



Center for Drug and Health Plan Choice
Medicare Plan Payment Group

Date: June 13, 2008

To: All Part D Plan Sponsors

From: Tom Hutchinson, Director
Medicare Plan Payment Group

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

On April 16, 2008, CMS released draft guidance on the reporting of direct and indirect remuneration (DIR) data for the contract year 2007 payment reconciliation. Comments on this draft guidance were accepted until May 9, 2008 for CMS to review. In response to the comments and questions received, CMS has revised the guidance to provide additional clarification on the reporting of DIR. In addition, CMS has extended the deadline for the submission of the DIR Report for Payment Reconciliation to **Tuesday, July 15, 2008** to allow Part D sponsors additional time to prepare, validate, and submit these data to CMS. Also, CMS has addressed concerns raised during the comment period regarding the format of the DIR Report for Payment Reconciliation. Provided below is a brief summary of some of the changes made in this revised guidance.

Format

1. We received several comments about the challenges of separately identifying rebates for reimbursed coordination of benefits claims and rebates for Plan-to-Plan (P2P) claims. To simplify the reporting of DIR, therefore, CMS has revised the guidance to direct that sponsors report all rebates for each plan (with the exception of PBM retained rebates and estimated rebates) in one line item, column DIR #3, All Other Rebates. Please see pages 8, 9, and 14 of the final guidance for more information regarding this change in the format of the DIR Report for Payment Reconciliation.
2. A few commenters stated that the format of the DIR Report for Payment Reconciliation can be difficult to utilize because the document format is locked. As a result of the lock, Part D sponsors are unable to hide columns, copy certain data, or print the report to a specified number of pages. While, we understand the challenges that these limitations may present to sponsors, we are currently unable to remove this lock. We must keep this report format locked in order to protect the formatting and formulas in this report. As other options become available, we will consider ways to make it easier for Part D sponsors to utilize the DIR Report for Payment

Reconciliation.

Policy Clarifications

1. As stated in the draft DIR guidance released on April 16, 2008, we are asking Part D sponsors to provide information regarding their contracted PBMs on HPMS prior to submitting their 2007 DIR Report for Payment Reconciliation. Some commenters requested clarification regarding whether CMS is requiring information regarding all PBMs with which the Part D sponsor has contracted or only those PBMs with which the Part D sponsor has contracted for the processing of rebates. We are aware that Part D sponsors may contract with PBMs for several different functions. Therefore, we are requesting that Part D sponsors only provide the names of the PBMs with which they have contracted for the negotiation or processing of rebates. Please see page 7 of the final guidance for more information.
2. We received several comments concerning the reporting of rebate administration fees and other amounts received from pharmaceutical manufacturers. Some commenters expressed concern that certain amounts received from pharmaceutical manufacturers, such as rebate administrative fees, represent fees for legitimate administrative services and do not serve to reduce the drug cost incurred by the Part D sponsor. As a result, they stated that these amounts should not be considered DIR. Specifically, they asked that CMS exclude from DIR amounts received from pharmaceutical manufacturers which represent bona fide service fees. We agree that bona fide service fees represent legitimate, fair market value fees for administrative services performed on behalf of the drug manufacturer which do not reduce the drug costs incurred by Part D sponsors. As a result, we have revised the final guidance to reflect this policy. In addition, we have included a definition for bona fide services, which is consistent with the definition provided in the July 2007 Final Rule on Medicaid Drug Pricing. Please see pages 2 and 3 of the final guidance for more information regarding the reporting of amounts received from manufacturers such as rebate administration fees.
3. We also received comments requesting that CMS provide additional information in the final guidance regarding the appropriate reporting of settlement amounts from lawsuits or other legal action. In response to the comments received, we have provided additional information concerning the reporting of legal judgments and settlement amounts. Legal judgments and settlement amounts which directly or indirectly impact the drug costs incurred by the Part D sponsor for a specified contract year are considered DIR and must be reported to CMS. This includes legal judgments and settlement amounts received from pharmaceutical manufacturers. However, Part D sponsors may exclude certain associated legal fees from the legal judgments and settlement amounts reported on the DIR Report for Payment Reconciliation. Please see pages 12 and 13 for additional information on the reporting of legal judgments and settlement amounts.
4. We also received comments requesting that CMS provide additional information in the final guidance regarding the reporting of rebates and other DIR amounts received

after the submission deadline. We are aware that there are instances when Part D sponsors may receive unanticipated rebate amounts, settlement amounts, or other price concessions after the submission deadline which could result in changes to the DIR data reported to CMS. Additional guidance regarding the reporting of these changes in DIR data will be provided at a later date.

Please find attached the final revised guidance document, “Medicare Part D DIR Reporting Requirements for Payment Reconciliation” on the reporting of DIR data for the purposes of the contract year 2007 payment reconciliation. Please note that for contract year 2007, Part D sponsors will be required to submit the Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor prior to the completion of the 2007 Part D Payment Reconciliation. In this attestation, Part D sponsors will be required to certify that the PDE and DIR data submitted to CMS for the 2007 payment reconciliation is accurate, complete, and truthful. Additional guidance regarding this attestation will be provided at a later date.

For technical assistance and questions regarding the download or upload of the DIR Report for Payment Reconciliation, 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 Meghan Elrington at (410) 786-8675 or Meghan.elrington@cms.hhs.gov.

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 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 or 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, settlements amounts from lawsuits or other legal

action, and other price concessions or similar benefits. However, rebates and other price concessions which are not considered to 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) which do not represent a change in the drug costs paid by the Part D sponsor, do not impact the drugs costs incurred by the Part D sponsor and, therefore, are excluded from DIR.

Please note, however, that CMS considers all rebates, grants, settlement amounts, or other price concessions 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 (p. 4308 - 4309), 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 their drug costs, Part D sponsors are required to report all grants, rebates, settlement amounts, or price concessions received by the Part D sponsor from pharmaceutical manufacturers (whether directly or indirectly) as DIR with the exception of bona fide services fees.

Bona fide service fees which 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, therefore, 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, which meet the definition of a bona fide service fee, are not considered DIR and therefore, may be excluded from the DIR Report for Payment Reconciliation. In the case of rebate administration fees or other amounts from pharmaceutical manufacturers which 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.

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 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, (with the exception of bona fide service fees) 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 applicable rebate administration fees which the PBM receives from pharmaceutical manufacturers to the extent that they do not represent bona fide service fees.

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, which 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, 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. To the extent that this DIR is already taken into account for payment purposes in the gross drug cost (sum of ingredient cost, dispensing fee, and applicable sales tax) reported to CMS on the prescription drug event (PDE) record, this DIR (with the exception of estimated rebates applied at the point of sale beginning in contract year 2008) 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.

DIR which is taken into account in the amount paid at the point of sale but is not reflected in the gross drug cost (sum of ingredient cost, dispensing fee, and applicable sales tax) reported on the PDE record, must be reported on the DIR Report for Payment Reconciliation. For example, Part D sponsors who elected to apply estimated rebates to the point-of-sale price in contract year 2007 were required to use the negotiated price net of the estimated rebates to administer the Part D benefit and calculate beneficiary cost sharing. However, on the PDE records for contract year 2007, these Part D sponsors were required to report the gross drug cost prior to the application of these estimated rebate amounts instead of the gross drug cost net of these estimated rebates because there was no "Estimated Rebate at POS" field on the PDE record for 2007. Thus, for payment reconciliation, these Part D sponsors are required to report the actual rebate amounts for the rebates which were estimated and applied at the point of sale on the 2007 DIR Report for Payment Reconciliation.

Please note 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. Although Part D sponsors will be required to report their gross drug costs on the PDE records net of any estimated rebates applied at point of sale in 2008, they will also be required to report the actual rebate amounts for estimated rebates which were applied at the point of sale 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 which 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. Please 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 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. 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. Please note that CMS has extended this deadline for contract year 2007 to July 15, 2008. This deadline applies to all Part D plans including non-calendar year Employer/Union-only Group Waiver Plans (EGWPs). 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 are expected to be 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 are 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 to the sponsor's best knowledge, information, and belief. Part D sponsors will be required to submit this attestation prior to the completion of the 2007 Part D Payment Reconciliation. Additional guidance regarding this attestation will be provided at a later 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 16, 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 2007 > DIR Reporting (for Payment Reconciliation). This report will be downloadable to an 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 (including non-calendar year Employer/Union-only Group Waiver Plans) by **July 15, 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 for the negotiation and processing of rebates. They will be asked to provide the name of any PBM with which the Part D sponsor contracted in 2007. Part D sponsors should only indicate the name of PBMs with which they contracted for the negotiation and processing of rebates. If a Part D sponsor did not contract with a PBM for the processing of rebates, the Part D sponsor should enter "N/A" for this question. Part D sponsors will also 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 16, 2008 and 11:59 p.m. EDT on Tuesday, July 15, 2008. CMS will use the DIR reported on the most recently uploaded report during payment reconciliation.

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 which could result in changes to the DIR data reported to CMS. CMS will provide additional guidance regarding the reporting of DIR received after the submission deadline at a later date.

Part D sponsors must prepare and submit the DIR Report for Payment Reconciliation to CMS for all of the Part D plans which they offered in 2007, even if they have no DIR to report for contract year 2007. For plans with 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

***To simplify the reporting of DIR, CMS is requiring Part D sponsors to report all applicable rebates in column DIR #3, "All Other Rebates" with the exception of PBM retained rebates and estimated rebates. Therefore, all applicable rebates for reimbursed coordination of benefits claims including those for P2P claims must be reported in column DIR #3, "All Other Rebates". Part D sponsors must report \$0.00 in column DIR #1.**

DIR # 2. PBM Retained Rebates

All rebates and applicable 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. Rebate administration fees that are bona fide service fees are not considered DIR and, therefore, should not be reported on the DIR Report for Payment Reconciliation. Rebates which PBMs have passed through to the Part D sponsor (and therefore, are not retained) are also 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 estimated rebates. 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 # 3, "All Other Rebates".

Also included in this column are rebates that the Part D sponsor receives from pharmaceutical manufacturers for Part D purchases such as market share rebates. In addition, rebates and applicable rebate administration fees that PBMs have received from pharmaceutical manufacturers for Part D purchases and passed through to the Part D sponsor must be included in this column. Please note that rebate administration fees that meet the definition of bona fide service fees are not considered DIR and, therefore, should not be reported on the DIR Report for Payment Reconciliation.

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_ReportingOver

[sight.asp](#) for information on the quarterly reporting of these LTC pharmacy rebates to CMS.

***Please note that to simplify the reporting of DIR, CMS is requiring Part D sponsors to report all applicable rebates in this column, DIR #3, with the exception of PBM retained rebates and estimated rebates. Therefore, all applicable rebates including rebates for reimbursed coordination of benefits claims and P2P claims must be reported in this column.**

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 (PBMs), 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 <https://questions.cms.hhs.gov/> 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 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 2007. To report legal judgments or settlement amounts which impacted the drug costs incurred in prior contract years, Part D sponsors must request a reopening and submit a revised DIR Report for Payment Reconciliation for the applicable contract year. Please note that 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 which 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. For legal judgments or settlement amounts from law suits or other legal action concerning drug costs for multiple contract years, Part D sponsors may use a reasonable methodology for allocating the legal judgments or settlement amounts to each 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 2007

must be reported in this column as a negative adjustment. Legal judgments or settlement amounts received by the Part D sponsor which serve to decrease the drug costs incurred by the sponsor for contract year 2007 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 law suit A which impacted drugs costs for contract year 2007 and \$100,000 for law suit B which impacted drug costs for contract year 2008. Sponsor A incurred \$100,000 in legal fees for law suit A and \$125,000 in legal fees for law suit B. Sponsor A would report \$400,000 on the 2007 DIR Report for Payment Reconciliation and \$0 on the 2008 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.

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 drugs 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 drugs 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 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.

***To simplify the reporting of DIR, CMS is requiring Part D sponsors to report all applicable rebates, with the exception of PBM retained rebates and estimated rebates, in column DIR #3, "All Other Rebates". Therefore, all applicable rebates for P2P claims must be reported in column DIR #3, "All Other Rebates", and not this column, DIR #8, "All Other DIR".**

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.

Total DIR

Reported in this column is a sum of all of the DIR reported for the Part D plan for contract year 2007. 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 #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 in contract year 2007, 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 Part D 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	+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	Part D sponsors must enter \$0.00 in this column. The sum of applicable rebates for reimbursed COB claims must be entered in DIR #3.
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 applicable 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 of all other applicable rebates including rebates for COB claims and P2P claims. 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 # 8 for Part D plan. Please leave blank if no DIR reported in DIR #8 for Part D plan. See guidance for details.

File Record Layout (Continued):

Field Name	Field Type	Field Length	Field Description
Total DIR	Number	12 digits before	Sum of all DIR reported for Part D plan. Automatically

	Required	the decimal and 2 digits after	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 Comments	Character	4000	Additional comments on DIR data reported in columns DIR #1- DIR #8. See guidance for details