlying their bid may request to amend their bid. The organization must demonstrate how the Q&A conflicts with their prior understandings. Plans must e-mail actuarial-bids@cms.hhs.gov with their request to amend their bids. This request must be received by Tuesday, June 27th at 11:59 p.m. EDT and must include the basis of the original bid submission and how the Q&A alters the bid development. This request must identify all of the plans for which the organization would like to amend. To the extent that sufficient documentation is provided, organizations will be notified that they have an opportunity to amend their bids. Sponsors will be permitted to amend their bids in order to reallocate costs between gross covered prescription drug costs and administrative expenses. While the total amount of the bid will likely increase, we expect gross covered prescription drug costs would decrease to reflect the lower amounts paid by the PBM to the pharmacy, rather than the amounts paid by the sponsor to the PBM. In addition, we would expect a corresponding increase in administrative expenses to account for any expected payments to the PBM

that are not included as allowable drug costs. If these amounts aren't known, the plan should make a reasonable estimate.

Upon final review, CMS has revised the May 19th Q&A with respect to contract year 2006. We have also made minor revisions to reflect the fact that the definition of "negotiated price" in 42 CFR 423.100 includes price concessions passed through at the point of sale. Plans are expected to continue their current operations for 2006 and are advised to consult the revised Q&A.

Further Information

If you have questions, please contact Meghan Elrington at (410) 786-8675.

Q&A

(revised as of June 22,2006)

Question: When reporting Prescription Drug Event Data, may the Plan Sponsor report the amount it pays to the PBM or must it determine and report the amount the PBM pays to the pharmacy?

Answer: The Plan Sponsor is required to report the amount ultimately paid to the pharmacy – not the amount paid to the PBM. In fact, the amount ultimately paid to the pharmacy by either the Sponsor or PBM must always be the basis for (i) calculating beneficiary cost sharing; (ii) reporting drug costs on the Prescription Drug Event (PDE) records, and (iii) developing bids submitted to CMS.

The above policy is required by the statutory and regulatory definitions of "allowable reinsurance costs" and "allowable risk corridor costs," which in both cases exclude any administrative costs of the Sponsor (including administrative fees paid to a PBM). By statute, "allowable reinsurance costs" are a subset of "gross covered prescription drug costs," and Congress specifically defined such gross costs as "not including administrative costs." 1860D-15(b)(2) and (3). Similarly, Congress defined "allowable risk corridor costs" as "not including administrative costs." 1860D-15(e)(1)(B). Our regulations at 42 C.F.R. 423.308 adopted these definitions. Because the PDE records are used to calculate both reinsurance and risk corridor payments, it is imperative that the amounts reported on such records exclude administrative fees paid to the PBM. Thus, the Ingredient Cost, Dispensing Fee, Sales Tax, Gross Drug Cost below the Out of Pocket Threshold (GDCB), and Gross Drug Cost above the Out of Pocket Threshold (GDCA) fields should never include administrative fees paid to a PBM – but rather should always reflect the final amount ultimately received by the pharmacy at the point of sale.

In addition, beneficiary coinsurance must be based on the amount paid to the pharmacy (minus any discounts, subsidies, rebates, or other price concessions that are passed through at the point of sale). According to our regulations at 42 C.F.R. 423.104, beneficiaries pay their applicable cost sharing based on the "actual costs" for covered Part D drugs. "Actual cost" is defined in 42 C.F.R. 423.100 as "the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy." "Negotiated prices" are "prices for covered Part D drugs . . . that are available to beneficiaries at the point of sale at network pharmacies. . . reduced by . . . discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations that the Part D sponsor has elected to pass through . . . at the point of sale." Therefore, beneficiaries are not responsible for paying cost-sharing on the plan's administrative costs but solely on the actual amount paid for the drug (including any dispensing fee) to the pharmacy by the plan or the plan's subcontracted PBM minus any rebates or price concessions passed through at the point of sale. Part D Sponsors are expected to take measures to ensure that beneficiary coinsurance is based on the amounts described above.

Also, when a Part D Sponsor contracts with a PBM that owns a mail-order pharmacy, the Sponsor must take special care that the PDE costs do not include administrative costs for PBM services. For example, the Ingredient Cost should not include any administrative costs, but should be an accurate reflection of the product purchased from the mail-order pharmacy in terms of manufacturer, strength, and acquisition price. In addition, while the Dispensing Fee reported may include overhead costs for operating the mail-order pharmacy, the Fee should not reflect other administrative costs of the PBM (such as operating a call-center for the Sponsor's plan, contracting with network pharmacies, or negotiating rebates with manufacturers). We are also concerned that in cases where the PBM owns the mail order pharmacy, the ingredient cost and dispensing fees may not reflect the fair market value and therefore will monitor these prices.

We have become aware that in some instances, the PDE records being submitted to us reflect the amount paid by a Sponsor to a PBM, and not the amount ultimately received by the pharmacy. In these cases, we view the higher fee reported on the claim (whether such fee is included in the Ingredient Cost or Dispensing Fee element) as reflecting administrative fees (including any profit margin) paid by the Sponsor to the PBM for administrative services (e.g., network access, use of the switch, call center services, formulary management). Including such higher fees on the PDE record has the effect of improperly including administrative costs in the reported drug costs, in violation of 42 C.F.R. 423.308 and the cost sharing requirements of 42 C.F.R. 423.104. Our expectation is that Sponsors will structure their contracts with PBMs such that the drug prices reported on the PDE record reflect the price paid to the pharmacy.

For the 2007 coverage year, all Sponsors are required to take whatever actions are necessary to comply with the regulatory reporting requirements. On the PDE record, Part D Sponsors or entities submitting on the Sponsors' behalf must report the price paid to the pharmacy, net of direct and indirect remuneration (DIR) reflected in the price at point of sale and net of administrative costs. Part D Sponsors' are reminded that administrative fees and DIR dollars are not interchangeable at any point in the reporting or payment processes. Administrative fees and DIR must be separately identified by the Part D Sponsor when (i) estimating their bid costs; (ii) reporting drug costs on the PDE net of both administrative costs and DIR reflected in point-of-sale pricing; and (iii) reporting all other DIR to CMS after the end of each coverage year for determination of allowable costs in reconciliation.

When developing bids for 2007, Part D Sponsors must (i) estimate gross prescription drug costs that do not reflect any administration costs, (ii) separately identify 100% of the plan's administrative costs performed by the plan, or by the plan's subcontracted PBM, as administrative costs and (iii) categorize these costs consistent with the instructions for reporting administrative costs on the bid tool. When contract arrangements cannot be finalized before June 2006, plans may submit estimates of their best expectation for 2007 costs for purposes of completing the bid tool.

Because plans have misunderstood CMS's policy for the 2006 year, we will permit plans to continue with current operations for 2006 and will not require any restatement of costs or change in operations.