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Center for Medicare
Medicare Plan Payment Group

Date: June 6, 2011

To: All Part D Plan Sponsors

From: Cheri Rice, Director
Medicare Plan Payment Group

Subject: Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report

On May 3, 2011, CMS released draft guidance on the reporting of direct and indirect remuneration (DIR) data in a Summary Report for the contract year 2010 payment reconciliation. Comments on this draft guidance were accepted until May 16, 2011. CMS has made revisions to the guidance in response to the comments and questions received. Provided below is an overview of the revisions made to the guidance and a brief summary of the comments we received. Part D sponsors must submit the 2010 DIR Report for Payment Reconciliation: Summary Report to CMS by **Thursday, June 30, 2011**.

Revisions to the "Medicare Part D DIR Reporting Requirements for Payment Reconciliation: Summary Report for Contract Year 2010":

1. One commenter expressed concerns that "PBM Spread" for the purpose of DIR reporting could be interpreted to mean that PBMs are required to report PBM spread for each pharmacy. We have revised the final guidance to clarify that Part D sponsors must report the aggregate amount of the difference between the amount paid to the PBM and the amount the PBM pays pharmacies. We emphasize that sponsors must report aggregate values for all PBM Spread amounts, and not the PBM Spread for each pharmacy. Note that PBM Spread Amounts are not considered DIR and thus are not included in the Total DIR column.

2. Two commenters noted CMS' responsibility to implement confidentiality protections for PBM Spread data. We have clarified this guidance to explain that PBM Spread amounts are confidential and shall not be disclosed by CMS, except in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs for the purposes of complying with Section 6005 of the ACA or to carry out Part D program functions.

3. Two commenters believe that CMS may not require reporting of bona fide service fees

per Section 6005 of the ACA. We are clarifying that CMS uses bona fide service fees to confirm the accuracy of Part D payments. We reiterate that bona fide service fees are not considered DIR. Consistent with the DIR reporting requirements for prior contract years, we are using our authority under section 1860D-15(f)(1)(A) to collect Rebate Administration Fees Reported as Bona Fide Service Fees" to ensure that fees above fair market value are included in the DIR data used in determining Part D payments.

4. A few commenters raised questions regarding our instructions on reporting changes to DIR via resubmitting DIR reports from prior years and/or requesting a reopening. We are modifying this guidance to clarify that for contract years 2006 and 2007, sponsors may not simply upload updated DIR reports. Instead, they must submit a reopening request. If the reopening request is granted, then sponsors would be notified to resubmit the DIR report.

   For contract years 2008 and 2009, sponsors must report a known change or error in the DIR amounts reported by submitting an updated DIR Report to CMS during the June 2011 submission period. Please see pages 19-21 of the attached guidance for additional detail on reporting changes to DIR.

5. Two commenters noted that the description of DIR #7-All Other Price Concessions from Manufacturers is vague or difficult to distinguish from DIR #5-Price Concessions for Administrative Services. One commenter further asked what "applicable price concessions" are referenced in DIR #7-All Other Price Concessions. We clarify that DIR #7-All Other Price Concessions includes all price concessions received from pharmaceutical manufacturers (either direct or indirectly) that cannot be categorized into columns DIR #1 though #6 and are associated with the Part D benefit. In so doing, we no longer use the term "applicable price concessions."

6. We updated the section regarding PBM (or Other Subcontractor) Retained Rebates on page 8 to reflect the regulation effective in 2010 codifying the definition of "negotiated prices" as net of discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale.

Additional Comments Received:

1. Two commenters suggested implementing a separate reporting mechanism to collect PBM Spread data. CMS must comply with the requirements of Section 6005 of the ACA and because we believe that adopting a separate reporting mechanism would impose an additional reporting burden on sponsors, we are retaining the requirement to report PBM Spread amounts in the 2010 DIR Report for Payment Reconciliation: Summary Report.

2. Two commenters support not requiring sponsors to submit updated DIR reports for negligible changes to Total DIR. While we appreciate the desire to minimize reporting burden, it is important that Part D sponsors fully inform CMS of changes to their cost data, including changes to their DIR data. Thus, in the final guidance we have retained

the requirement that Part D sponsors report changes in DIR per pages 20-21 in the attached guidance.

3. Commenters requested extensions to submit the 2010 DIR Report for Payment Reconciliation: Summary Report. Because these submitted DIR data are critical for starting the reconciliation process, we are unable to extend the June 30, 2011 deadline for submission of the 2010 DIR Report for Payment Reconciliation.

4. One commenter requested the option of reporting relatively small litigation amounts impacting drug costs in a prior contract year in the current DIR Report for Payment Reconciliation: Summary Report instead of submitting a revised report for the applicable contract year. We disagree with this recommendation. Legal settlement amounts must be reported to CMS based on the contract year for which the associated drug costs were impacted. For example, a legal settlement amount received in 2011 impacting drug costs in 2008 must be resubmitted on a revised 2008 DIR Report for Payment Reconciliation. This requirement ensures that when determining Part D payments, CMS applies the DIR amounts to the associated drug costs reported for the corresponding year.

5. Two commenters requested clarification that sponsors are required to submit DIR for covered Part D drugs only on the 2010 DIR Report for Payment Reconciliation: Summary Report. DIR for non-Part D covered drugs (drugs covered by the Part D sponsor that are not Part D drugs) should not be included on this report. Two commenters requested verification that reported PBM Spread be limited to covered Part D drugs. CMS agrees with these comments.

6. One commenter requested a clarification regarding how DIR #4- Rebate Administration Fees Reported as DIR is distinguished from DIR #5-Price Concessions for Administrative Services.

   DIR #4-Rebate Administration Fees Reported as DIR includes the amount of such rebate administration fees that would be considered bona fide service fees had they not exceeded fair market value. In other words, rebate administration fees must be reported in one of two ways: the portion at or below fair market value as bona fide service fees that are not considered DIR (reported in the field titled "Rebate Administration Fees Reported as Bona Fide Service Fees"), and the portion exceeding fair market value (reported in DIR #4-Rebate Administration Fees Reported as DIR).

   DIR #5-Price Concessions for Administrative Services are price concessions that are not bona fide service fees for administrative services associated with the Part D benefit. Programs, such as utilization management and medical education grants, are reported in DIR #5-Price Concessions for Administrative Services.

7. Several commenters requested an opportunity to comment on a draft of the guidance we will be issuing regarding the Detailed 2010 DIR Report. CMS will be issuing draft guidance regarding the Detailed 2010 DIR Report and will invite comments prior to finalizing the reporting requirements.

Please find the final revised guidance document attached, "Medicare Part D DIR Reporting Requirements for Payment Reconciliation: Summary Report for Contract Year 2010." Please note that for contract year 2010, Part D sponsors will be required to submit the Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor after the submission of the 2010 DIR Report for Payment Reconciliation. Part D sponsors will be required to certify that the PDE and DIR data submitted to CMS for the 2010 payment reconciliation are accurate, complete, and truthful. Additional guidance regarding this attestation will be provided at a later date.

Further Information:
For technical assistance and questions regarding the download or upload of the DIR Report for Payment Reconciliation: Summary Report, please contact the HPMS Help Desk at 1-800-220-2028 or hpms@cms.hhs.gov. For any other questions regarding this guidance, please contact Ilina Chaudhuri at Ilina.Chaudhuri@cms.hhs.gov or Andrew Keenan at Andrew.Keenan@cms.hhs.gov.

Medicare Part D DIR Reporting Requirements for Payment Reconciliation: Summary Report for Contract Year 2010

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MEDICARE PART D DIR REPORTING REQUIREMENTS FOR PAYMENT RECONCILIATION: SUMMARY REPORT FOR CONTRACT YEAR 2010

I. Introduction

In December 2003, Congress passed the Medicare Prescription Drug Benefit, Improvement and Modernization Act (MMA), allowing coverage of outpatient prescription drugs under the new Medicare Part D benefit. Reinsurance payments and risk sharing are two of the payment mechanisms by which the Medicare Program reimburses Part D sponsors for providing prescription drug coverage under Medicare Part D. CMS is required by statute to calculate these payments using "allowable reinsurance costs" and "allowable risk corridor costs", which must be "actually paid". As defined at 42 C.F.R. 423.308, "actually paid" costs must be actually incurred by the Part D sponsor and net of any applicable direct or indirect remuneration (DIR).

Section 1860D-15(f)(1)(A) of the Act requires Part D sponsors to fully disclose to CMS any information necessary for carrying out the payment provisions of Part D, including the calculation of reinsurance and risk sharing. Therefore, Part D sponsors are required to report drug costs and DIR associated with the Medicare prescription drug benefit to CMS for the purposes of determining reinsurance payments and risk sharing. Consistent with section 1860D-15(d)(2)(A), CMS payments to a Part D sponsor are conditioned upon the provision of this requisite data.

The purpose of this document is to provide an overview of CMS' DIR reporting requirements for Medicare Part D payment and the format of the DIR Report for Payment Reconciliation-Summary Report for 2010. This document explains the data elements to be reported by Part D sponsors at the distinct Plan level (i.e., data will be reported for each Plan Benefit Package or PBP offered under each Part D Contract) and the established reporting timeframes. CMS' goal is to ensure a common understanding of DIR reporting requirements and how these data will be used to determine Medicare Part D payments.

For guidance regarding the reporting of rebates and other price concessions for the RDS program, please see the Retiree Drug Subsidy Program Guidance: Rebates and Other Price Concessions available on the CMS website at: http://www.cms.hhs.gov/EmployerRetireeDrugSubsid/Downloads/20090112RebateGuidancePaper.pdf.

CMS will release future guidance regarding submission of the Detailed 2010 DIR Report.

II. Defining Direct and Indirect Remuneration (DIR)

Per 42 C.F.R. 423.308, direct and indirect remuneration (DIR) is any and all rebates, subsidies, or other price concessions from any source (including manufacturers, pharmacies, enrollees, or any other person) that serve to decrease the costs incurred by the Part D sponsor (whether directly or indirectly) for the Part D drug. Thus, DIR includes discounts, chargebacks, rebates,

cash discounts, free goods contingent on a purchase agreement, up-front payments, and coupons. DIR also includes goods in kind, free or reduced-price services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal action, and other price concessions or similar benefits. However, price concessions that are not considered to directly or indirectly impact drug costs incurred by the Part D sponsor are not included in DIR. Please see Table 1 below for examples of remuneration that are and are not considered DIR. Each of these examples is described below in Sections III and IV.

Table 1. Examples of Remuneration That Are and Are Not Considered DIR

Remuneration Considered DIR	**Remuneration Not Considered DIR**
A. Remuneration from pharmaceutical manufacturers (e.g. rebates, grants, reduced price administrative services, or legal settlement amounts)	A. Bona fide service fees from pharmaceutical manufacturers
B. PBM retained rebates	B. Remuneration for administrative services (e.g. PBM incentive payments)
C. PBM rebate guarantee amounts	C. Private reinsurance amounts
D. PBM penalty payments and repayments that impact Part D drug costs	D. PBM penalty payments and repayments that do not impact Part D drug costs
E. Dispensing incentive payments to pharmacies after the POS	E. Rebate amounts received by long term care (LTC) pharmacies
E. Prompt pay discounts from pharmacies	F. Claims data
F. Pharmacy payment adjustments	
G. Risk sharing amounts	

III. Examples of Remuneration Considered DIR

A. Remuneration from Pharmaceutical Manufacturers

CMS considers all remuneration received directly or indirectly from pharmaceutical manufacturers, with the exception of bona fide services fees, to be price concessions that serve to reduce the drug costs incurred by the Part D sponsor. As stated in the preamble to subpart G of the Medicare Part D final rule (70 FR 4308 - 4309), and further explained in the preamble to the January 12, 2009 final rule entitled "Medicare Advantage and Prescription Drug Benefit: Negotiated Pricing and Remaining Revisions" (74 FR 1505-1515), CMS has a responsibility to ensure that price concessions are not masked as administrative fees. Therefore, to guarantee that a Part D sponsor's administrative costs are not inappropriately shifted to its drug costs, Part D sponsors are required to report all rebates, grants, settlement amounts, or price concessions received from pharmaceutical manufacturers (whether directly or indirectly) as DIR with the exception of bona fide services fees. Please see page 11 for a discussion of bona fide service fees.

i. Administrative Services

When Part D sponsors receive administrative services from pharmaceutical manufacturers at a cost below market value, the difference between the fair market value of the administrative service and the price paid by the Part D sponsor is considered DIR. Similarly, when a Part D sponsor (directly or indirectly through their PBM) receives payments from pharmaceutical manufacturers for administrative services that are above the fair market value of the services provided, the difference between the price paid by the pharmaceutical manufacturer and the fair market value of the administrative service is considered DIR. For example, in the case of rebate administration fees from pharmaceutical manufacturers that exceed fair market value but otherwise meet the definition of a bona fide service fee, Part D sponsors must report the differential between the rebate administration fee and the fair market value as DIR.

ii. Legal Judgments and Settlement Amounts

All legal judgments and settlement amounts received from pharmaceutical manufacturers for covered Part D drugs (with the exception of litigation concerning bona fide service fees) are considered price concessions that impact the drug costs incurred by the Part D sponsor and, therefore, must be reported as DIR. This includes legal judgments or settlement amounts from litigation due to inappropriate utilization, market competition, and the manipulation of the patient process.

B. PBM (or Other Subcontractor) Retained Rebates

Rebates, discounts, and other price concessions from pharmaceutical manufacturers for purchases under the Medicare prescription drug benefit are considered DIR even if they are received by subcontractors of Part D sponsors, such as pharmacy benefit managers (PBMs), and retained by the subcontractor in lieu of higher service fees from the Part D sponsor. These amounts are considered price concessions received indirectly from pharmaceutical manufacturers that must be reported as DIR for payment purposes.

A Part D sponsor must report 100% of the manufacturer rebates, discounts, and other price concessions (with the exception of bona fide service fees) retained by its PBM as DIR, regardless of the relationship between the sponsor and the PBM and the provisions of the contract(s) between the sponsor and the PBM. Applicable rebate administration fees that the PBM receives from pharmaceutical manufacturers must also be reported to the extent that they do not represent bona fide service fees.

Per 42 C.F.R. 423.100, Part D sponsors must base price reporting to CMS on the price ultimately received by the pharmacy or other dispensing provider, also known as the pass-through price. CMS must assume that if a PBM retains a portion of the manufacturer rebates it negotiates on behalf of a Part D sponsor, the direct payment the sponsor pays the PBM for its services will be less, such that the sponsor receives a price concession from the PBM. Thus, because retained rebates function as additional administrative fees paid to the PBM,

consistent with 42 C.F.R. 423.308, Part D sponsors must **also** account for these retained rebate amounts in the administrative expense component of their Part D bids.

C. PBM Rebate Guarantee Amounts

Rebate guarantee amounts are rebate amounts received from PBMs to account for the difference between a rebate amount guaranteed by a PBM and the actual rebate amount received from a pharmaceutical manufacturer. These rebate amounts reduce the drug costs incurred by the Part D sponsor and therefore are considered DIR.

D. PBM Penalty Payments and Repayments

Penalty payments or repayments from PBMs that directly or indirectly impact the drug costs incurred by the Part D sponsor are considered DIR. Some PBM penalty payments include a price concession for administrative services provided by the PBM as well as remuneration for drug cost. In these cases, only the portion of the PBM penalty that impacts the drug costs incurred by the Part D sponsor is considered DIR. Thus, the portion of the penalty payment representing drug cost reimbursed by the PBM must be reported as DIR. The remaining portion of the PBM penalty is not considered DIR because it does not directly or indirectly impact the drug costs incurred by the Part D sponsor.

For example, if a PBM is required to pay the Part D sponsor $1,000 plus claim costs due to an error associated with allowing coverage of a drug on step 2 of a step-therapy program, when a drug on step 1 of the same program should have been required, the amount paid by the PBM that is equivalent to the cost of the affected claims is considered DIR. The Part D sponsor must report this amount as DIR because the Prescription Drug Event (PDE) data submitted to CMS would not reflect this reduction in drug costs for the Part D sponsor. Any additional amount above the cost of the drug does not directly or indirectly impact the Part D sponsor's drug costs and is not considered DIR. Alternatively, if the PBM is required to pay the Part D sponsor $1,000 plus the difference between the cost of the drug on step 2 and the cost of the drug on step 1, the portion representing drug cost reimbursed by the PBM (the difference between the cost of the two drugs) is considered DIR. In both examples, the remaining $1,000 payment received from the PBM does not directly or indirectly impact the drug costs incurred by the Part D sponsor and therefore is not considered DIR.

Please note that in most cases, Part D sponsors should submit an adjusted PDE record with a revised gross drug cost if their PBM has administered the benefit incorrectly. In these cases, the PBM penalty associated with the errors in drug cost should not be reported as DIR since the PDE record has been adjusted to reflect the appropriate gross drug cost.

E. Dispensing Incentive Payments to Pharmacies After POS

Dispensing fees paid to pharmacies and other dispensing providers are considered part of the drug cost incurred by Part D sponsors. Therefore, dispensing incentive payments made to the pharmacy **at** the point of sale (POS) are part of the dispensing fee reported on the PDE record and are not reported as DIR. In contrast, dispensing incentive payments and

adjustments to dispensing incentive payments made to pharmacies **after** the point of sale are not reflected in the drug costs reported on PDE records. As a result, these post-POS dispensing incentive payments and adjustments must be reported as DIR to ensure that the Part D sponsor's allowable reinsurance and risk corridor costs appropriately reflect the drug costs actually incurred by the Part D sponsor.

i. Generic Dispensing Incentive Payments

Generic dispensing incentive payments are payments made to pharmacies to encourage the dispensing of generic drugs. If a Part D sponsor makes a generic dispensing incentive payment to the pharmacy at the POS, CMS considers it part of the dispensing fee and the sponsor or its third party submitter must report this cost as part of the dispensing fee on their PDE. As a result, generic dispensing incentive payments made **at** the point of sale are not reported as DIR. However, if the sponsor pays the pharmacy a generic dispensing incentive payment **after** the POS or makes any post-POS adjustments to prospective generic dispensing incentive payments, the sponsor must report the post-POS payments or adjustments as DIR.

F. Prompt Pay Discounts from Pharmacies

Part D sponsors may receive discounts from pharmacies for the timely payment of Part D claims. These prompt payment discounts are considered DIR and must be reported on the DIR Report for Payment Reconciliation if they are (i) received after the point of sale and (ii) not reflected on the PDE records submitted to CMS.

If a Part D sponsor expects to receive a prompt payment discount from a pharmacy, the Part D sponsor should reflect this discount on the PDE records submitted to CMS by reducing the reported drug costs.

G. Pharmacy Payment Adjustments

Adjustments made to pharmacy payments after the point-of-sale that (i) directly or indirectly impact the drug costs incurred by the Part D sponsor and (ii) are not reflected in the PDE data are considered DIR. These adjustments include penalties or pharmacy repayments stipulated in the Part D sponsor's contract with its network pharmacies that represent incorrect drug costs paid or reported by the Part D sponsor due to an error made by the pharmacy. For these types of pharmacy penalties, the portion of the penalty that is equivalent to the amount by which the drug costs paid by the Part D sponsor or reported to CMS on the PDE data exceeds the correct drug costs is considered DIR. The remaining portion of the pharmacy penalty is considered a price concession for administrative services provided by the pharmacy that does not directly or indirectly impact the drug costs incurred by the Part D sponsor and therefore is not reported as DIR.

Please note that in most cases, the Part D sponsor should submit an adjusted PDE with a revised gross drug cost if the pharmacy made an error in determining the POS drug price. In these cases, the pharmacy payment adjustment should not be reported as DIR since it is

already reflected in the gross drug cost reported on the PDE record. For example, if a Part D sponsor recoups an overpayment to the pharmacy due to an error in POS drug price and the recouped amount is reported to CMS via an adjusted PDE record with a revised gross drug cost, the Part D sponsor would not report the pharmacy payment adjustment on the DIR Report for Payment Reconciliation.

Adjustments made to beneficiary cost-sharing due to changes in low-income subsidy eligibility status impact the low-income cost sharing subsidy amounts received from CMS. However, these adjustments do not impact the drug costs actually incurred by Part D sponsors. This type of adjustment does not affect the negotiated price or the plan's liability for the drug claim. Thus, these adjustments are not considered DIR. Adjustments to beneficiary cost sharing should be reflected on the PDE records submitted to CMS.

Amounts credited to the Part D sponsor by the pharmacy due to beneficiary cost-sharing that exceeds the gross drug cost are considered DIR, provided that these payments are not already reflected in the covered plan paid (CPP) amounts reported on the PDE record. This credit occurs when the beneficiary's co-payment exceeds the negotiated drug price and the pharmacy credits the differential amount to the Part D sponsor. If this payment is not reflected in the CPP amount reported on the PDE record, the amount by which the beneficiary's co-payment exceeds the negotiated price must be reported as DIR to reduce the plan's allowable costs. Please note that in cases where the pharmacy retains this differential amount, this amount is considered payment to the pharmacy and, thus, is not reported as DIR.

H. Risk Sharing Amounts

It is permissible under the Part D rule for sponsors to enter into certain types of risk sharing arrangements with entities other than CMS. Risk sharing arrangements are arrangements in which the Part D sponsor shares risk with a provider (e.g., pharmacy) or other party involved in the administration or delivery of the Part D benefit. Any risk sharing arrangement between the sponsor and another party must be based on the cost of Part D covered drugs. Under no circumstances can a risk sharing arrangement be developed around administrative costs. Risk sharing amounts received from or credited to other parties constitute DIR and must be offset against prescription drug costs in the calculation of allowable reinsurance and risk corridor costs. As with other types of DIR, the value of risk sharing may be negative. Please note that private reinsurance amounts are not considered DIR. See page 12 for a discussion of amounts from private reinsurance arrangements.

IV. Examples of Remuneration Not Considered DIR

A. Bona Fide Service Fees from Pharmaceutical Manufacturers

Bona fide service fees that Part D sponsors or subcontractors of Part D sponsors (such as PBMs) receive from pharmaceutical manufacturers are not considered price concessions that reduce the drug costs incurred by the Part D sponsor and are not considered DIR. Bona fide service fees are fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the

manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Rebate administration fees paid to a Part D sponsor or a PBM that meet the definition of a bona fide service fee are not considered DIR. Therefore, they may be excluded from the DIR amounts reported on the DIR Report for Payment Reconciliation-Summary Report (i.e. excluded from columns DIR #1-DIR #11 of the DIR Report). In the case of rebate administration fees or other amounts from pharmaceutical manufacturers that exceed fair market value, but otherwise meet the definition of a bona fide service fee, the differential between the rebate administration fee or other amount and fair market value must be reported as DIR in column DIR #4.

Although rebate administration fees that meet the definition of a bona fide service fee are not considered DIR, Part D sponsors are required to report these amounts to CMS in the column "Rebate Administration Fees Reported as Bona Fide Service Fees" to allow confirmation of the accuracy of Part D payments. This information will be used to ensure that rebate administration fees above fair market value are included in the DIR data used for Part D payment reconciliation. The amounts reported under the Rebate Administration Fees column will not be included in the DIR amounts used to determine allowable reinsurance costs and allowable risk corridor costs.

B. Remuneration for Administrative Services

Price concessions for administrative services that do not directly or indirectly impact the drug costs incurred by the Part D sponsor are not included in DIR. For example, price concessions from a pharmacy for administrative services only (excluding dispensing fees) that do not represent a change in the drug costs paid by the Part D sponsor do not impact the drug costs incurred by the Part D sponsor and therefore are not considered DIR.

i. PBM Incentive Payments

Part D sponsors may pay incentive payments to PBMs for performing administrative services such as negotiating rebates and drug prices as well as increasing generic utilization. These incentive payments represent an increase in the administrative fees paid by the Part D sponsor to their PBM and are not considered DIR. (Note that this is in contrast to generic dispensing fees, discussed above, that are paid to pharmacies where the Part D sponsor pays a higher dispensing fee to the pharmacy as an incentive for dispensing generic drugs instead of brand drugs. The dispensing fee is a component of the negotiated price paid to the pharmacy. As a result, adjustments to the dispensing fee directly impact the drug costs incurred by the Part D sponsor and must be reported as DIR if applied after the point of sale.)

C. Private Reinsurance Amounts

Private reinsurance arrangements are arrangements in which the Part D sponsor shares risk with a party otherwise uninvolved in the administration or delivery of the Medicare prescription drug benefit. Private reinsurance amounts do not constitute DIR and should not be reported on the DIR Report for Payment Reconciliation. Instead, similar to Part D sponsors' direct and indirect administration costs, reinsurance amounts from private reinsurance arrangements are included in the Part D sponsor's bid as a non-benefit expense.

D. PBM Penalty Payments and Repayments That Do Not Impact Part D Drug Costs

Penalty payments or repayments from PBMs that do not impact the drug costs incurred by the Part D sponsor are not considered DIR. Some PBM penalty payments include a price concession for administrative services provided by the PBM as well as remuneration for drug cost. In these cases, only the portion of the PBM penalty that impacts the drug costs incurred by the Part D sponsor is considered DIR. Thus, the portion of the penalty payment representing drug cost reimbursed by the PBM must be reported as DIR. The remaining portion of the PBM penalty is not considered DIR because it does not directly or indirectly impact the drug costs incurred by the Part D sponsor.

E. Rebate Amounts Received by Long Term Care (LTC) Pharmacies

Part D sponsors purchase Part D drugs directly from long term care (LTC) pharmacies. The rebate amounts and price concessions received by these dispensing providers do not serve to further reduce the drug cost paid by Part D sponsors at the point of sale. Therefore, pharmaceutical manufacturer rebates received by LTC pharmacies are not considered DIR.

F. Claims Data

Claims data are not considered DIR and therefore must not be reported on the DIR Report for Payment Reconciliation. Instead, Part D sponsors should report all applicable claims data on PDE records. This policy is applicable to all claims data, including data received or processed after the PDE data submission deadline.

V. DIR Included on the DIR Report for Payment Reconciliation

Part D sponsors must report DIR associated with purchases under the Medicare prescription drug benefit on the DIR Report for Payment Reconciliation. DIR that is not generated from the sponsor's Medicare Part D book of business should not be included on this report. The DIR included on the DIR Report for Payment Reconciliation-Summary Report will be excluded from allowable reinsurance costs and allowable risk corridor costs when CMS calculates reinsurance and risk sharing payments during the Part D payment reconciliation process. Thus, Part D sponsors should consider their best expectation of DIR when developing their Part D bids.

Accurate and complete DIR data are necessary for the accurate completion of Part D payment reconciliation. Data reported on the DIR Report for Payment Reconciliation are subject to audit. Part D sponsors are required to maintain records of all related transactions, claims, contracts, and other materials. Please note that misrepresentations or omissions in the DIR data provided to CMS may result in Federal civil action and/or criminal prosecution. In addition, per 42 C.F.R. 423.343(d)(2) of the Part D Regulations, if a Part D sponsor does not provide adequate data to determine risk corridor costs, including DIR data, CMS assumes that the Part D plan's adjusted allowable risk corridor costs are 50 percent of the plan's target amount.

A. DIR Not Applied at the Point of Sale

Some DIR is reflected in the amount paid at the point of sale. To the extent that DIR is already taken into account in the gross drug cost (sum of ingredient cost, dispensing fee, applicable sales tax, and vaccine administration fee) reported to CMS on the PDE record, this DIR (with the exception of estimated rebates applied at the point of sale) should not be reported on the DIR Report for Payment Reconciliation.

B. Estimated Rebates Applied at the Point of Sale

Part D sponsors may elect to make rebates available to their beneficiaries at the point of sale by applying estimated rebates to the negotiated price. For rebates that were estimated and applied to the point of sale price, Part D sponsors are required to report the estimated rebate amounts in the "Estimated Rebate at POS" field of the PDE record.

Although Part D sponsors are required to report their gross drug costs on the PDE record net of any estimated rebates applied at the point of sale, they are **also** required to report the actual rebate amounts for these estimated rebates on the DIR Report for Payment Reconciliation. CMS will subtract the amounts reported in the Estimated Rebate at POS field of the PDE record for covered Part D drugs from the total DIR amount reported on the DIR Report for Payment Reconciliation when determining the appropriate DIR amount for the calculation of allowable reinsurance costs and adjusted allowable risk corridor costs. This will capture any difference between the estimated rebates and the actual rebates. In addition, this will ensure that only price concessions that were not already included in the gross covered drug costs reported to CMS are included in the DIR amount used to calculate allowable reinsurance costs and adjusted allowable risk corridor costs. For additional information, please see the June 1, 2007 HPMS memorandum, "Reporting Estimated Rebates Applied to the Point-of-Sale Price".

C. DIR for Covered Part D Drugs

CMS provides reinsurance and risk sharing for costs associated with covered Part D drugs only. Covered Part D drugs, as defined in 42 C.F.R. 423.100, are Part D drugs that are included in a Part D plan's formulary or treated as included in the formulary as a result of the plan's exceptions process, a coverage determination appeal, or a transition period. When calculating allowable reinsurance and risk corridor costs, CMS will only apply DIR dollars for covered Part D drugs. Therefore, on the DIR Report for Payment Reconciliation, Part D

sponsors are required to submit DIR for covered Part D drugs only. DIR for non-Part D covered drugs (drugs covered by the Part D sponsor that are not Part D drugs) should not be included on this report.

D. DIR Associated with Supplemental Benefits and Benefit Phases with 100% Coinsurance

Applicable DIR for covered Part D drugs must be reported in full on the DIR Report for Payment Reconciliation. This includes DIR for supplemental prescription drug benefits as well as DIR associated with drug purchases in the deductible phase and the coverage gap. Consistent with our instructions for the development of the Part D bids, all applicable DIR will be excluded from allowable costs when CMS determines final reinsurance and risk sharing payments.

E. DIR Associated with Rejected PDE Records

All applicable DIR received for Part D plan expenditures incurred during the contract year must be reported on the DIR Report for Payment Reconciliation. DIR associated with non-Part D expenditures reported on rejected PDE records (for example, DIR from drug costs covered under Medicare Part B) may be excluded from the DIR Report for Payment Reconciliation. It is inappropriate, however, for a Part D sponsor to exclude from the DIR report all DIR associated with rejected PDE records when the Part D sponsor expects that a portion of the rejected PDE records will ultimately be accepted by CMS either prior to or after the Part D payment reconciliation. As a result, DIR received for Part D plan expenditures reported on PDE records that were initially rejected by CMS' systems but that the Part D sponsor believes will ultimately be accepted must be reported on the DIR Report for Payment Reconciliation.

F. Estimates of Expected DIR Not Yet Received

Part D sponsors must include on the DIR Report for Payment Reconciliation good faith estimates for DIR that is expected for the applicable contract year but has not yet been received. This includes estimates for rebates expected from pharmaceutical manufacturers that have not yet been received as well as estimates for DIR associated with claims for the contract year that are expected to be submitted and processed after the PDE data submission deadline. Estimated DIR amounts reported on the DIR Report for Payment Reconciliation will be included in the total DIR amount subtracted from Part D sponsors' drug costs when determining allowable reinsurance costs and allowable risk corridor costs.

VI. Reporting Requirements *[New Clarification]*

Part D sponsors must submit their DIR data at the plan benefit package (referred to as "plan") level on the DIR Report for Payment Reconciliation within 6 months of the end of the coverage year. **The submission deadline for the 2010 DIR Report for Payment Reconciliation-Summary Report is Thursday, June 30, 2011.** This deadline applies to all Part D plans, including non-calendar year Employer/Union-only Group Waiver Plans (EGWPs).

A. Allocation Methodology

Some Part D sponsors may receive or record their DIR at the sponsor or contract level. In these cases, the Part D sponsor must allocate its DIR to the plan level by applying a *reasonable* allocation methodology. Part D sponsors should allocate rebates for a specific drug to the plan level based on the actual utilization of that specific drug. Other allocation methodologies may be subject to additional validation. Table 2 provides examples of allocation methodologies and indicates whether they are generally considered reasonable for allocating rebates to the plan level. When considering an allocation methodology for rebates, Part D sponsors should consider whether the rebate dollars are appropriately allocated to each plan given the drug costs associated with the rebatable drugs purchased under each plan.

Part D sponsors may also receive legal judgments or settlement amounts from lawsuits or other legal action, which are associated with drug costs incurred across multiple contract years. The portion of the judgment or settlement amounts associated with the drug costs for each contract year should be reported on the corresponding DIR Reports for Payment Reconciliation. Thus, for legal judgments or settlement amounts from lawsuits or other legal action concerning drug costs for multiple contract years, Part D sponsors must use a *reasonable* methodology to allocate the legal judgments or settlement amounts to each applicable contract year.

A brief description of any allocation methodology used must be submitted by the Part D sponsor on HPMS when uploading the DIR Report for Payment Reconciliation. Part D sponsors are expected to maintain internal documentation of any allocation methodology applied.

Table 2. Examples of Methodologies for Allocating Rebates To the Plan Level

Allocation Methodology	Description	Considered Reasonable?	Explanation
Based on Actual Drug Utilization	Rebate amounts received for a specific drug are allocated to a plan based on the number of units of the specific drug that were purchased under the plan as a percent of the total number of units purchased by the sponsor.	Yes	Appropriately accounts for differences in a specific drug's utilization across Part D plans.
Based on Plan's Total Drug Spend	Rebate amounts received for multiple drugs are allocated to a plan based on the total drug spend under the plan as a percent of the total drug spend under all of sponsor's Part D plans.	Yes	Approximates differences in utilization and spending on rebate eligible drugs across Part D plans.
Based on Plan's Brand Drug Spend	Rebate amounts received for multiple drugs are allocated to a plan based on the total drug spend for brand drugs under the plan	Yes	Accounts for differences in utilization and spending on rebate eligible drugs across

	as a percent of the total drug spend for brand drugs under all of the sponsor's Part D plans.		Part D plans.
Based on Total Drug Spend for Drugs in Preferred Brand Tier	Rebates received for multiple drugs are allocated to a plan based on the total drug spend for drugs in the plan's preferred brand tier as a percent of the total drug spend for drugs in the preferred brand tier of all of the sponsor's Part D plans.	Yes, if the sponsor only receives rebates for drugs in the preferred brand tier.	Accounts for differences in utilization and spending on rebate eligible drugs across Part D plans.
Based on Enrollment	Rebates received for multiple drugs are allocated to a plan based on the number of beneficiaries enrolled in the plan as a percent of the total number of beneficiaries enrolled in all of the sponsor's Part D plans.	No	Does not sufficiently approximate differences in utilization and spending on rebate eligible drugs across Part D plans.
Based on LIS Enrollment	Rebates received for multiple drugs are allocated to a plan based on the number of LIS beneficiaries enrolled in the plan as a percent of the total number of LIS beneficiaries enrolled in all of the sponsor's Part D plans.	No	Does not sufficiently approximate differences in utilization and spending on rebate eligible drugs across Part D plans.
Based on Billed Rebate Amounts	Rebates received for a specific drug are allocated to a plan based on the rebate amounts billed to the pharmaceutical manufacturer for the specific plan and drug as a percent of the total rebate amount billed to the pharmaceutical manufacturer for all of the sponsor's Part D plans.	Yes	Appropriately accounts for differences in a specific drug's utilization across Part D plans.
Based on Number of Claims	Rebates received for multiple drugs are allocated to a plan based on the number of claims under the plan as a percent of the total number of claims received under all of the sponsor's Part D plans. Thus, allocation is based on the total number of claims for all of the drugs rather than the number of claims received for each drug.	No	Does not sufficiently approximate differences in utilization and spending on rebate eligible drugs across Part D plans.

B. DIR Submission Information

Prior to uploading the 2010 DIR Report for Payment Reconciliation on HPMS, Part D sponsors are required to provide additional information at the contract level regarding their DIR and PDE data. Descriptions of the information required are provided below.

1) **Description of Allocation Methodology**: Part D sponsors must provide a description of any methodology used to allocate DIR to the plan level. If this question is not applicable, Part D sponsors should enter "N/A".

2) **Description of Services Provided for Rebate Administration Fees**: Part D sponsors must describe the services provided for the rebate administration fees reported as DIR as well as those reported as bona fide service fees. If this question is not applicable, Part D sponsors should enter "N/A".

3) **Description of Legal Settlement Amounts**: Part D sponsors must provide a description of any legal judgment or settlement amounts, including the source or recipient of the judgment or settlement amount and the services or drugs at issue. If this question is not applicable, Part D sponsors should enter "N/A".

4) **Description of Services Provided for Other Bona Fide Service Fees**: Part D sponsors must describe the services provided for any bona fide service fees that are not rebate administration fees and the allocation methodology used to determine this amount. If this question is not applicable, Part D sponsors should enter "N/A".

5) **Description of Risk Sharing Arrangement(s)**: Part D sponsors must describe all risk sharing arrangements. If this question is not applicable, Part D sponsors should enter "N/A".

6) **Name of 2010 Claims Processing PBM(s)**: Part D sponsors must provide the name of any PBM or other entity with which the sponsor contracted for the processing of claims or submission of PDE records for 2010. If the Part D sponsor conducted claims processing and PDE record submission internally and did not contract with a PBM for these services, the Part D sponsor should indicate "Self" for this question.

7) **Name of PBM(s) for Rebate Negotiation**: Part D sponsors must provide the name of any PBM or other entity with which the Part D sponsor contracted for the negotiation or processing of rebates for 2010. Part D sponsors that conducted rebate negotiation and processing using their internal resources and did not contract with a PBM for these services should indicate "Self" for this question. If the Part D sponsor did not negotiate or process rebates, the Part D sponsor should enter "N/A" for this question.

8) **Did PBM for Rebate Negotiation change from 2009 to 2010?** Part D sponsors must indicate whether they contracted with a different PBM or entity in 2009 for the negotiation or processing of rebates. If the Part D sponsor did not negotiate or process rebates in 2009 and 2010, the sponsor should enter "N/A" for this question. If the Part D sponsor contracted with a PBM or other entity for the negotiation or processing of rebates in 2010 but not in 2009, the sponsor should enter "Yes" for this question. Similarly, if the sponsor contracted with a PBM or other entity for the negotiation or processing of rebates in 2009 but not in 2010, the sponsor should enter "Yes" for this question.

9) **Were any of the plans in the contract owned by a different sponsor in 2009?** Part D sponsors must indicate whether any of the plans in the contract were owned by a different

sponsor in 2009. For any applicable plans, the sponsor must provide the plan ID, the name of the sponsor that owned the plan in 2009, and the contract number that the plan was under in 2009. If all of the plans in the contract were owned by a different sponsor in 2009, the sponsor may indicate "all plans in contract" instead of listing all of the plan IDs.

10) **Did your parent organization acquire any of the plans in this contract during the 2010 contract year?** Part D sponsors must indicate whether any of the plans in the contract were acquired mid-contract year. For any applicable plans, the sponsor must provide the plan ID, the name of the sponsor that previously owned the plan, and the contract number that the plan was under prior to the sponsor's acquisition of the plan.

11) **Reason for Resubmission**: When resubmitting the DIR Report for Payment Reconciliation, Part D sponsors are required to provide an explanation for the resubmission of their DIR data.

C. DIR Report for Payment Reconciliation-Summary Report

The 2010 DIR Report for Payment Reconciliation-Summary Report will be made available on June 6, 2011. Part D sponsors will be able to download it from HPMS using the following navigation path: HPMS Homepage > Plan Bids > DIR Reporting > Contract Year 2010 > DIR Reporting (for Payment Reconciliation). This report will be downloadable to an MS Excel spreadsheet in the format provided in Section VIII: Report Format and Layout. Part D sponsors must prepare and upload to HPMS the 2010 DIR Report for Payment Reconciliation-Summary Report for each of their Part D plans (including non-calendar year Employer/Union-only Group Waiver Plans). In order to upload successfully, **Part D sponsors must use the actual downloaded MS Excel spreadsheet and name the file DIR.xls**.

Part D sponsors must prepare and submit the DIR Report for Payment Reconciliation-Summary Report to CMS for all of the Part D plans that they offered in 2010, even if they have no DIR to report for contract year 2010. For plans with no DIR to report for contract year 2010, the Part D sponsor must include a brief explanation in the column "Additional Comments".

Sponsors may upload the 2010 DIR Report for Payment Reconciliation-Summary Report as many times as they choose until 11:59 p.m. PDT on Thursday, June 30, 2011. CMS will use the DIR reported on the most recently uploaded Summary Report during payment reconciliation.

CMS will review the DIR data submitted. DIR reports that have been reviewed and accepted by CMS will receive an "accepted" status in HPMS. If CMS identifies a potential error, CMS will contact the Part D sponsor. Part D sponsors may see the status of submitted DIR reports on the DIR Contract Status page in HPMS using the following navigation path: HPMS Homepage > Plan Bids > DIR Reporting > Contract Year 2010 > DIR Reports > DIR Contract Status Report.

For technical assistance, Part D sponsors can contact the HPMS Help Desk at either 1-800-

220-2028 or hpms@cms.hhs.gov. For other questions regarding the 2010 DIR Report for Payment Reconciliation-Summary Report, sponsors can contact Ilina Chaudhuri at Ilina.Chaudhuri@cms.hhs.gov or Andrew Keenan at Andrew.Keenan@cms.hhs.gov.

D. Reporting Changes to the DIR Report for Payment Reconciliation-Summary Report

CMS is aware that there are instances when Part D sponsors may receive unanticipated rebate amounts, settlement amounts, or other price concessions after the submission deadline that could result in changes to the DIR data reported to CMS. Per 42 C.F.R. §423.346, CMS has the authority to reopen and revise initial or reconsidered final Part D payment determinations within specified time periods. Therefore, to ensure that CMS has the information needed to determine whether a reopening of a sponsor's final Part D payment determination is warranted, Part D sponsors must inform CMS of changes in their DIR data that affect the Total DIR reported to CMS.

i. Reporting changes to 2006 and 2007 DIR

To report a change or error in the DIR amounts reported for contract years 2006 or 2007, sponsors may not simply upload updated DIR reports. Instead, they must submit a reopening request. CMS will review the updated DIR Reports as well as PDE data to make a determination on whether the sponsor's final Part D payment determinations will be reopened. If the reopening request is granted, then sponsors would be notified to resubmit an updated DIR report (using the 2006 and/or 2007 report template, as appropriate). The reopening request must be sent to StrategicHealthSolutions, LLC at PartDPaymentReview@Strategichs.com.

ii. Reporting changes to 2008 DIR

To report a known change or error in the DIR amounts reported for contract year 2008, Part D sponsors must submit an updated DIR Report using the 2008 report template during the DIR submission period in June 2011 in HPMS. Part D sponsors also have the option to request that CMS, at its discretion, reopen and revise the sponsor's final Part D payment determinations to reflect their reported changes in DIR.

To report a change or error in the DIR amounts reported for contract year 2008 after the current submission period that ends on June 30, 2011, Part D sponsors must submit a reopening request. CMS will review the updated DIR Reports as well as PDE data to make a determination on whether the sponsor's final Part D payment determinations will be reopened. If the reopening request is granted, then sponsors would be notified to resubmit an updated DIR report using the 2008 report template. The reopening request must be sent to StrategicHealthSolutions, LLC at:
PartDPaymentReview@Strategichs.com.

iii. Reporting changes to 2009 DIR

To report a known change or error in the DIR amounts reported for contract year 2009,

Part D sponsors must submit an updated DIR Report using the 2009 report template during the DIR submission period in June 2011 in HPMS. Part D sponsors also have the option to request that CMS, at its discretion, reopen and revise the sponsor's final Part D payment determinations to reflect their reported changes in DIR.

To report a change or error in the DIR amounts reported for contract year 2009 after the current submission period that ends on June 30, 2011, Part D sponsors must submit an updated DIR Report using the 2009 report template during the 2011 DIR submission period in 2012.

Part D sponsors are not required to submit an updated DIR Report for any year if there has been no change to the total DIR previously reported to CMS. Thus, if there have been changes in the DIR data that result in no change to the "Total DIR" column, Part D sponsors are not required to submit an updated DIR Report.

These scenarios are summarized in the table below. Note that if CMS conducts a reopening, we may consider only those sponsors who have submitted a reopening request.

Scenario	**Sponsor Action**
Part D sponsor must report a change or error in DIR amounts for contract year 2006 or 2007	Part D sponsor must submit a reopening request. If the reopening request is granted, then sponsors would be notified to resubmit an updated DIR report (using the 2006 and/or 2007 report template, as appropriate).
Part D sponsor must report a change or error for contract year 2008 or 2009 prior to submission period elapsing for contract year 2010 (i.e., before June 30, 2011)	Part D sponsor must submit an updated DIR Report (using the 2008 or 2009 report template, as appropriate) during the DIR submission period in June 2011 in HPMS. Part D sponsors also have the option to request that CMS, at its discretion, reopen and revise the sponsor's final Part D payment determinations to reflect their reported changes in DIR.
Part D sponsor must report a change or error in DIR amounts for contract year 2008 after submission period has elapsed for contract year 2010 (i.e., after June 30, 2011)	Part D sponsor must submit a reopening request. If the reopening request is granted, then sponsors would be notified to resubmit an updated DIR report using the 2008 report template.
Part D sponsor must report a change or error in DIR amounts for contract year 2009 after submission period has elapsed for contract year 2010 (i.e., after June 30, 2011)	Part D sponsors must submit an updated DIR Report using the 2009 report template during the 2011 DIR submission period in 2012. Part D sponsors also have the option to request that CMS, at its discretion, reopen and revise the sponsor's final Part D payment determinations to reflect their reported changes in DIR.
No change to the total DIR previously reported to CMS	Part D sponsors are not required to submit an updated DIR Report for any year if there has been no change to the total DIR previously reported to CMS.

CMS will review all submitted reopening requests and make a determination on whether the sponsor's final Part D payment determinations will be reopened. Reopening requests must be submitted to StrategicHealthSolutions, LLC (Strategic) at: PartDPaymentReview@Strategichs.com. Please see the May 8, 2008 HPMS memo, "The Part D Reopenings Process and the Part D Appeals Process" for additional guidance regarding how to submit a reopening request. Please note that the reopening process requires substantial CMS preparation and resources. Therefore, it may take some time to receive a determination regarding a request for reopening from CMS. In addition, Part D sponsors should not expect the reopening to be performed immediately after receiving a decision to reopen.

E. Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor

In accordance with 42 CFR 423.505(k)(5), Part D sponsors will be required to submit an attestation, "Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor", after the submission of the DIR Report for Payment Reconciliation but prior to the completion of the 2010 Part D Payment Reconciliation. In this attestation, Part D sponsors must certify that all information provided for the purposes of determining allowable reinsurance costs and risk corridor costs (for example, PDE data and DIR data) is accurate, complete, and truthful to the sponsor's best knowledge, information, and belief. Part D sponsors must certify in this attestation and maintain documentation that all entities that have generated or submitted this information on their behalf have certified that this information is accurate, complete, and truthful based on the entity's best knowledge, information, and belief.

For DIR data submitted after the Part D payment reconciliation, Part D sponsors must submit a new attestation when requested by CMS due to a determination regarding whether sponsor's Part D payments will be reopened and revised. Additional guidance regarding the submission of the Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor will be provided at a later date.

VII. Reporting Elements *[New Clarification]*

Beginning in 2010, there will be two components to DIR reporting. The first component is the DIR Reporting Requirements for Payment Reconciliation: Summary Report, in which Part D sponsors will be responsible for reporting multiple data elements related to DIR at the plan level. DIR data must be summarized for each plan and reported in aggregate to include multiple drugs and price concessions.

The second component of DIR reporting is the Detailed DIR Report. In this report, Part D sponsors will be responsible for providing more detailed price concession data at the drug level (NDC 11) for each Part D contract. These reporting requirements support the provisions in Section 9008 of the ACA, which imposes an annual fee on covered entities (any manufacturer or importer with gross receipts from branded prescription drug sales). Section 9008 requires that the manufacturer fee be computed by using per-unit ingredient cost net of per-unit rebate, discount, or other price concession provided by the covered entity. As the Detailed 2010 DIR

Report is a new addition this year, it will not be due until Fall 2011. CMS will provide future guidance regarding the Detailed 2010 DIR Report.

DIR REPORT FOR PAYMENT RECONCILIATION: DESCRIPTION OF COLUMNS IN SUMMARY REPORT

In the Summary Report, Part D sponsors will be responsible for reporting multiple data elements related to DIR at the plan level. DIR data must be summarized for each plan and reported in aggregate to include multiple drugs and price concessions.

DIR # 1. PBM Retained Rebates

All rebates associated with the Medicare prescription drug benefit that are received by PBMs from pharmaceutical manufacturers and retained by the PBMs must be reported in this column. Please note that rebates that PBMs have passed through to the Part D sponsor (and therefore, are not retained) are reported in column DIR #3, All Other Rebates.

DIR #2. Rebates Expected But Not Yet Received

Good faith estimates of rebate amounts that are expected for the applicable contract year, but have not yet been received are reported in this column. This column should not include rebate amounts that have been received by the sponsor prior to the latest submission of the DIR report unless the rebate amounts are received by the sponsor after the DIR data for the report are compiled. Part D sponsors are advised that the DIR data used to produce the DIR report should be reasonably current, reflecting at a minimum the DIR amounts received up to three months prior to the submission deadline.

DIR # 3. All Other Rebates

All rebates associated with the Medicare prescription drug benefit are reported in this column with the exception of the rebate amounts reported in columns DIR #1 and DIR #2. Included in this column are rebate guarantee amounts from PBMs and rebates received from pharmaceutical manufacturers for Part D purchases, such as market share rebates. The actual rebate amounts received for rebates that were estimated and applied to the negotiated price at the point of sale are also reported in this column. Rebates that PBMs have received from pharmaceutical manufacturers for Part D purchases and passed through to the Part D sponsor must also be included in this column.

Per 42 C.F.R. 423.464, Part D sponsors are required to coordinate benefits with State Pharmaceutical Assistance Programs (SPAPs) and entities providing other prescription drug coverage (described in 42 C.F.R. 423.464(f)(1)). CMS has taken many steps to help facilitate the coordination of benefits between Part D sponsors and third party providers of prescription drug coverage. However, there are instances in which Part D sponsors must reimburse third party payers for Part D claims due to COB errors. All rebates associated with these incurred Part D drug costs must be reported in this column.

Also reported in this column are rebates associated with Plan-to-Plan (P2P) claims. Under the current process for reimbursing P2P claims, the Part D sponsor actually incurring the Part D drug costs (the plan of record) does not have claim level data and therefore is unable to receive rebates for these claims. The submitting plan, however, may receive rebates for these claims and is required to report them to CMS. Rebates received by the submitting plan for P2P claims must be reported in this column.

DIR #4. Rebate Administration Fees Reported as DIR [New Requirement]
Rebate administration fees amounts that do not meet the definition of a bona fide service fee and that are received in connection with the Medicare Part D program are considered DIR. These rebate administration fee amounts, including rebate administration fees received by PBMs, must be reported in this column of the DIR Report for Payment Reconciliation-Summary Report. If the rebate administration fee exceeds fair market value, but otherwise meets the definition of a bona fide service fee, the differential between the rebate administration fee and fair market value must be reported in this column. The amounts reported in this column of the DIR Report are considered DIR and therefore, will be included in the Total DIR column.

DIR # 5. Price Concessions for Administrative Services
Price concessions from pharmaceutical manufacturers for administrative services associated with the Part D benefit are reported in this column. This includes administrative services received by the Part D sponsor from pharmaceutical manufacturers at a cost below market value. The difference between the market value of the administrative service and the price paid by the Part D sponsor should be reported in this column. Also reported in this column are grants received by the Part D sponsor from pharmaceutical manufacturers for services and programs such as utilization management and medical education. Applicable price concessions for administrative services that are not associated with a specific drug must be reported in full in this column with no portion allocated for non-Part D Covered drugs. This DIR must fully accrue to the government and beneficiaries and cannot be kept by the Part D sponsor. Please note that PBM retained rebates must be reported in column DIR #1, "PBM Retained Rebates", and are therefore not included in this column (DIR #5).

DIR # 6. Legal Settlement Amounts [New Requirement]
Reported in this column are legal judgments or settlement amounts from lawsuits or other legal action, which directly or indirectly impact the drug costs incurred by the Part D sponsor for contract year 2010. To report legal judgments or settlement amounts that impacted the drug costs incurred in prior contract years, Part D sponsors must submit a revised DIR Report for Payment Reconciliation for the applicable contract year. Legal judgments or settlement amounts paid by the Part D sponsor which serve to increase the drug costs incurred by the sponsor for contract year 2010 must be reported in this column as a negative adjustment. Legal judgments or settlement amounts received by the Part D sponsor that serve to decrease the drug costs incurred by the sponsor for contract year 2010 must be reported as a positive adjustment.

Legal fees associated with the lawsuit or legal action for each legal judgment or settlement amount received may be excluded from the amount reported on the DIR Report for Payment Reconciliation for the applicable contract year up to the total amount of the judgment or settlement associated with the applicable lawsuit or legal action. For example, Sponsor A received a settlement amount of $500,000 for lawsuit A that impacted drugs costs for contract year 2008 and $100,000 for lawsuit B that impacted drug costs for contract year 2009. Sponsor A incurred $100,000 in legal fees for lawsuit A and $125,000 in legal fees for lawsuit B. Sponsor A would report $400,000 on the 2008 DIR Report for Payment Reconciliation and $0 on the 2009 DIR Report for Payment Reconciliation. Please note, however, that Part D

sponsors cannot include legal fees associated with lawsuits or legal action in which the Part D sponsor is required to pay a judgment or settlement amount on the DIR Report for Payment Reconciliation as a negative adjustment.

DIR # 7. All Other Price Concessions from Manufacturers [New Requirement]
All price concessions received from pharmaceutical manufacturers (either direct or indirectly) that cannot be categorized into columns DIR #1 though #6 and are associated with the Part D benefit are reported in this column.

If all price concessions received from pharmaceutical manufacturers are captured in DIR #1 though #6, the value in this column will be zero.

DIR # 8. Generic Dispensing Incentive Payments and Adjustments
Reported in this column are generic dispensing incentive payments or adjustments made after the point of sale. Specifically, if a plan pays the pharmacy a prospective dispensing fee per event but recoups some of the fee if the pharmacy does not meet a target generic dispensing rate, the amount recouped by the plan must be reported to CMS as a positive adjustment that will reduce the drug costs of the Part D sponsor. Conversely, the sponsor should report payments made to the pharmacy after the point of sale as a negative adjustment.

DIR # 9. Pharmacy Payment Adjustments
With the exception of adjustments to generic dispensing incentive payments and adjustments, which are reported in column DIR #8, applicable adjustments to pharmacy payments are reported in this column. These include penalties or pharmacy repayments stipulated in the Part D sponsor's contract with its network pharmacies that represent incorrect drug costs that were paid or reported by the Part D sponsor due to an error made by the pharmacy. For these types of pharmacy penalties, the portion of the penalty that is equivalent to the amount by which the drug costs paid by the Part D sponsor or reported to CMS on the PDE exceeds the correct drug costs must be reported as DIR in this column.

Applicable pharmacy adjustments that reduce the total payments made to the pharmacy should be reported as a positive adjustment that will serve to reduce the plan's drug costs. Applicable pharmacy adjustments that increase the total payments made to the pharmacy should be reported as a negative adjustment that increases the plan's drug costs.

Amounts credited to the Part D sponsor by the pharmacy due to beneficiary cost-sharing that exceeds the gross drug cost are also reported in this column, provided that these payments are not already reflected in the covered plan paid (CPP) amounts reported on the PDE data.

DIR # 10. Risk Sharing Arrangement Payments and Adjustments
Gains or losses that the Part D sponsor may receive as a result of risk sharing arrangements with entities other than CMS that are permissible under the Part D rule are reported in this column. Risk sharing amounts received from other parties must be reported in this column as a positive adjustment. Risk sharing amounts credited to other parties must be reported in this column as a negative adjustment.

DIR # 11. All Other DIR
All applicable DIR (as well as adjustments to DIR) that is not reported in the previous columns must be included in this column.

PBM penalty payments or repayments that have not been submitted on adjusted PDE records are also included in this column. In cases where a PBM penalty represents incorrect drug costs that were paid or reported by the Part D sponsor due to an error made by the PBM, the portion of the penalty that is equivalent to the amount by which the drug costs paid by the plan or reported to CMS on the PDE exceed the correct drug costs should be reported as DIR.

DIR included in this column that is not associated with a specific drug must be reported in full on the DIR Report for Payment Reconciliation-Summary Report with no portion allocated to non-Part D covered drugs. This DIR must fully accrue to the government and beneficiaries and cannot be kept by the Part D sponsor.

Other DIR Text Description
A short description indicating the type of price concession, the type of entity from (or to) that the Part D sponsor is collecting (or paying) the amount (e.g., pharmacy or PBM), and the associated dollar amount is required in this column for each price concession or DIR adjustment included in column DIR #11 – All Other DIR. This field must be left blank if there is no dollar amount reported in column DIR #11.

Total DIR
Reported in this column is the sum of all of the DIR reported for the Part D plan for the applicable contract year. The values in this field are automatically generated on the DIR Report for Payment Reconciliation and represent a sum of the values reported in columns DIR #1 – DIR #11. If reporting zero total DIR dollars for a specific Part D plan, Part D sponsors must provide a short explanation in the "Additional Comments" column of the DIR Report for Payment Reconciliation-Summary Report.

Rebates at POS?
If the Part D sponsor applied (estimated) rebates to the negotiated price at the point of sale in the applicable contract year, the Part D sponsor should enter "Y" in this column for each applicable Part D plan. Otherwise, this field should be left blank to indicate that rebates were not applied to the negotiated price at the point of sale.

Rebate Administration Fees Reported as Bona Fide Service Fees [New Requirement]

Rebate administration fees that meet the definition of a bona fide service fee and are received in connection with the Medicare Part D program must be reported in this column of the DIR Report for Payment Reconciliation-Summary Report. This includes rebate administration fees received by PBMs that are not passed through to the Part D sponsor. If the rebate administration fee exceeds fair market value, but otherwise meets the definition of a bona fide service fee, the differential between the rebate administration fee and fair market value must be reported in column DIR #4-Rebate Administration Fee Reported as DIR. Bona fide service fees are not considered DIR, therefore **the amounts reported in the column titled "Rebate**

Administration Fees Reported as Bona Fide Service Fees" will not be included in the Total DIR column. In addition, these amounts will not be excluded from allowable reinsurance costs and allowable risk corridor costs when CMS calculates reinsurance and risk sharing payments during the Part D payment reconciliation process.

All Other Bona Fide Service Fees [New Requirement]
Any bona fide service fees that are received in connection with the Medicare Part D program and are not included in rebate administration fees must be reported in this column.

PBM Spread Amounts [New Requirement]
The aggregate amount of the difference between the amount paid to the PBM and the amount the PBM pays pharmacies, sometimes referred to as "PBM spread" or "risk premium", must be reported in this column of the DIR Report for Payment Reconciliation. Section 6005 of the ACA establishes PBM transparency requirements, and we are therefore requiring sponsors to submit PBM spread amounts data. We emphasize that sponsors must report aggregate values for all PBM Spread amounts, and not the PBM Spread for each pharmacy. These amounts are for all drug costs under the Part D program, and thus include both covered and non-covered drugs under the Part D program.

The PBM Spread Amounts are not considered DIR because they do not serve to change the drug cost paid by Part D sponsors at the point of sale. Therefore the amounts reported in this column of the DIR Report will not be included in the Total DIR column. In addition, these amounts will not be excluded from allowable reinsurance costs and allowable risk corridor costs when CMS calculates reinsurance and risk sharing payments during the Part D payment reconciliation process.

PBM Spread amounts are confidential and shall not be disclosed by CMS, except in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs for the purposes of complying with Section 6005 of the ACA or to carry out Part D program functions.

If sponsors use pass-through pricing, this value should be zero.

Additional Comments
Additional notes or comments on the data provided in columns DIR #1 — DIR #11 are included in this column. For example, sponsors must provide a short explanation if reporting zero total DIR dollars for a specific Part D plan. In addition, Part D sponsors must provide a description in this column for any PBM manual adjustments or PBM penalty amounts reported in column DIR #11-All Other DIR.

Part D sponsors are also encouraged to provide a description for any risk sharing arrangement amounts reported in column DIR #10. If the Part D sponsor, or its PBM, receives bona fide service fees from pharmaceutical manufacturers other than rebate administration fees, which are reported in the column titled All Other Bona Fide Service Fees, a short description should be reported in this column.

VIII. Report Format and Layout *[New Clarification]*

DIR Report for Payment Reconciliation-Summary Report (With Sample Values)

Contract-Plan	DIR #1 – PBM Retained Rebates	DIR #2 – Rebates Expected But Not Yet Received	DIR # 3 – All Other Rebates	DIR #4 Rebate Administration Fees Reported as DIR	DIR # 5 – Price Concessions for Administrative Services	DIR #6 - Legal Settlement Amounts	DIR #7 - All Other Price Concessions from Manufacturers	DIR # 8 – Generic Dispensing Incentive Payments and Adjustments	DIR # 9 – Pharmacy Payment Adjustments
S####-001	27500.25	7000.00	137500.65	9000.00	2000.00	0.00	0.00	-3500.50	-4500.00
S####-002	0.00	250.00	12000.76	1500.00	1500.25	5000.00	1000.00	-500.00	-1550.00
S####-003	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

(…columns continued…)

DIR # 10 – Risk Sharing Arrangement Payments and Adjustments	DIR # 11 – All Other DIR	Other DIR Text Description	Total DIR	Rebates at POS?	Rebate Administration Fees Reported as Bona Fide Service Fees	All Other Bona Fide Service Fees	PBM Spread Amounts	Additional Comments
6000.00	0.00		181000.40	Y	27,150.06	0.00	50000.00	DIR #10-Received $6000 from risk sharing arrangement with physicians for prescription drug costs.
-2250.77	1500.00	1. DIR for PBM penalty: $1500.00	18450.24		1867.54	0.00	0.00	DIR #6-Received $5000 net of legal fees in manufacturer legal settlement. DIR #10-Paid $2250.77 to physicians due to risk sharing arrangement for prescription drug costs. DIR #11- Received $1500 from PBM due to error in applying step therapy requirements.
0.00	0.00		0.00		0.00	0.00	0.00	No DIR due to very low membership, no claims with associated DIR.

File Record Layout:
DIR Report for Payment Reconciliation-Summary Report

Field Name	Field Type	Field Length	Field Description (see guidance for details)
Contract-Plan	Character	9	Contract number and plan ID, e.g. S0001-001. This number must be entered as an alphanumeric value and must be entered as one letter followed by the four digit contract number, a dash, and the three digit plan ID. The values in this field must be entered for each Part D plan as it will not be automatically generated.
DIR #1 – PBM Retained Rebates	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, the sum of all applicable PBM retained rebates and applicable rebate administration fees.
DIR #2 – Rebates Expected But Not Yet Received	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide a good faith estimate of the sum of applicable rebates expected but not yet received.
DIR #3 – All Other Rebates	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of all other applicable rebates including rebates for COB claims and P2P claims.
DIR #4 – Rebate Administration Fees Reported as DIR	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of all applicable rebate administration fees that are not considered bona fide service fees.
DIR #5 – Price Concessions for Administrative Services	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of applicable price concessions for administrative services.
DIR #6 – Legal Settlement Amounts	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of all applicable legal settlement and judgment amounts. For a negative value, enter a minus sign and the value for the field.
DIR #7 – All Other Price Concessions from Manufacturers	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of all other applicable price concessions received from manufacturers that are not reported in columns DIR #1-6.

DIR #8 – Generic Dispensing Incentive Payments and Adjustments	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of applicable generic dispensing incentive payments and adjustments. For a negative value, enter a minus sign and the value for the field.
DIR #9 – Pharmacy Payment Adjustments	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of applicable pharmacy payment adjustments. For a negative value, enter a minus sign and the value for the field.
DIR #10 – Risk Sharing Arrangement Payments and Adjustments	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of DIR from risk sharing arrangements. For a negative value, enter a minus sign and the value for the field.
DIR #11 – All Other DIR	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of all other applicable DIR not reported in columns DIR # 1-10. For a negative value, enter a minus sign and the value for the field.
Other DIR Text Description	Character	4000	Description required for **all** DIR reported in DIR # 11 for each Part D plan. Please leave blank if no DIR reported in DIR #11 for Part D plan.
Total DIR	Number Required	15 digits before the decimal and 2 digits after	Sum of all DIR reported for Part D plan. Automatically generated. Does not include amounts reported in the following columns: Rebate Administration Fees Reported as Bona Fide Service Fees, All Other Bona Fide Service Fees, and PBM Spread Amounts.
Rebates at POS?	Character	1	For each Part D plan, indicate "Y" if estimated rebates were applied to the negotiated price at the point of sale. Please leave blank if estimated rebates were not applied to the negotiated price at the point of sale.
Rebate Administration Fees Reported as Bona Fide Service Fees	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of all rebate administration fees considered bona fide service fees.
All Other Bona Fide Service Fees	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of all applicable bona fide service fees not reported in the Rebate Administration Fees Reported as Bona Fide Service Fees column.
PBM Spread Amounts	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of all applicable PBM Spread Amounts. For a negative value, enter a minus sign and the value for the field.
Additional Comments	Character	4000	Additional comments on data reported on DIR Report for Payment Reconciliation.

IX. Steps for Submitting DIR Report for Payment Reconciliation *[New Clarification]*

1. Enter DIR Submission Information
    a. Go to the DIR Submission Information page using the following pathway: HPMS Homepage > Plan Bids > DIR Reporting (for Payment Reconciliation) > Contract Year 2010 > DIR Submission Info.
    b. For each contract, provide a response for each question or enter "N/A" as applicable. If the 2010 DIR Report for Payment Reconciliation was previously submitted, provide a reason for resubmitting the DIR Report.

2. Download DIR Report Template
    a. Go to the DIR Download page using the following navigation path: HPMS Homepage > Plan Bids > DIR Reporting > Contract Year 2010 > Download Template.
    b. Download the DIR Report Template.

3. Enter data into DIR Report Template to create new DIR Report
    a. Enter the Contract-Plan number into the DIR Report Template. This number must be entered as a 9 character alphanumeric value and must be entered as one letter followed by the four digit contract number, a dash, and the three digit plan ID (e.g., S0001-001). The values in this field must be entered for each Part D plan as it will not be automatically generated.
    b. Enter the DIR values for each plan into the DIR Report Template.
        i. If your organization has no DIR to report for plan, enter $0 in DIR columns #1-#11 and provide an explanation in the "Additional Comments" column of the DIR Report.
        ii. If a value is entered in DIR column #11, "All Other DIR", enter a description of the amounts entered in the "Other Text Description" column.
        iii. The amounts in the "Total DIR" column are automatically generated. Review the totals in this column to ensure that they are correct.
        iv. If your organization applied estimate rebates at the point of sale, enter "Y" in the "Rebates at POS" column. Otherwise, enter "N".
    c. Enter the amounts for any rebate administration fees considered bona fide service fees in the "Rebate Administration Fees Reported as Bona Fide Service Fees" column.
    d. Enter a description and dollar amount for any other bona fide service fees received in the "Additional Comments" column of the DIR Report.

4. Save DIR Report as **DIR.xls**. The DIR report cannot be uploaded if it is not named DIR.xls or DIR_2010.xls.

5. Upload DIR Report
    a. Go to the DIR Upload page using the following navigation path: HPMS Homepage > Plan Bids > DIR Reporting (for Payment Reconciliation) > Contract Year 2010 > (Submission) Upload.
    b. Upload the completed DIR Report saved as DIR.xls.
    c. If you receive any error messages, make corrections to the DIR Report, save as DIR.xls, and attempt to upload again.

d. If you are unable to resolve the error messages, contact the HPMS Help Desk at either 1-800-220-2028 or hpms@cms.hhs.gov.

6. Review DIR Report saved in HPMS
   a. Go to the DIR Download page using the following navigation path: HPMS Homepage > Plan Bids > DIR Reporting (for Payment Reconciliation) > Contract Year 2010 > DIR Reports > Go to the DIR Report page.
   b. Review the submission information and DIR values in the DIR Data Report saved on HPMS.
   c. Check the Total DIR values for each plan to ensure they are accurate.
   d. If there any errors, make corrections to the DIR Report, save as DIR.xls, and upload the corrected DIR report. If you are unable to resolve the errors, contact the HPMS Help Desk.