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Center for Beneficiary Choices
Medicare Plan Payment Group

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To: All Part D Plan Sponsors

From: Tom Hutchinson, Acting Director
Medicare Plan Payment Group

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

In response to questions concerning the reporting of drug costs on Prescription Drug Events (PDEs), CMS is releasing the attached Question and Answer (Q&A). This Q&A clarifies how drug costs must be reported on PDEs, particularly when a Part D Sponsor has contracted with a Pharmacy Benefit Manager (PBM) for administrative services. For the purposes of reinsurance and risk corridor payments, it is imperative that the appropriate drug costs are reported on PDEs. This Q&A provides guidance which should help Part D Sponsors ensure that they are reporting the correct amounts.

Further Information
If you have questions about this Q&A, please contact Meghan Elrington at (410) 786-8675.

Q&A

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. 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." 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. Part D Sponsors are expected to take measures to ensure that beneficiary coinsurance is based on the amount paid to the pharmacy – so that beneficiaries are not paying any amount based on the Sponsor's administrative fees to a PBM. In addition, the amount paid by the beneficiary should reflect any point-of-sale price concessions.

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.

Because both the regulations and the statute were clear that allowable reinsurance and risk-corridor costs must not include any administrative costs, our expectation was that Sponsors would structure their contracts with PBMs such that the drug prices reported on the PDE record reflect the price paid to the pharmacy. However, we understand that in rare instances, for the 2006 coverage year, some Part D Sponsors' contracts with PBMs did not identify administrative fees separately from drug cost, and did not specify that PDEs would reflect the price ultimately paid to the pharmacy. In these rare cases, where (a) the contract does not distinguish these two costs and (b) the PDEs reflect the prices paid to the PBM inclusive of administrative fees instead of to the pharmacy, we will allow Part D Sponsors to report an estimate of the administrative costs paid to the PBMs in the 2006 reconciliation process. CMS will use this estimate in determining Part D Sponsor's allowable costs for purposes of making final payment and reconciliation for the 2006 coverage year. These estimates may be subject to further audit by our program integrity division, as well as by the Office of the Inspector General.

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.