



Center for Beneficiary Choices
Medicare Plan Payment Group

Date: April 16, 2008

To: All Part D Plan Sponsors

From: Tom Hutchinson, Director
Medicare Plan Payment Group

Subject: Draft Medicare Part D DIR Reporting Requirements for 2007 Payment Reconciliation

Part D sponsors are required to report their direct and indirect remuneration (DIR) data for the Medicare Prescription Drug Benefit to CMS within six months of the end of the coverage year for the purposes of payment reconciliation. In the attached document, “Medicare Part D DIR Reporting Requirements for Payment Reconciliation”, CMS provides proposed guidance for Part D sponsors on reporting DIR data for contract year 2007. This proposed guidance incorporates several clarifications and changes from the DIR reporting requirements for contract year 2006.

We are proposing to add three new columns to the DIR Report for Payment Reconciliation. In the first new column, DIR #2- PBM Retained Rebates, Part D sponsors will be required to report rebates which PBMs have received and retained from pharmaceutical manufacturers. In the new column, Rebates at POS?, Part D sponsors will indicate whether they applied estimated rebates at the point of sale during contract year 2007. The third new column, Additional Comments, provides a place for Part D sponsors to document any additional comments regarding their reported DIR data. Please see pages 7, 11, and 12 of the proposed guidance for additional information on these new columns of the DIR Report for Payment Reconciliation.

For contract year 2007, we are asking Part D sponsors to provide additional information on HPMS prior to submitting their DIR Report for Payment Reconciliation. Specifically, we are asking Part D sponsors to provide information regarding any PBMs which the sponsors contracted with in contract year 2007. In addition, Part D sponsors will be asked to provide a description of any methodology used to allocated DIR or rebates between Part D plans. We are also asking Part D sponsors to provide an explanation for their resubmissions, when resubmitting the DIR Report for Payment Reconciliation. Please see page 5 of the proposed guidance for additional information on these changes.

We have also included additional guidance clarifying that certain settlement amounts

from lawsuits should be reported as DIR. In addition, we have clarified that rebate administration fees and any price concession received from pharmaceutical manufacturers must be reported on the DIR Report for Payment Reconciliation. Please see pages 2, 7, and 10 of the proposed guidance for additional information.

CMS will accept comments for review on this proposed guidance until Friday, May 9, 2008. We will review the comments received and post the final contract year 2007 DIR reporting requirements. Part D sponsors must submit the 2007 DIR Report for Payment Reconciliation to CMS by Monday, June 30, 2008.

Comments may be submitted electronically to Meghan.elrington@cms.hhs.gov.

Comments also may be mailed to:

Meghan Elrington
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Baltimore, Maryland 21244

Further Information

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

MEDICARE PART D DIR REPORTING REQUIREMENTS FOR PAYMENT RECONCILIATION- CONTRACT YEAR 2007

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 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 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.

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. 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. Per Section 1860D-15(d)(2)(a) of the Act, CMS payments to a Part D sponsor are conditioned upon the provision of data necessary to determine payment, which include the requisite DIR data. 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. These requirements will be in effect for Contract Year 2007.

II. Defining Direct and Indirect Remuneration (DIR)

Per 42 C.F.R. Section 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 serves to decrease the costs incurred by the Part D sponsor (whether directly or indirectly) for the Part D drug. DIR includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits. This includes settlement amounts from lawsuits or other legal action, which directly or indirectly impact the drug costs incurred by

Part D sponsors for Part D drugs. However, rebates and other price concessions which do not directly or indirectly impact the drug costs incurred by the Part D sponsor are not included in DIR. Please note that DIR includes all grants, rebates, settlement amounts, or price concessions received by the Part D sponsor from pharmaceutical manufacturers (whether directly or indirectly). As stated in the preamble to subpart G of the Medicare Part D final rule (p. 4308 - 4309), CMS has a responsibility to ensure that price concessions are not masked as administrative fees. Therefore, we must assume that all rebates, grants, or other price concessions received directly or indirectly from pharmaceutical manufacturers serve to reduce the drug costs incurred by the Part D sponsor.

DIR includes rebates, discounts, and other price concessions from pharmaceutical manufacturers for purchases under the Medicare prescription drug benefit even if they are received by subcontractors of Part D sponsors, such as pharmaceutical benefit managers (PBM), and retained by the subcontractor in lieu of higher service fees from the Part D sponsor. As stated in the 2007 Call letter released on April 3, 2006, 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, as a price concession received by the Part D sponsor, these retained rebates must be reported as DIR for payment purposes.

Part D sponsors must report these price concessions in accordance with the "Reporting of Manufacturer Rebates in Part D" guidance provided in the 2007 call letter and therefore, must report 100% of the manufacturer rebates, discounts, and other price concessions retained by the PBM as DIR, regardless of the relationship between the sponsor and the PBM and the provisions of the contracts between the sponsor and the PBM. This includes rebate administration fees which the PBM receives from pharmaceutical manufacturers.

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 could a risk sharing arrangement be developed around administrative costs. All 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 can be negative. Please note that this policy does not apply to private reinsurance arrangements, arrangements in which the Part D sponsor shares risk with a party otherwise uninvolved in the administration or delivery of the Medicare Part D benefit. Private reinsurance amounts do not constitute DIR and should not be reported on the DIR Report for Payment Reconciliation.

Instead, reinsurance amounts from private reinsurance arrangements are included in the Part D sponsor's bid as a non-pharmacy expense.

Dispensing incentive payments and adjustments to dispensing incentive payments made to pharmacies after the point of sale dispensing event are also considered DIR. Please note that dispensing incentive payments made to the pharmacy at the point of sale are part of the dispensing fee reported on the prescription drug event (PDE) record and therefore are not included in the DIR Report for Payment Reconciliation.

III. Reporting Requirements

Part D sponsors must report DIR associated with purchases under the Medicare prescription drug benefit on the DIR Report for Payment Reconciliation. The DIR included on the DIR Report for Payment Reconciliation 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. As a result, Part D sponsors should consider their best expectation of DIR when developing their bids.

Some DIR is reflected in the amount paid at the point of sale (sum of ingredient cost, dispensing fee, and applicable sales tax). As a result, this DIR is already taken into account for payment purposes in the gross drug cost reported to CMS on the prescription drug event (PDE) record and therefore, should not be reported on the DIR Report for Payment Reconciliation. Part D sponsors must establish mechanisms to distinguish point of sale price concessions that reduce the gross drug cost reported on the PDE record, and exclude this DIR from the DIR Report for Payment Reconciliation. Please note, however, that beginning in 2008, actual rebate amounts for rebates which were estimated, applied at the point of sale, and reported in the "Estimated Rebate at POS" field of the PDE records, must be reported on the DIR Report for Payment Reconciliation. See the June 1, 2007 memorandum, "Reporting Estimated Rebates Applied to the Point-of-Sale Price", available on the CMS website at www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/EstimatedRebates0607.pdf for additional information.

CMS provides reinsurance or 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. Please refer to 42 C.F.R. 423.100 for the definitions of Part D drug and covered Part D drug. When calculating allowable reinsurance and risk sharing costs, CMS will only apply DIR dollars for covered Part D drugs. Therefore, Part D sponsors are required to submit DIR for covered Part D drugs only on the DIR Report for Payment Reconciliation. DIR for non-

Part D covered drugs (drugs covered by the Part D sponsor which are not Part D drugs) should not be included on this report.

All applicable DIR for covered Part D drugs must be reported in full on the DIR Report for Payment Reconciliation with no reduction for administrative cost or any other fees. This includes DIR for supplemental prescription drug benefits as well as DIR for purchases in the deductible phase and the coverage gap. This DIR will be excluded from allowable costs when CMS determines final reinsurance and risk sharing payments. Part D sponsors are required to report this DIR to CMS in the report format provided below (please see section V. Report Format and Layout).

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. Several Part D sponsors may receive or record their DIR at the sponsor or contract level. In these cases, the Part D sponsor must allocate their DIR to the plan level by applying a *reasonable* allocation methodology. A brief description of this reasonable allocation methodology should be submitted on HPMS by the Part D sponsor when uploading the 2007 DIR Report for Payment Reconciliation. Part D sponsors are expected to maintain documentation of the allocation methodology which was applied.

All applicable DIR received for Part D plan expenditures during the contract year must be reported on the DIR Report for Payment Reconciliation. In addition, Part D sponsors must include good faith estimates for DIR that has not yet been received but is expected for the applicable contract year. This would include 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 which have been submitted and processed after the PDE data submission deadline. These estimated DIR amounts should be reported in column 8 of the DIR Report for Payment Reconciliation, “All Other DIR”.

Please note that 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 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.

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 is subject to audit. Part D sponsors are required to maintain records of all related transactions, claims, contracts, and other materials. In addition, in accordance with 42 CFR 423.505(k)(5), Part D sponsors will be required to submit an attestation in which they must certify that the 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. Additional guidance regarding this attestation will be provided at a future date. Please note that misrepresentations or omissions in the DIR data provided to CMS may result in Federal civil action and/or criminal prosecution.

The 2007 DIR Report for Payment Reconciliation will become available on June 9, 2008. Part D sponsors will be able to download it from HPMS using the following navigation path: HPMS Homepage > Plan Bids > DIR Reporting > Contract Year 2006 > DIR Reporting (for Payment Reconciliation). This report will be downloadable to a MS Excel spreadsheet in the format provided below in Section V: Report Format and Layout. Part D sponsors must prepare and upload to HPMS the 2007 DIR Report for Payment Reconciliation for each of their Part D plans by **June 30, 2008**. In order to upload successfully, **Part D sponsors must use the actual downloaded MS Excel spreadsheet and name the file DIR.xls**. When uploading the 2007 DIR Report for Payment Reconciliation on HPMS, Part D sponsors will be required to provide additional information. Specifically, Part D sponsors will be asked to indicate whether they contracted with the same PBM in contract years 2006 and 2007. They will be asked to provide the name of any PBM with which the Part D sponsor contracted in 2007. In addition, Part D sponsors will be asked to provide a description of any methodology used to allocate DIR or rebates between Part D plans. Please note that when resubmitting the 2007 DIR Report for Payment Reconciliation, Part D sponsors will also be required to provide an explanation for the resubmission of their DIR data. If any of these questions are not applicable to the Part D sponsor's plans, the sponsor should enter "N/A".

Sponsors may upload the 2007 DIR Report for Payment Reconciliation as many times as they choose between June 9, 2008 and 11:59 p.m. EDT on Monday, June 30, 2008. CMS will use the DIR reported on the most recently uploaded report during payment reconciliation. Please note that per §423.346, CMS has discretion to reopen and revise initial or reconsidered final Part D payment determinations. One of the grounds for finding good cause to reopen a final payment determination is the furnishing of new and material evidence that was not readily available at the time the final determination was made. Thus, Part D sponsors may request a reopening of their final Part D payments if DIR data (or PDE data) becomes available after the June 30, 2008 submission deadline which would have a material impact on the final Part D payments. CMS will review the request to determine whether, consistent with §423.346, to reopen the final determination.

Part D sponsors must prepare and submit the DIR Report for Payment Reconciliation to CMS even if they have no DIR to report for contract year 2007. For plans that have no DIR to report for contract year 2007, the Part D sponsor must include a brief explanation in the column "Additional Comments". 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 2007 DIR Report for Payment Reconciliation, sponsors can contact Meghan Elrington at (410) 786-8675 or meghan.elrington@cms.hhs.gov.

IV. Summary of Reporting Elements

Part D sponsors will be responsible for reporting multiple data elements related to DIR. DIR will be reported to CMS at the Part D plan level. DIR data must be summarized for each plan and reported in aggregate to include multiple drugs and price concessions. DIR that is not generated from the sponsor's Medicare Part D book of business should not be reported.

Reporting Elements:

DIR # 1. Rebates for Reimbursed Coordination of Benefits (COB) Claims
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 with the exception of those 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 column DIR # 8, "All Other DIR", and are therefore not included in this column (DIR # 1).

DIR # 2. PBM Retained Rebates

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

DIR # 3. All Other Rebates

All rebates associated with the Medicare prescription drug benefit are reported in this column with the exception of PBM retained rebates and rebates associated with plan reimbursed coordination of benefits (COB) claims. Included in this column are rebates that the Part D sponsor receives from pharmaceutical manufacturers for Part D purchases such as market share rebates. Also included in this column are rebates and rebate administration fees that PBMs

have received from pharmaceutical manufacturers for Part D purchases and passed through to the Part D sponsor. Please note that pharmaceutical manufacturer rebates received by long term care (LTC) pharmacies are not reported on the DIR Report for Payment Reconciliation and therefore are not included in this column. Part D sponsors are required to report these LTC pharmacy rebates to CMS quarterly for oversight purposes as described in the Call Letter for 2007. Please see the Medicare Part D Reporting Requirements for contract year 2007 available on the CMS website at www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp for information on the quarterly reporting of these LTC pharmacy rebates to CMS.

DIR # 4. Price Concessions for Administrative Services

Part D sponsors must report in this column price concessions for administrative services that (i) are associated with the Part D benefit and (ii) directly or indirectly impact the drug costs incurred by the Part D sponsor. 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 grants. 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 rebates received by subcontractors of Part D sponsors, such as pharmaceutical benefit managers (PBM), and retained by the subcontractor in lieu of higher service fees from the Part D sponsor must be reported in column DIR # 2, "PBM Retained Rebates", and are therefore not included in this column (DIR # 4).

DIR # 5. Generic Dispensing Incentive Payments and Adjustments

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 point of sale (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. This payment is not reported as DIR and therefore is not included in this column.

However, if the sponsor should pay the pharmacy a generic dispensing incentive payment after the point of sale or make any post-POS adjustments to prospective generic dispensing incentive payments, the sponsor must report the post- POS payments or adjustments as DIR and include them in this column. Specifically, if the plan pays the pharmacy a prospective dispensing fee per event but recoups some of the cost if the pharmacy does not meet a target

dispensing rate, the amount recouped by the plan must be reported to CMS as a positive adjustment that will reduce the cost of the drug to the plan sponsor. Conversely, the sponsor should report payments made to the pharmacy after the point of sale as a negative adjustment. For example, if the plan pays the pharmacy more than the prospective amount based on meeting or exceeding a dispensing target, the plan should report the later payment to the pharmacy as a negative adjustment that will decrease the total for this column. See Q&A # 9035 available on the CMS website at http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php?p_sid=ukDaKb*i&p_accessibility=0 for more information regarding the reporting of dispensing incentive payments.

DIR # 6. 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 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. Gains or losses from all applicable risk sharing arrangements must be reported in this column. Risk sharing amounts received from other parties must be reported in this column as a positive adjustment to reduce prescription drug costs in the calculation of allowable reinsurance and risk corridor costs. Risk sharing amounts credited to other parties must be reported in this column as a negative adjustment to increase prescription drug costs in the calculation of allowable reinsurance and risk corridor costs.

Please note that the net cost of private reinsurance is included in the bid as a non-pharmacy expense. Therefore, gains or losses from private reinsurance arrangements in which the Part D sponsor shares risk with a party otherwise uninvolved in the administration or delivery of the Medicare Part D benefit, are not reported in this column or on the DIR Report for Payment Reconciliation.

DIR # 7. Pharmacy Payment Adjustments

With the exception of adjustments to dispensing incentive payments, which are reported in column DIR # 5, 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 reported in this column. This includes penalties or pharmacy repayments stipulated in the Part D sponsor's contract with its network pharmacies which 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. The remaining portion of the pharmacy penalty is not reported as DIR because it is considered a price concession for administrative services which does not directly or indirectly impact the drug costs incurred by the Part D sponsor.

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.

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 are also not reported as DIR and therefore are not reflected in this column.

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. This may occur when the beneficiary's copayment 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 data, this amount 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 included on this report as DIR.

DIR # 8. 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. This includes rebates associated with Plan-to-Plan (P2P) claims. Under the current process for reimbursing P2P claims, the submitting plan may receive rebates for these claims and is required to report them to CMS in this column.

Settlement amounts from lawsuits, which directly or indirectly impact the drug costs incurred by the Part D sponsor are also included in this column, DIR #8. This includes all settlement amounts received from pharmaceutical manufacturers for covered Part D drugs. Settlement amounts paid by the Part D sponsor which serve to increase the drug costs incurred by the sponsor should be reported in this column as a negative adjustment. Settlement amounts received by the Part D sponsor which serve to decrease the drug costs incurred by the sponsor should be reported as a positive adjustment.

Also reported in this column, DIR #8, are good faith estimates of DIR that is expected for the applicable contract year, but has not yet been received. This would include good faith estimates for rebates expected from pharmaceutical manufacturers that have not yet been received. It also includes good faith estimates for DIR associated with claims for the contract year which have been submitted and processed after the PDE data submission deadline.

Part D sponsors must also include in this column PBM penalty payments or repayments stipulated in their contracts with PBMs that (i) occur after the point of sale and (ii) directly or indirectly impact the drug costs incurred by the Part D sponsor. For example, if a PBM (instead of the Part D sponsor) is required to pay the entire cost of a claim 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 Part D sponsor must report the amount of this claim as DIR. This is required because the PDE data submitted to CMS would not reflect this reduction in drug costs for the Part D sponsor. Another example is a PBM penalty stipulated in the Part D sponsor's contract with the PBM which represents incorrect drug costs that were paid or reported by the Part D sponsor due to an error made by the PBM. For this type of PBM penalty, 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 exceeds the correct drug costs must be reported as DIR. The remaining portion of the PBM penalty is not reported as DIR because it is considered a price concession for administrative services which does not directly or indirectly impact the drug costs incurred by the Part D sponsor. Please note that in most cases, the Part D sponsor should submit an adjusted PDE with a revised gross drug cost if the PBM has administered the benefit incorrectly. In these cases, the PBM penalty associated with the error in drug cost should not be reported as DIR since the PDE record has been adjusted to reflect the appropriate gross drug cost.

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 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.

Please note that claims data or estimates of claims data are not considered DIR and therefore are not reported on the DIR Report for Payment Reconciliation. Claims data received or processed after the PDE data submission deadline should be reported on PDE records and must not be reported on the DIR Report for Payment Reconciliation.

Other Text Description

A short description indicating the type of price concession, the type of entity from which the Part D sponsor is collecting (or paying) the amount (e.g. pharmacy, manufacturer, PBM), and the associated dollar amount is required in this column for each price concession or DIR adjustment included in column DIR # 8 – All

Other DIR. This field must be left blank if there is no dollar amount reported in column DIR #8.

Rebate at POS?

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 at the point of sale. If the Part D sponsor applied (estimated) rebates to the negotiated price at the point of sale, 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.

Additional comments

Additional notes or comments on the data provided in columns DIR #1- DIR # 8. For example, sponsors must provide a short explanation if reporting zero total DIR dollars for a specific plan.

V. Report Format and Layout

DIR Report for Payment Reconciliation (With Sample Values)

Contract-Plan	DIR # 1- Rebates for Reimbursed Coordination of Benefits Claims	DIR #2 – PBM Retained Rebates	DIR # 3 – All Other Rebates	DIR # 4 – Price Concessions for Administrative Services	DIR # 5 – Generic Dispensing Incentive Payments and Adjustments	DIR # 6 – Risk Sharing Arrange ment Payments and Adjustments	DIR # 7 – Pharmacy Payment Adjust ments	DIR # 8 – All Other DIR	Other DIR Text Description	Total DIR	Rebates at POS?	Additional Comments
S0001-001	+0.00	+305.25	+1450.65	+200.00	-350.50	+600.00	-450.00	+100.00	1. Expected manufacturer Rebates not yet received: \$100.00	+1855.40	Y	
S0001-002	+0.00		+1300.76	+150.25	-50.00	+225.77	-155.00	+225.00	1. DIR for PBM penalty: \$150.00 2. Expected manufacturer rebates not yet received: \$75.00	+1696.78		
S0001-003	+0.00	+0.00	+0.00	+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

Field Name	Field Type	Field Length	Field Description
Contract-Plan	Character	9	Contract number and plan ID, e.g. S0001-001. Automatically generated.
DIR # 1- Rebates for Reimbursed Coordination of Benefits Claims	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of applicable rebates for reimbursed COB claims. See guidance for details. For a negative value, enter a minus sign and the value for the cell.
DIR #2 – PBM Retained Rebates	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum of all applicable PBM retained rebates and rebate administration fees. See guidance for details. For a negative value, enter a minus sign and the value for the cell.
DIR # 3 – All Other Rebates	Number Required	12 digits before the decimal and 2 digits after	For each Part D plan, provide the sum all other applicable rebates. See guidance for details. For a negative value, enter a minus sign and the value for the cell.
DIR # 4 – 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. See guidance for details. For a negative value, enter a minus sign and the value for the cell.
DIR # 5 – 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. See guidance for details. For a negative value, enter a minus sign and the value for the cell.
DIR # 6 – 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. See guidance for details. For a negative value, enter a minus sign and the value for the cell.
DIR # 7 – 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. See guidance for details. For a negative value, enter a minus sign and the value for the cell.
DIR # 8 – 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 # 1-7. See guidance for details. For a negative value, enter a minus sign and the value for the cell.
Other Text Description	Character	4000	Description of DIR reported in All Other DIR for Part D plan. Required for all DIR reported in DIR # 7 for Part D plan. Please leave blank if no DIR reported in DIR #8 for Part D plan. See guidance for details.
Total DIR	Number Required	12 digits before the decimal and 2 digits after	Sum of all DIR reported for Part D plan. Automatically generated.
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.
Additional Notes	Character	4000	Additional comments on DIR data reported in columns DIR #1- DIR #8. See guidance for details