DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: April 21, 2025

TO: All Part D Plan Sponsors

FROM: Jennifer R. Shapiro, Director, Medicare Plan Payment Group

SUBJECT: Final Medicare Part D DIR Reporting Guidance for 2024

In this memorandum, the Centers for Medicare & Medicaid Services (CMS) provides final guidance for Medicare Part D sponsors on reporting direct and indirect remuneration (DIR) data for contract year (CY) 2024.

As described below, section 1860D-15(f)(1)(A) of the Social Security Act requires Part D sponsors to fully disclose to CMS any information necessary for carrying out the payment provisions of section 1860D-15, including the calculation of reinsurance and risk-sharing. As such, Part D sponsors are required to report DIR data associated with the Voluntary Medicare Prescription Drug Benefit at the plan benefit package (PBP) level ("summary level") on the Summary DIR Report to CMS for purposes of Part D payment reconciliation. Part D sponsors are also required to report DIR data at the 11-digit National Drug Code (NDC) level ("detailed level") in the Detailed DIR Report to support implementation of section 9008 of the Affordable Care Act (ACA), which imposes an annual fee on certain manufacturers based on their share of brand drug sales net of rebates, discounts, or other price concessions.

Clarifications and Changes for the DIR Reporting Guidance for 2024

Effective for 2024, CMS redefined negotiated price as the lowest possible reimbursement that a pharmacy will receive for a drug[1]. As such, the DIR Reporting Guidance for 2024 provides clarification to the reporting instructions for Amounts Received from Pharmacies (DIR #8) and Amounts Paid to Pharmacies (DIR #9) for pharmacy price concessions. Part D sponsors are to report the amounts received from the pharmacy (DIR #8) as always equal to the maximum price concession reported as the Estimated Remuneration at POS Amount (ERPOSA) in the Prescription Drug Event (PDE). Similarly, Part D sponsors are to report amounts paid to the pharmacy (DIR #9) as the difference between the negotiated price and the final reimbursement.

[1] 87 Fed. Reg. 27899 (May 9, 2022) (to be codified at 42 C.F.R. §§ 423.100 and 423.2305 under "Negotiated price")

DIR #9 is to be reported as a negative amount and the summation of DIR #8 and DIR #9 is equal to the actual remuneration amount.

Contact Information

For technical assistance and questions regarding the download or upload of the DIR Reports, please contact the Health Plan Management System (HPMS) Help Desk at 1-800-220-2028 or hpms@cms.hhs.gov. For any other questions regarding this guidance, please contact: DIR_Reporting_Reqts@cms.hhs.gov.

DIR Submission Deadlines

Part D sponsors can begin to submit the 2024 DIR Submission Information and upload the Summary 2024 DIR Report and Detailed 2024 DIR Report on June 1, 2025. The deadline for submissions is **11:59 PM PT on Monday, June 30, 2025**. Summary and Detailed DIR Reports must be uploaded into HPMS and will not be accepted via email. This deadline applies to all Part D sponsors, including calendar year and non-calendar year employer/union-only group waiver plans (EGWPs) and Program of All-inclusive Care for the Elderly (PACE) organizations.

The resubmission window for sponsors to upload an updated Summary DIR Report for contract years 2020, 2021, 2022, and 2023 will be July 1 through July 31, 2025. This July 31, 2025, deadline also applies to all Part D sponsors, including calendar year and non-calendar year EGWPs and PACE organizations.

We strongly encourage Part D sponsors to submit early during the submission and resubmission windows to ensure complete, accurate, and successful submissions by the applicable deadline. Very large files will not be processed immediately, so to ensure timely submission please do not wait until the submission deadline to upload your Summary and Detailed DIR Reports. Sponsors should reserve the last week of the submission period to correct any reject error codes that might be received on initial submission attempts.

CMS provides "Helpful Hints" documents within the DIR module on HPMS. Sponsors are strongly encouraged to use these documents when completing the 2024 DIR Submission Information, Summary 2024 DIR Report, and Detailed 2024 DIR Report. There is also a "Helpful Hints" document for "Troubleshooting Text File Uploads," which will be very beneficial when uploading the reports into HPMS.

Attachments

FINAL MEDICARE PART D DIR REPORTING GUIDANCE FOR 2024

I. INTRODUCTION

A. Purpose

The purpose of this guidance document is to explain how Part D sponsors should report DIR for purposes of the Summary and Detailed 2024 DIR Reports. This document provides the format in which data must be submitted in order to be accepted by HPMS, explains the data elements to be reported by Part D sponsors at the PBP and 11-digit NDC levels, and establishes reporting timeframes. CMS' goal is to ensure a common understanding of the guidelines for reporting DIR.

B. Background

In December 2003, Congress passed the Medicare Prescription Drug Benefit, Improvement and Modernization Act (MMA) (P.L. 108-173), allowing coverage of certain outpatient prescription drugs under the new Medicare Part D benefit. Reinsurance and risk-sharing are two of the payment mechanisms by which the Medicare Program reimburses Part D sponsors for providing prescription drug coverage. CMS is required by statute to base these payments on a Part D sponsor's "allowable reinsurance costs" and "allowable risk corridor costs," which must be "actually paid." As defined at 42 CFR 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 Social Security Act (the Act) requires Part D sponsors to fully disclose to CMS any information necessary for carrying out the payment provisions of section 1860D-15, 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, and each year, we issue explanatory guidance and instructions for reporting DIR. Consistent with section 1860D-15(d)(2)(A) of the Act, CMS payments to a Part D sponsor are conditioned upon the provision of the requisite data.

Section 9008 of the Patient Protection and Affordable Care Act (ACA) (P.L. 111–148), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (HCERA) (P.L. 111–152), imposes an aggregate annual fee on certain manufacturers of branded prescription drugs (please refer to Section 9008 of the ACA for a definition of branded prescription drugs). The aggregate annual fee from 2019 and thereafter is $2.8 billion and will be paid by manufacturers or importers with aggregate gross receipts from branded prescription drug sales over $5 million to specified government programs, including Medicare Part D. CMS is required to provide dollar amounts of sales of branded prescription drugs under the Medicare Part D program on a yearly basis to the Secretary of the Treasury in order to determine the fee amount to be paid by each manufacturer. Sales dollar amounts are reported at the 11-digit NDC level and must be reduced by rebates and other price concessions and Coverage Gap Discount amounts. See 26 CFR 51.4(b). The Detailed DIR Report is required as part of this effort.

C. Overview of DIR Reporting Process

Part D sponsors should prepare and submit the DIR Submission Information and upload the Summary DIR Report and Detailed DIR Report to CMS for all of the Part D PBPs that they offered in 2024, even if they have no DIR to report for contract year 2024. The Summary DIR Report contains data at the PBP level and is broken into multiple categories of DIR and non-DIR data. The Detailed DIR Report contains DIR data at the PBP level for each 11-digit NDC and is broken into two categories (Rebates and "All Other DIR").

Sponsors may input the 2024 DIR Submission Information and upload the Summary and/or Detailed 2024 DIR Reports as many times as necessary prior to the DIR submission deadline. CMS will use only the most recent Summary and Detailed DIR Reports uploaded during the submission window in our reviews. Sponsors can access their latest submissions via HPMS.

CMS will review the DIR data submitted. If CMS identifies a potential error, CMS will prepare a Summary Review Results and/or Detailed Review Results package. The review packages will be available to download through HPMS. Sponsors will receive an email if review packages are available for their contracts. (Please note that emails will be sent to the email addresses stored in HPMS for the Medicare Compliance Officer and the DIR Contact(s). For instructions on how to view or change your contact information, please see the January 10, 2025, memorandum titled "Annual Request for Part D Payment Reconciliation Contact Information"). Part D sponsors will be able to view the status of submitted DIR reports during the submission and review process in HPMS.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

D. DIR Reporting for PACE Organizations

PACE organizations reporting $0 in all Summary DIR categories in the Summary 2024 DIR Report should submit the 2024 DIR Submission Information and upload the Summary 2024 DIR Report, but these PACE organizations do not need to submit a Detailed 2024 DIR Report. PACE organizations reporting a non-zero value in any column in the Summary DIR Report should submit the 2024 DIR Submission Information, Summary 2024 DIR Report, and Detailed 2024 DIR Report.

E. Retiree Drug Subsidy (RDS) Rebate Guidance

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

II. DEFINING DIRECT AND INDIRECT REMUNERATION (DIR)

Per the regulations at 42 CFR 423.308, DIR is any form of price concession, received either by the Part D sponsor or by an intermediary contracting organization (a Pharmacy Benefits Manager, or PBM, for instance) with which the sponsor has contracted, from any source (including manufacturers, pharmacies, enrollees, or any other person or entity) that serves to decrease the costs incurred under the Part D plan by the Part D sponsor, either directly or indirectly. Thus, DIR includes discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, 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. DIR also includes price concessions from and additional contingent payments to network pharmacies that cannot reasonably be determined at the point of sale. *See* 42 CFR 423.100 (definition of negotiated prices).

Such price concessions must be reported as DIR in the Summary and Detailed DIR Reports regardless of whether the intermediary contracting organization retains all or a portion of the price concession or passes through the entire amount to the sponsor. However, any price concessions or payments that do not directly or indirectly impact drug costs incurred by the Part D sponsor are not considered DIR.

Please see Table 1 below for examples of types of remuneration that are and are not considered DIR. Please also refer to pages 7-13 of the June 6, 2011. HPMS memorandum titled "Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report."

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

Remuneration Considered DIR	Remuneration Not Considered DIR
Remuneration from pharmaceutical manufacturers (e.g., rebates, grants, reduced price administrative services, or legal settlement amounts)	Bona fide service fees from pharmaceutical manufacturers (except for any portion of such fees that exceed fair market value)
PBM retained rebates	Fair market value remuneration for administrative services with no impact on the sponsor's or PBM's drug costs (e.g., PBM incentive payments)
PBM rebate guarantee amounts	Private reinsurance amounts
PBM penalty payments and repayments that impact Part D drug costs	PBM penalty payments and repayments that do not impact Part D drug costs

Remuneration Considered DIR	Remuneration Not Considered DIR
Dispensing incentive payments to pharmacies after the POS that are not included in the negotiated price	Rebate amounts received by long term care (LTC) pharmacies
Prompt pay discounts from pharmacies that are not included in the negotiated price	Payment for claims
Post-POS pharmacy payment adjustments that are not already included in the negotiated price	
All risk-sharing amounts	

III. DIR SUBMISSION INFORMATION

As the first step in the DIR reporting process, Part D sponsors should ensure that sponsor information in HPMS is up to date. For instructions on how to view or change your contact information, please see the January 10, 2025, HPMS memorandum titled "Annual Request for Part D Payment Reconciliation Contact Information."

Next, we request that Part D sponsors complete the 2024 DIR Submission Information Report, which will provide additional information at the contract level regarding DIR and PDE data. This step needs to be completed prior to uploading the Summary and Detailed DIR Reports. The 2024 DIR Submission Information Report must be completed for each contract, as follows, in order for HPMS to accept a DIR data file.

A. Allocation Methodology

Part D sponsors must report DIR data at the PBP and 11-digit NDC level. We are aware, however, that some sponsors may receive and/or record DIR at the sponsor or contract level, instead. Therefore, such Part D sponsors should allocate DIR to the PBP and 11-digit NDC level using reasonable allocation methodologies. A description of all allocation methodologies used to report DIR at the PBP and/or 11-digit NDC level should be submitted by the sponsor in HPMS as part of the 2024 DIR Submission Information Report.

CMS has identified several reasonable allocation methodologies (see below) for Part D sponsors to select from a dropdown menu when reporting the allocation methodology used. Sponsors should make one selection from a dropdown menu specifying an allocation methodology to the PBP level and one selection from a dropdown menu specifying an allocation methodology to the 11-digit NDC level. If DIR was already received from the manufacturers at the PBP and/or 11-digit NDC level, sponsors should make the "No allocation method needed" selection from the dropdown menu.

In the event that a Part D sponsor uses different allocation methodologies for different types of DIR, it should select the "Other" option and describe in a comment the allocation methodologies used and the DIR category for which each methodology was used.

The dropdown menu also contains a specific selection intended only for PACE organizations that do not have any type of DIR to report.

Part D sponsors are expected to maintain internal documentation of all methodologies used to allocate DIR, and CMS may follow-up with the sponsors to better understand the allocation methodology used.

The options included in each dropdown menu are the following:

Allocation Methodology to the PBP level

1. No allocation method needed to the PBP level. DIR was processed at the PBP level
2. Allocation to the PBP level based on Actual Drug Utilization
3. Allocation to the PBP level based on Plan's Total Drug Spend
4. Allocation to the PBP level based on Plan's Brand Drug Spend
5. Allocation to the PBP level based on Total Drug Spend for Drugs in Preferred Brand Tier
6. Allocation to the PBP level based on Billed DIR Amounts
7. This PACE Organization does not participate in DIR; no methodology required (This option may only be selected by PACE contracts)
8. Other allocation to the PBP level (comments are required)

Allocation Methodology to the 11-digit NDC level

1. No allocation method needed to the 11-digit NDC level. DIR was processed at the 11-digit NDC level
2. Allocation to the 11-digit NDC level based on Actual Drug Utilization
3. Allocation to the 11-digit NDC level based on Plan's Total Drug Spend
4. Allocation to the 11-digit NDC level based on Plan's Brand Drug Spend
5. Allocation to the 11-digit NDC level based on Total Drug Spend for Drugs in Preferred Brand Tier
6. Allocation to the 11-digit NDC level based on Billed DIR Amounts
7. This PACE Organization does not participate in DIR; no methodology required (This option may only be selected by PACE contracts)
8. Other allocation to the 11-digit NDC level (comments are required)

Table 2 provides examples of the allocation methodologies listed above and indicates whether they are considered reasonable for allocating DIR to the PBP and 11-digit NDC levels. Please note that our determination of the reasonableness of the various allocation methodologies presented in Table 2 below is specific to the allocation of manufacturer rebates, and that some of the methodologies

determined to be unreasonable for rebate allocation may in fact be reasonable for allocating other categories of DIR to a PBP or 11-digit NDC. For instance, allocation based on the number of claims, while unreasonable for use with manufacturer rebates, could be appropriate for use with per-claim administrative fees charged to pharmacies.

Part D sponsors, when able, should allocate rebates for a specific drug to the PBP and 11-digit NDC levels based on the actual utilization of that specific drug. Other allocation methodologies may be subject to additional validation. When selecting among the options allowed, Part D sponsors should consider the accuracy with which an allocation methodology applies rebate dollars to the applicable PBP or 11-digit NDC.

Sponsors selecting "Other allocation to the PBP level" or "Other allocation to the 11-digit NDC level" must provide comments, which should identify the entity responsible for applying the allocation methodology (whether it is the Part D sponsor or PBM) *and* include a clear explanation of the methodology, as well as a specification of each category of DIR for which the methodology was used. The response "Not Applicable," or any of its variations, is not an acceptable explanation and will be rejected.

Part D sponsors may also receive legal judgments or settlement amounts from lawsuits or other legal action that 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 must be reported on the DIR reports for corresponding years. Thus, for legal judgments or settlement amounts from lawsuits or other legal actions concerning drug costs for multiple contract years, Part D sponsors should use a *reasonable* methodology to allocate the legal judgments or settlement amounts to each applicable contract year. We recognize that the specific allocation methodology for legal judgments or settlement amounts may differ from the primary allocation methodology that is used for other types of DIR. In this circumstance, as stated above, Part D sponsors should select the "Other" option from the dropdown menu and describe in a comment the allocation methodologies used for each DIR category.

Table 2. Examples of Methodologies for Allocating Rebates to the Plan Benefit Package (PBP) Level and 11-Digit NDC Levels

Allocation Methodology	Description	Considered Reasonable?	Explanation
Based on Actual Drug Utilization	Rebate amounts received for a specific drug are allocated to a PBP and 11-digit NDC based on the number of units of the specific drug that were purchased under the PBP 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 PBPs.
Based on	Rebate amounts received for multiple	Yes	Approximates

Allocation Methodology	Description	Considered Reasonable?	Explanation
Plan's Total Drug Spend	drugs are allocated to a PBP based on the total drug spend under the PBP as a percent of the total drug spend under all of sponsor's Part D PBPs, and further to an 11-digit NDC based on the NDC-specific total drug spend under the PBP as a percent of the total drug spending under the PBP.		differences in utilization and spending on rebate eligible drugs across Part D PBPs.
Based on Plan's Brand Drug Spend	Rebate amounts received for multiple drugs are allocated to a PBP based on the total drug spend for brand drugs under the PBP as a percent of the total drug spend for brand drugs under all of the sponsor's Part D PBPs, and further to an 11-digit NDC based on the NDC-specific total drug spend under the PBP as a percent of the total drug spend for brand drugs under the PBP.	Yes, but only if the sponsor receives rebates only for brand drugs.	Accounts for differences in utilization and spending on rebate eligible drugs across Part D PBPs.
Based on Total Drug Spend for Drugs in Preferred Brand Tier	Rebates received for multiple drugs are allocated to a PBP based on the total drug spend for drugs in the PBP'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 PBPs, and further to an 11-digit NDC based on the NDC-specific total drug spend under the PBP as a percent of the total drug spend for drugs in the preferred brand tier under the PBP.	Yes, but only if the sponsor receives rebates only for drugs in the preferred brand tier.	Accounts for differences in utilization and spending on rebate eligible drugs across Part D PBPs.
Based on Billed DIR Amounts	Rebates received for a specific drug are allocated to a PBP and 11-digit NDC based on the rebate amounts billed to the pharmaceutical manufacturer for the specific PBP and drug as a percent of the total rebate amount billed to the pharmaceutical manufacturer for all of the sponsor's Part D PBPs.	Yes	Appropriately accounts for differences in a specific drug's utilization across Part D PBPs.
Based on Enrollment	Rebates received for multiple drugs are allocated to a PBP or 11-digit NDC based on the number of beneficiaries enrolled in the PBP as a percent of the total number of beneficiaries enrolled in all of the sponsor's Part D PBPs.	No	Does not sufficiently approximate differences in utilization and spending on rebate eligible drugs across Part D PBPs.

Allocation Methodology	Description	Considered Reasonable?	Explanation
Based on Low-Income Subsidy (LIS) Enrollment	Rebates received for multiple drugs are allocated to a PBP or 11-digit NDC based on the number of LIS beneficiaries enrolled in the PBP as a percent of the total number of LIS beneficiaries enrolled in all of the sponsor's Part D PBPs.	No	Does not sufficiently approximate differences in utilization and spending on rebate eligible drugs across Part D PBPs.
Based on Number of Claims	Rebates received for multiple drugs are allocated to a PBP or 11-digit NDC based on the number of claims under the PBP as a percent of the total number of claims received under all of the sponsor's Part D PBPs. 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 PBPs.

CMS will evaluate the appropriateness of an allocation methodology we have not already identified as appropriate, on a case-by-case basis, using the information sponsors provide on the methodology in the comment field. If a new and acceptable allocation methodology is identified, it will be included in the chart above in future DIR reporting guidance documents.

B. Name of 2024 Claims Processing PBM(s)

Part D sponsors should 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 2024. If the Part D sponsor conducted claims processing and PDE record submission internally and did not contract with a PBM for these services, the sponsor should indicate "Self" for this question. Sponsors may not leave this field blank.

C. Did PBM for Rebate Negotiation or Processing change from 2023 to 2024?

Part D sponsors should indicate whether they contracted with a different PBM or entity in 2024 for the negotiation or processing of rebates than they contracted with in 2023. If the sponsor did not negotiate or process rebates in 2023 and 2024, 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 2024 but not in 2023, 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 2023 but not in 2024, the sponsor should enter "Yes" for this question. Sponsors may not leave this field blank.

D. Name of 2024 PBM(s) for Rebate Negotiation or Processing

Part D sponsors should provide the name of any PBM or other entity with which the Part D sponsor contracted for the negotiation or processing of rebates in 2024. Part D sponsors that conducted rebate negotiation or 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 sponsor should enter "N/A" for this question. Sponsors may not leave this field blank.

E. Were any of the plans in the contract owned by a different sponsor in 2023?

Part D sponsors should indicate whether any of the plans in the contract were owned by a different sponsor in 2023. For any applicable plans, the sponsor should provide the plan ID, the name of the sponsor that owned the plan in 2023, and the contract number that the plan was under in 2023. If all of the plans in the contract were owned by a different sponsor in 2023, the sponsor may indicate "all plans in contract" instead of listing all plan IDs.

F. Did your parent organization acquire any of the plans in this contract during the 2024 contract year?

Part D sponsors should indicate whether any of the plans in the contract were acquired mid-contract year. For any applicable plans, the sponsor should 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.

G. Explanation for Resubmission

When resubmitting the Summary or Detailed DIR Report for 2024 due to a plan or CMS discovered data error, Part D sponsors should provide an explanation for the resubmission of their DIR data.

IV. SUMMARY AND DETAILED DIR DATA REPORTS

A. Descriptions of Columns in the Summary DIR Report

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

Sponsors must use reasonably current DIR data to produce the Summary and Detailed DIR Reports, reflecting, at a minimum, the DIR amounts received up to three months prior to the submission deadline. Part D sponsors should also include on the Summary DIR Report good faith estimates for DIR that is expected for the applicable contract year but has not yet been received.

Enhanced Alternative plans should report DIR for all Part D covered drugs, regardless of enhanced cost sharing. Please refer to pages 13-15 of the June 6, 2011, HPMS memorandum titled "Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report" for additional details on the Summary DIR reporting guidelines.

All mandatory fields must be filled out; none may be left blank for the DIR data file to be accepted by HPMS.

Column Name	Column Description, Type, and Field Length
Contract-Plan	Contract number and plan ID (e.g., S0001-001). This number must be 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. This field must be populated with 9 alpha-numeric characters.
DIR #1 – PBM Retained Rebates	DIR Type: Manufacturer Rebates Entity From: Drug Manufacturer Exclusions: Do not include any manufacturer rebates passed through to the Part D sponsor, which should be reported in the DIR #3 column. Do not include any rebates expected but not yet received in this column, which should be reported in the DIR #2 column. Do not include any rebate administration fees, which should either be reported as DIR in the DIR #4 column or as bona fide service fees later in the Report. Do not include any other types of DIR, even if retained by the PBM. Additional Details: Include all manufacturer rebates associated with the Medicare prescription drug benefit retained by the PBM and not passed through to the sponsor. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. The value reported in this field may be negative. This field must not be left blank.
DIR #1C – PBM Retained Rebates *(Additional Comments)*	Additional comments explaining why a negative amount was reported are required when DIR #1 is negative. This field is limited to 500 characters.
DIR #2 – Rebates Expected But Not Yet Received	DIR Type: Manufacturer Rebates Entity From: 1. Drug Manufacturer, 2. PBM Exclusions: Do not include any manufacturer rebates reported in the DIR #1 column. Do not include any other types of DIR. Additional Details:

Column Name	Column Description, Type, and Field Length
	Include in this column good faith estimates of rebate amounts that are expected by the Part D sponsor or its PBM for the applicable contract year but have not yet been received from a drug manufacturer. All rebate guarantee amounts expected but not yet received from PBMs should also be reported in this column (see the DIR #3 column description for a definition of PBM rebate guarantee amounts). Similarly, all rebate amounts received by the PBM that are expected to be passed on to the Part D sponsor but have not yet, as of the compilation of this Report, been passed to the sponsor should be reported in this column. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. The value reported in this field may be negative. This field must not be left blank.
DIR #2C – Rebates Expected But Not Yet Received *(Additional Comments)*	Additional comments explaining why a negative amount was reported must be provided when DIR #2 is negative. This field is limited to 500 characters.
DIR #3 – All Other Rebates	DIR Type: Manufacturer Rebates Entity From: 1. Drug Manufacturer, 2. PBM Exclusions: Do not include any manufacturer rebates reported in the DIR #1 or DIR #2 columns. Do not include rebate guarantee amounts that are expected but not yet received; such amounts should be reported under the DIR #2 column. Do not include any other types of DIR from any other sources. Additional Details: Include all manufacturer rebates for Part D purchases actually received from a manufacturer, either by the Part D sponsor directly or by its PBM and passed through to the Part D sponsor. *PBM Rebate Guarantee Amounts*. Also include any rebate guarantee amounts received from PBMs in connection with the Medicare Part D program. Rebate guarantee amounts, generally, are payments received by Part D sponsors from PBMs to account for the difference between the rebate amount guaranteed by a PBM, as likely delineated in the contract between the two parties, and the actual rebate amount received from a drug manufacturer. *Estimated Remuneration at the Point-of-Sale*. The actual manufacturer rebate amounts received for rebates that were estimated and applied to the negotiated price at the POS are also reported in this column. Although Part D sponsors are required to report their gross drug costs on the PDE record net of any estimated rebates applied at the POS, they should also report the actual rebate amounts for these estimated rebates on the Summary DIR Report. CMS will subtract the amounts reported in the Estimated Remuneration at POS Amount (ERPOSA) field of the PDE record from the total DIR amount reported in this

Column Name	Column Description, Type, and Field Length
	Report for the purposes of calculating allowable risk corridor and reinsurance costs. *Rebates Related to Third-Party Payer Claims.* Per 42 CFR 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 CFR 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 should be reported in this column. *Rebates Related to P2P Claims.* 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 sponsor, however, may receive rebates for these claims and is required to report them to CMS. Rebates received by the submitting sponsor for P2P claims should be reported in this column. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. The value reported in this field may be negative. This field must not be blank.
DIR #3C – All Other Rebates *(Additional Comments)*	Additional comments must be provided. When DIR #3 is zero, provide an explanation as to why there were no other rebates negotiated or reported. When DIR #3 is not zero, describe the type of rebate being reported and the type of entity that is providing the rebate by structuring the comment under the following guidelines. When DIR #3 is negative, also provide an explanation for why a negative amount was reported. Identify the option(s) from the list below that best describe the reason(s) for the rebates reported in the DIR #3 column: A. Formulary access/Tier placement rebates B. Market share target rebates C. Volume target rebates D. Exceeding price inflation threshold rebates E. Rebate guarantee amount – from PBM F. Other rebates The comment in this column should indicate the applicable selection(s) and the value(s) associated with the applicable selection(s). If there are multiple applicable selections, separate the value for each selection with a pound sign (#). For example, if options A and D apply, the comment here would be: "A. $2,245,262# D. $4,685,794." If the "Other" option (Option F) is selected, the Part D sponsor should also explain why it was selected by describing the unique reason for the rebate in this field. For example, if options A, D, and F (Other) apply, the comment

Column Name	Column Description, Type, and Field Length
	here would be: "A. $2,245,262# D. $4,685,794# F. $245,000 for a value-based arrangement." This field is limited to 500 characters. This field must not be left blank.
DIR #4 – Administrative Service Fees Reported as DIR	DIR Type: Fees Entity From: 1. Drug Manufacturer, 2. PBM Exclusions: Do not include any bona fide service fees. Do not include any other types of DIR. Additional Details: The DIR amounts reported in this column include administrative fees charged to manufacturers to the extent that they exceed fair market value. Only the difference between the price paid by the manufacturer and the fair market value of the services provided by the Part D sponsor or PBM should be reported in this column. The amount reported in this column is considered DIR and, therefore, must be included in the Total DIR column. The fee amounts included here should be received by a Part D sponsor or its PBM for administrative services provided to drug manufacturers in connection with the Medicare Part D program. Even in the event that a PBM receives and retains all or a portion of the administrative fee, the entire difference between the price paid by the manufacturer and the fair market value of the services rendered must be here. *DIR vs. Bona Fide Service Fees.* In the event that an administrative fee from a manufacturer exceeds fair market value but otherwise meets the definition of a bona fide service fee (see the Bona Fide Service Fees column description for this definition), only the portion that exceeds fair market value is considered DIR and should be reported in this column. The remaining portion should instead be reported in the Bona Fide Service Fees column of the Summary DIR Report and is not considered DIR. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. This field must not be left blank.
DIR #4C – Administrative Service Fees Reported as DIR *(Additional Comments)*	Additional comments must be provided when DIR #4 is greater than zero in order to specify the administrative services for which the administrative service fees reported as DIR were received. This field is limited to 500 characters.
DIR #5 – Price Concessions for Administrative Services	DIR Type: Price Concessions and Grants Entity From: Drug Manufacturer Exclusions: Do not include any rebate administration fees collected by the Part D sponsor or the PBM, which are reported either as DIR in the DIR #4

Column Name	Column Description, Type, and Field Length
	column or as bona fide service fees later in the Summary DIR Report. Do not include any pharmacy payments, fees, or adjustments, which are to be reported in the DIR #8 and DIR #9 columns instead. Do not include any other types of DIR. Additional Details: Include in this column of the Summary DIR Report all price concessions received by a Part D sponsor or PBM from drug manufacturers for administrative services associated with the Part D benefit. Price concessions that are reported here are received when the manufacturer provides administrative services to the Part D sponsor or PBM 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 is considered DIR and must be reported in this column. Also reported in this column are grants 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 should be reported in full in this column, inclusive of any amount for non-Part D covered drugs. This DIR should fully accrue to the government and beneficiaries and should not be kept by the Part D sponsor. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. This field must not be left blank.

Column Name	Column Description, Type, and Field Length
DIR #5C – Price Concessions for Administrative Services *(Additional Comments)*	Additional comments must be provided when DIR #5 is greater than zero in order to specify the administrative services for which the price concessions were provided. The comment should be structured according to the guidelines that follow. Identify the option(s) from the list below that best describe the administrative service(s) for which the price concessions reported in the DIR #5 column were provided: A. Utilization management B. Medical education C. Medication monitoring/Medication therapy management D. Other The comment in this column should indicate the applicable selection(s) and the value(s) associated with the applicable selection(s). If there are multiple applicable selections, separate the value for each selection with a pound sign (#). For example, if options A and C apply, the comment here would be: "A. $2,000# C. $3,500." If the Other option (Option D) is selected, the Part D sponsor should also explain the unique administrative service for which the price concession was received. For example, if options A, C, and D apply, the comment here would be: "A. $2,000# C. $3,500# D. $12,000 for compliance management." This field is limited to 500 characters.
DIR #6 – Legal Settlement Amounts	DIR Type: Legal Settlement Amounts Entity From or To: Any Exclusions: Do not include judgment or settlement amounts related to litigation concerning bona fide service fees or amounts that impact drug costs incurred in years other than 2024. Do not include any other types of DIR. Additional Details: 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 2024 are reported in this column. To report legal judgments or settlement amounts that impacted the drug costs incurred in prior contract years, Part D sponsors must submit a revised Summary DIR Report for the applicable contract year. When legal judgments or settlement amounts are paid *by* the Part D sponsor—serving to increase the drug costs incurred by the sponsor—the value should be reported in this column as a negative adjustment. When such payments are made *to* the Part D sponsor—serving to decrease the drug costs incurred by the sponsor—the value should be reported in this column as a positive adjustment.

Column Name	Column Description, Type, and Field Length
	In the event of a positive adjustment (i.e., payment made *to* the sponsor), any legal fees associated with the lawsuit or legal action resulting in the settlement or judgment may be excluded from the amount reported on the Summary DIR Report for the applicable contract year, up to the total amount of the associated settlement or judgment. For example, Sponsor A received a settlement amount of $500,000 for lawsuit A and $100,000 for lawsuit B, both of which impacted drug costs for contract year 2024. Sponsor A incurred $100,000 in legal fees for lawsuit A and $125,000 in legal fees for lawsuit B. Sponsor A would report a total of $400,000 on the Summary 2024 DIR Report—$400,000 for lawsuit A and $0 for lawsuit B. Please note, however, that Part D sponsors should not include in this field legal fees associated with a lawsuit or legal action resulting in a negative adjustment (i.e., legal judgment or settlement paid *by* the sponsor). This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. The value reported in this field may be negative. This field must not be left blank.
DIR #6C – Legal Settlement Amounts *(Additional Comments)*	Additional comments must be provided when DIR #6 is non-zero. Describe each legal settlement, including the source or recipient of the judgment or settlement amount and the services or drugs at issue, and when multiple legal settlements are reported, provide the amount tied to each settlement individually. This field is limited to 500 characters.
DIR #7 – All Other Price Concessions from Manufacturers	DIR Type: Price Concessions and Grants Entity From: 1. Drug Manufacturer, 2. PBM Exclusions: Do not include any price concessions accounted for in the DIR #1 through DIR #6 columns. Do not include price concessions from pharmacies, which are reported in the DIR #8 and DIR #9 columns, or any other types of DIR. Additional Details: All price concessions received by a PBM or Part D sponsor (directly or indirectly through the PBM) from pharmaceutical manufacturers for reasons not already captured by the previous columns are reported here. Include any amounts received and retained by PBMs. If all price concessions received from manufacturers are captured in the prior columns, the value reported here will be zero. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. This field must not be left blank.

Column Name	Column Description, Type, and Field Length
DIR #7C – All Other Price Concessions from Manufacturers *(Additional Comments)*	Additional comments must be provided when DIR #7 is a non-zero value. Describe the nature of all other price concessions reported in the DIR #7 column. This field is limited to 500 characters.
DIR #8 – Amounts Received from Pharmacies	DIR Type: Price Concessions, Fees, and Payment Adjustments Entity From: Pharmacy Exclusions: Do not include any DIR from entities other than pharmacies. Exclude any positive adjustments *to* pharmacy payments, which should be reported in the DIR #9 column. Do not include other types of DIR. Additional Details: Reported in this column are pharmacy price concessions that were applied to the negotiated price at the point of sale. Include any amounts received and retained by PBMs (i.e., those not passed through to the sponsor). Examples of adjustments to be reported in this field include the maximum pharmacy price concessions and contingent fees related to, for instance, generic dispensing rates, audit performance/error rates, refill rates, preferred dispensing rates, and/or other performance metrics, including qualitative measures. Such adjustments should only be reported in this column if they reduce the Part D sponsor's or PBM's costs. If the adjustments serve to increase costs, they should be reported later in the Summary DIR Report. This column should also include per-claim administrative fees collected, not paid, by a Part D sponsor or PBM from pharmacies. Examples of such fees include, but are not limited to, preferred pharmacy fees, fees related to extended supply rates, etc. *Estimated Remuneration at the Point-of-Sale*. Pharmacy price concessions that were applied to the negotiated price (see the definition of "negotiated prices" under 42 CFR 423.100) at the POS are reported in this column. Part D sponsors are required to report their gross drug costs on the PDE record net of any estimated remuneration applied at the POS – which, include pharmacy price concessions applied at the POS – they are also required to report the pharmacy price concessions applied at the POS in this column as DIR#8. CMS will subtract the amounts reported in the Estimated Remuneration at the POS Amount (ERPOSA) field of the PDE record from the total DIR amount reported in this Report for the purposes of calculating allowable risk corridor and reinsurance costs.

Column Name	Column Description, Type, and Field Length
	To provide a specific example, a sponsor charges the pharmacy a maximum price concession of $30 for a drug. The Part D sponsor will report the maximum price concession of $30 as DIR#8 in this column no matter the final pharmacy reimbursement amount. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. This field must not be left blank.
DIR #8C – Amounts Received from Pharmacies *(Additional Comments)*	Additional comments must be provided when DIR #8 is a non-zero value. Describe the types of pharmacy price concessions reported in the DIR #8 column and detail the metrics by which pharmacy performance was assessed, if relevant to the price concession calculation. If there are multiple types of pharmacy price concessions, separate the descriptions with a pound sign (#). This field is limited to 500 characters.

Column Name	Column Description, Type, and Field Length
DIR #9 – Amounts Paid to Pharmacies	DIR Type: Incentive Payments and Payment Adjustments Entity To: Pharmacy Exclusions: Do not include any payments to entities other than pharmacies. Exclude any DIR received *from* pharmacies (which is reported in the DIR #8 column). Do not include other types of DIR. Additional Details: Reported in this column is any sum *paid by* a PBM or Part D sponsor to a pharmacy *after* the POS that is not otherwise required to be included in the negotiated price (see the definition of "negotiated prices" under 42 CFR 423.100). Examples of adjustments to be reported in this field include any reconciliation amount that accounts for differences between the contracted rate and the lower adjudicated rate achieved by the pharmacy at the POS and contingent incentive payments related to, for instance, generic dispensing rates, audit performance/error rates, refill rates, preferred dispensing rates, and/or other performance metrics, including qualitative measures. Such adjustments should only be reported in this column if they increase the Part D sponsor's or PBM's costs and are not otherwise included in the negotiated price. *Estimated Remuneration Applied at the Point-of-Sale*. The difference between the reported negotiated price and the pharmacy's final reimbursement is reported in this column. To provide a specific example, a sponsor agrees to pay a pharmacy $100 at the point-of sale for a drug and the sponsor charges the pharmacy a maximum price concession of $30 for the drug. After the POS, even though the pharmacy could have paid a maximum price concession of $30, the pharmacy pays the plan $5 in pharmacy price concessions. The Part D sponsor will report the difference between the reported negotiated price and the pharmacy's final reimbursement of negative $25 ($5 minus $30) as DIR #9 in this column. The summation of DIR#8 and DIR#9 will equal the actual remuneration amount of $5. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. The value reported in this field must be negative or zero. This field must not be left blank.

Column Name	Column Description, Type, and Field Length
DIR #9C – Amounts Paid to Pharmacies *(Additional Comments)*	Additional comments must be provided when DIR #9 is a non-zero value. Describe the types of pharmacy incentive payments reported in the DIR #9 column. Please detail the metrics by which pharmacy performance was assessed, if relevant to the incentive payment calculation. If there are multiple types of pharmacy incentive payments, separate the descriptions with a pound sign (#). This field is limited to 500 characters.
DIR #10 – Risk-Sharing Arrangement Payments and Adjustments	DIR Type: Price Concessions, Fees, Incentive Payments, and Payment Adjustments Entity From or To: Any Non-Pharmacy Exclusions: Do not include any amount related to risk-sharing arrangements with CMS or any amount not related to Part D drug costs. Do not include any rebate guarantee amounts from PBMs, which should be reported in the DIR #3 column. Do not include any pharmacy payments, fees, or adjustments, which should be reported in the DIR #8 or DIR #9 columns. Do not include any PBM penalty or repayment related to PBM error, which should be reported in the DIR #11 column. Additional Details: This field should include all gains or losses that are attributable to Part D drug costs that the Part D sponsor may receive or pay resulting from risk-sharing arrangements with entities other than CMS and that are permissible under the Part D regulations and other applicable laws. All risk-sharing payments and adjustments for Part D drugs should be included in this column, including payments and adjustments related to basic and supplemental coverage of Part D drugs. For any payments or adjustments resulting from global risk-sharing arrangements with other entities—those which do not revolve only around Part D drug costs—the sponsor should determine and report as DIR only the portion specifically related to Part D drug costs. Examples of other entities include, but are not limited to, providers, accountable care organizations, other sponsors, PBMs, and other parties involved in the administration or delivery of the Part D benefit. Report risk-sharing amounts received in this column as a positive adjustment. Report risk-sharing amounts credited to other parties in this column as a negative adjustment. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. The value reported in this field may be negative. This field must not be left blank.

Column Name	Column Description, Type, and Field Length
DIR #10C – Risk-Sharing Arrangement Payments and Adjustments *(Additional Comments)*	Additional comments should be provided when DIR #10 is a non-zero value. Describe the risk-sharing arrangement(s) with which the sum reported in the DIR #10 column is associated, and the party with which the risk is shared. If the DIR #10 amount is related to a global risk-sharing arrangement, also describe the methodology by which the Part D portion of the total was determined. This field is limited to 500 characters.
DIR #11 – All Other DIR	DIR Type: Any Entity From or To: Any Exclusions: Do not include any DIR reported in the preceding columns (DIR #1 through DIR #10). All rebate guarantee amounts received should be reported in the DIR #3 column. Additional Details: Report here any DIR that has not yet been reported and serves to increase or decrease the drug costs of the Part D sponsor. Include any amounts received and retained by PBMs. One example of DIR that should be reported here is a PBM penalty payment or repayment that has not been submitted on an adjusted PDE record and directly or indirectly impacts the drug costs incurred by the Part D sponsor. Such a penalty is often assessed on a PBM in cases where incorrect drug costs were paid or reported by the Part D sponsor because of the PBM's error. Some PBM penalty payments include a price concession for administrative services provided by the PBM as well as remuneration for drug costs. In such an event, the sponsor should report as DIR the portion of the penalty that is equal to the amount by which the drug costs paid by the sponsor, or reported on the adjusted PDE, differs from the correct drug costs. The remaining portion of the penalty does not impact drug costs incurred by the sponsor. Instead, it represents a price concession for administrative services which is not considered DIR and would not be reported in this column. DIR that is not associated with a specific drug, should be reported in full in this column, including any amount for non-Part D covered drugs. This DIR should fully accrue to the government and beneficiaries and cannot be kept by the Part D sponsor. Report here any remuneration associated with the U.S. Government Patient Assistance Program for Paxlovid. The All Other DIR field cannot be used to report claim level adjustments; the sponsor should submit an adjusted PDE record to account for any change in drug costs paid on specific claims or groups of claims. Pursuant to

Column Name	Column Description, Type, and Field Length
	§ 423.505(k)(3), the sponsor must certify that claims data are accurate, complete, and truthful. Thus, in most cases, Part D sponsors will need to submit an adjusted PDE record with revised gross drug costs if their PBM has administered the benefit incorrectly. In these cases, the PBM penalty associated with the errors in drug costs should not be reported as DIR since the PDE record has been adjusted to reflect the appropriate gross drug costs. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. The value reported in this field may be negative. This field must not be left blank.
DIR #11C – All Other DIR *(Additional Comments)*	Additional comments should be provided when DIR #11 is a non-zero value. Describe the type of price concession, the type of entity from (or to) which the Part D sponsor collected (or paid) the price concession (e.g., PBM), and the associated dollar amount in this column for each price concession or DIR adjustment amount included in DIR #11. Additionally, any PBM manual adjustments or PBM penalty amounts reported in column DIR #11 should be explained in this column. This field is limited to 500 characters.
Total DIR	This field represents the sum of all DIR reported for each Part D PBP and is automatically generated. It does not include amounts reported in the columns that follow this one (Bona Fide Service Fees, PBM Incentive Payments, and PBM Spread Amounts for Retail and Mail Order Pharmacies). This field is numeric and may contain up to 14 digits before the decimal and 2 digits after the decimal. The value reported in this field may be negative. This field must not be left blank.
Total DIR *(Additional Comments)*	Additional comments must be provided when Total DIR reported is zero or negative. Provide an explanation of why the specific Part D PBP has no DIR or negative DIR. This field is limited to 500 characters.
Rebates and/or Other Price Concessions at POS?	If the Part D sponsor applied (estimated) manufacturer rebates and/or other price concessions from other entities, such as pharmacy price concessions, to the negotiated price at the POS in the applicable contract year, it should enter "Y" in this column for each applicable Part D PBP. Otherwise, the sponsor should enter "N" in this column to indicate that no such rebates or other price concessions were applied to the negotiated price at the POS. This field must be populated with one character, either "Y" or "N." This field must not be left blank.
Bona Fide Service Fees	Include in this column of the Summary DIR Report the portions of all fees that meet the definition for "bona fide service fees" provided below. The fee amounts included here should be either received directly and retained by a Part D sponsor, or received directly and retained by a PBM.

Column Name	Column Description, Type, and Field Length
	Bona fide service fees, as defined at 42 CFR 423.501, are fees paid by a manufacturer to an entity that meet all of the following conditions: 1) The fee must be paid for a bona fide, itemized service that is actually performed on behalf of the manufacturer; 2) The manufacturer would otherwise perform or contract for the service in the absence of the service arrangement; 3) The fee represents fair market value; and 4) The fee is 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. We interpret the first two elements of the definition of bona fide services to mean any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs. Services "on behalf of" the manufacturer include both those the manufacturer has the capacity to perform and those that can only be performed by another entity. The element of "fair market value" means the manufacturer must pay the Part D sponsor or PBM the same rate for performing these services that it would have paid had the services been performed by other or similarly situated entities. Manufacturers should determine the fair market value themselves, using the most appropriate, industry-accepted method, which we believe manufacturers are well-equipped to identify. Documentation of the fair market value analysis needs to be maintained by the sponsor. This documentation should include, at a minimum, assumptions, methodology, and rationale used to determine fair market value. The final element of the definition of "bona fide service fees" dictates that a fee must not be reported as a bona fide service fee if the Part D sponsor passes the fee on, in whole or in part, to beneficiaries, whether or not the sponsor takes title to the drug. Similarly, a fee must not be reported as a bona fide service fee if the entity providing PBM services passes the fee on, in whole or in part, to the Part D sponsor, whether or not the entity providing PBM services takes title to the drug. All of these conditions must be met for a fee to be considered a bona fide service fee. The sponsor must maintain documentation supporting the evaluation of the above criteria for bona fide service fees. *Bona Fide Service Fees vs. DIR.* In the event that an administrative fee from a manufacturer exceeds fair market value but otherwise meets the definition of a bona fide service fee, only the portion that exceeds fair market value is considered DIR and should be reported in the DIR #4 column of the Summary DIR Report. The remaining portion should instead be reported in this column and is not considered DIR. Bona fide service fees are not considered price concessions that reduce the drug costs incurred by the Part D sponsor and are not considered DIR. Therefore, the amounts reported in this column 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

Column Name	Column Description, Type, and Field Length
	calculates final reinsurance and risk corridor payments during the Part D payment reconciliation process. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. This field must not be left blank.
Bona Fide Service Fees *(Additional Comments)*	Additional comments must be provided when the Bona Fide Service Fees amount reported is non-zero. Provide a short description of the nature of the fees, including the services for which the payment is received. This field is limited to 500 characters.
PBM Incentive Payments	Include in this column any incentive or bonus payments paid by the Part D sponsor to PBMs for performing administrative services such as negotiating rebates and drug prices as well as increasing generic utilization. These incentive or bonus payments represent an increase in the administrative fees paid by the Part D sponsor to its PBM and are not considered DIR. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. This field must not be left blank.
PBM Incentive Payments *(Additional Comments)*	Additional comments should be provided when the amount of PBM Incentive Payments reported is non-zero. Describe the factor motivating the PBM incentive payments. The comment should be structured according to the guidelines that follow. Identify the option(s) from the list below which best describe why the PBM incentive payments that are reported were made: A. Rebate threshold B. Total drug costs savings threshold C. Generic dispensing rate D. Dispensing fees savings E. Other The comment in this column should indicate the applicable selection(s) and the value(s) associated with the applicable selection(s). If there are multiple applicable selections, separate the value for each selection with a pound sign (#). For example, if options A and C apply, the comment here would be: "A. $1,000# C. $5,000." If the Other option (Option E) is selected, the Part D sponsor should also explain the unique reason for the PBM incentive payment received. For example, if options A, C, and E apply, the comment here would be: "A. $1,000# C. $5,000# E. $12,000 for error free rate." This field is limited to 500 characters.
PBM Spread Amounts for Retail Pharmacies	The aggregate amount of the difference between the amount paid by the Part D sponsor to the PBM and the amount the PBM pays retail pharmacies, sometimes referred to as "PBM spread" or "risk premium," should be reported in this column of the Summary DIR Report. We emphasize that

Column Name	Column Description, Type, and Field Length
	sponsors should report aggregate values for all PBM spread amounts, not the PBM spread for each retail pharmacy. The value reported here should be for all covered drug costs under the Part D program, excluding spreads for drugs not covered under the Part D program. If sponsors use pass-through pricing to pay PBMs, this value should be zero. Sponsors that use lock-in pricing to pay PBMs should report in this column the difference between the lock-in price and the price ultimately received by the pharmacy. The PBM Spread Amounts for Retail Pharmacies are not considered DIR because they do not serve to change the cost of drugs for Part D sponsors. Therefore, the amounts reported in this column of the Summary 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 for Retail Pharmacies 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 carrying out Section 6005 of the ACA and Part D program functions or as otherwise specifically provided under section 6005 of the ACA. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. For a negative value, enter a minus sign and the value for the field. This field must not be left blank.
PBM Spread Amounts for Mail Order Pharmacies	The aggregate amount of the difference between the amount paid to the PBM and the amount the PBM pays mail order pharmacies, sometimes referred to as "PBM spread" or "risk premium," should be reported in this column of the Summary DIR Report. We emphasize that sponsors should report aggregate values for all PBM spread amounts, not the PBM spread for each mail order pharmacy. The value reported here should be for all covered drug costs under the Part D program, excluding spreads for drugs not covered under the Part D program. If sponsors use pass-through pricing to pay PBMs, this value should be zero. Sponsors that use lock-in pricing to pay PBMs should report in this column the difference between the lock-in price and the price ultimately received by the pharmacy. The PBM Spread Amounts for Mail Order Pharmacies are not considered DIR because they do not serve to change the cost of drugs for Part D sponsors. Therefore, the amounts reported in this column of the Summary 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

Column Name	Column Description, Type, and Field Length
	costs when CMS calculates reinsurance and risk-sharing payments during the Part D payment reconciliation process. PBM Spread Amounts for Mail Order Pharmacies 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 carrying out Section 6005 of the ACA and Part D program functions or as otherwise specifically provided under section 6005 of the ACA. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal. For a negative value, enter a minus sign and the value for the field. This field must not be left blank.

B. Description of Columns in the Detailed DIR Report

DIR data must be reported for each PBP and reported in aggregate for each 11-digit NDC. The Detailed DIR Report contains two columns of DIR dollars. The column titled "Rebate Dollars" should equal the sum of the values reported in columns #1 through #3 in the Summary DIR Report for the same contract year. The column titled "All Other DIR (i.e., non-rebate DIR)" should equal the sum of columns #4 through #11 in the Summary DIR Report for the same contract year. In the Detailed DIR Report, values must be reported for all Part D-covered NDCs with utilization, regardless of the NDC's brand or generic status, the acceptance status of any PDE records for it, or the magnitude and/or the presence of any rebates and/or all other DIR.

Column Name	Column Description, Type, and Field Length
Contract-Plan	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 column must be entered for each Part D PBP as they will not be automatically generated. This field must be populated with 9 alpha-numeric characters.
11-digit NDC	Enter the 11-digit National Drug Code in this column. This number must be entered as exactly 11 digits with no dashes (e.g., 55555000102). The sponsor must report only one NDC per line. Moreover, an NDC can only be reported once for each Contract-Plan. In other words, CMS will accept only one Contract-Plan-NDC combination. In the event that a Contract-Plan has no NDCs with utilization, this field may be left blank. If the field is left blank, plans should provide a short explanation in the "Comments" column of the Detailed DIR Report.
Rebate Dollars	Report total rebate dollars associated with drug sales under Medicare Part D

Column Name	Column Description, Type, and Field Length
	that are received by Part D sponsors for each 11-digit NDC. This includes good faith estimates of rebate amounts that are expected for the applicable contract year, as well as rebates already received. The Rebate Dollars column in the Detailed 2024 DIR Report will include all rebates reported under columns #1-3 on the Summary 2024 DIR Report. For each 11-digit NDC with utilization, provide the total rebate dollars for all Part D plan expenditures incurred during contract year 2024. Even rebates received for Part D plan expenditures reported on PDE records that were initially rejected but that the Part D sponsor believes will ultimately be accepted should be reported on the Detailed DIR Report. This field is numeric and may have up to 12 digits before the decimal and 3 digits after the decimal. The value reported in this field may be negative. This field must not be left blank.
All Other DIR (i.e., non-rebate DIR)	Report total non-rebate DIR in this column. The All Other DIR column in the Detailed 2024 DIR Report will include DIR reported in columns #4-11 on the Summary 2024 DIR Report. For each 11-digit NDC with utilization, provide the total amount of non-rebate DIR. All other DIR received for Part D plan expenditures incurred during contract year 2024 should be reported. All non-rebate DIR amounts that reduce Part D covered costs reported on PDE records that were initially rejected by CMS's systems but that the Part D sponsor believes will ultimately be accepted should be reported on the Detailed DIR Report. This field is numeric and may have up to 12 digits before the decimal and 3 digits after the decimal. The value reported in this field may be negative. This field must not be left blank.
Comments	If reporting zero in **both** "Rebate Dollars" and "All Other DIR" for a specific 11-Digit NDC, or if the 11-digit NDC field is blank, provide a short explanation in the "Comments" column of the Detailed DIR Report. If reporting a negative amount in either the Rebate column or All Other DIR column for a specific 11-Digit NDC, Part D sponsors should briefly explain the reasons for the negative amount in the "Comments" column of the Detailed DIR Report. If Rebate Dollars and All Other DIR are both zero for the row, the sponsor should provide a comment. If a Contract-Plan has no NDCs with utilization and leaves the 11-digit NDC field blank, the Part D sponsor should provide a short explanation in this column as well. This field is a character field and may have up to 4,000 characters.

C. Steps for Submitting 2024 DIR Submission Information and DIR Reports

Sponsors may upload the DIR Submission Information Report and the Summary and Detailed DIR Reports as many times as they choose until the DIR submission deadline. In our reviews, CMS will use only the information reported on the DIR Submission Information Report, Summary DIR Report, and Detailed DIR Report that were most recently uploaded by the deadline. Please refer to the Helpful Hints documents in HPMS when preparing your DIR submissions. These documents contain the HPMS pathways and systems specifications for successful upload.

D. Attestations of DIR Related Data

Consistent with 42 CFR 423.505(k)(5), Part D sponsors will be required to submit an attestation for each DIR report. In this attestation, Part D sponsors must certify that all information provided is accurate, complete, and truthful to the sponsor's best knowledge, information, and belief. Part D sponsors must also certify in the attestations and maintain documentation to verify that all entities that have generated or submitted this information on their behalf have certified that all information is accurate, complete, and truthful, based on the entity's best knowledge, information, and belief.

PACE organizations that report $0 in all DIR categories in the Summary DIR Report, and therefore do not submit a Detailed DIR Report, are not required to submit the Attestation of Data Relating to Detailed DIR Data. However, all PACE organizations are required to submit the Attestation of Data Relating to CMS Payment to a Medicare Part D sponsor.

Additional guidance regarding attestation submissions, including the submission deadline, will be provided at a later date through HPMS.

E. Resubmitting Summary DIR Reports for Prior Contract Years

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. Sponsors may also have findings from government audits or reports that require resubmission of Summary DIR. Pursuant to 42 CFR 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. In the event of a reopening under § 423.346, and consistent with § 423.505(k)(5), CMS will require that Part D sponsors submit an attestation that certifies that the DIR information provided and used in the reopening is accurate, complete, and truthful to the sponsor's best knowledge, information, and belief. In addition, in the event that changes in DIR result in an overpayment for a prior contract year, there may also be additional requirements under section 1128J(d) of the Social Security Act.

The resubmission window is limited to resubmissions of the Summary DIR Reports. CMS does not intend to reopen the window for resubmission of Detailed DIR Reports at this time.

i. Contract years 2006 through 2019

CMS does not generally require Part D sponsors to report changes or errors in DIR for contract years 2006 through 2019. However, under the authority codified at 42 CFR 423.346(a)(3), whereby CMS may reopen and revise an initial or reconsidered final payment determination at any time, we continue to require Part D sponsors to report changes for these years that arise from fraud or similar fault of the Part D sponsor or any subcontractor of the Part D sponsor. We note that the government may rely on other authority and have other avenues for pursuing the return of overpayments due to false and fraudulent claims.

To report a change or error in the DIR amounts reported for these contract years, sponsors may not simply upload updated Summary DIR Reports. Instead, they should submit a reopening request, as described in the June 1, 2017, HPMS memorandum titled "Updates to the Reopening Request Spreadsheet." If a reopening request is granted, the sponsor will be notified to resubmit an updated Summary DIR Report (using the applicable template for the applicable contract year).

ii. Reporting changes to 2020 DIR

As described in our final rule published April 23, 2024, CMS modified the reopening timeframe at § 423.346(a)(2) such that, upon an establishment of good cause, CMS may reopen and revise an initial or reconsidered final payment determination within 6 years after the date of the notice of reconciliation determination to Part D sponsors.[2] CMS modified the timeframe from "within 4 years" to "within 6 years" to align the timing of the scheduled global reopening to the 6-year overpayment look-back period, described at § 423.360(f). For additional details, please refer to the final rule published April 23, 2024.[3]

Prior to the change in the regulation, the July 2025 window would have been the last opportunity for sponsors to submit an updated Summary DIR Report for the global reopening of the 2020 Part D payment reconciliation. However, given the regulatory change to the reopening timeframe, CMS plans to announce the global reopening of contract year 2020 in or around the first quarter of 2027, which allows for sponsors to submit an updated Summary DIR Report for contract year 2020 consistent with section *iii* below.

iii. Reporting changes to 2020 through 2023 DIR

To report a known change or error in the DIR amounts reported for contract years 2020, 2021, 2022, and 2023, Part D sponsors must upload an updated Summary DIR Report in HPMS using

[2] Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE), 89 Fed. Reg. 30448 (April 23, 2023)

[3] *See id.* at 30461-30462.

the 2020, 2021, 2022, and 2023 report template, as appropriate, during the DIR resubmission period from July 1, 2025, through 11:59 PM PT on July 31, 2025. 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 its reported changes in DIR.

To submit 2020, 2021, 2022, or 2023 DIR, use the following pathway: HPMS Homepage > Plan Bids > DIR Reporting > from the Dashboard, Select the appropriate contract year from the dropdown on the right.

To report a change or error in the DIR amounts reported for contract years 2020, 2021, 2022, or 2023 after the current submission period that ends on July 31, 2025, Part D sponsors must upload an updated Summary DIR Report using the 2020, 2021, 2022, or 2023 report template, as appropriate, during the 2025 DIR reporting cycle in the summer of 2026.

Part D sponsors are not required to submit an updated Summary 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 additional reopenings, after the scheduled global reopening, we may, at our discretion, elect to limit reopenings to only those sponsors that have affirmatively requested a reopening.

Table 3. Scenarios for resubmitting Summary DIR Reports for prior contract years

Scenario	Sponsor Action
If a Part D sponsor needs to report a change or error for contract years 2020, 2021, 2022 or 2023 prior to the close of the July 2025 window	Part D sponsor must upload an updated Summary DIR Report (using the 2020, 2021, 2022, or 2023 Summary Report template, as appropriate) during the DIR resubmission period from July 1, 2025, through 11:59 PM PT on July 31, 2025, in HPMS.
If a Part D sponsor needs to report a change or error in DIR amounts for contract years 2020, 2021, 2022, or 2023 after July 31, 2025	Part D sponsor must upload an updated Summary DIR Report using the 2020, 2021, 2022, or 2023 Report template, as appropriate, during the DIR submission cycle in summer of 2026. 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.

Scenario	Sponsor Action
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. Disregard any email notifications sent from HPMS when the DIR resubmission window opens.

Note that there may also be obligations under section 1128J(d) of the Social Security Act.

V. STEPS FOR SUBMITTING DIR REPORT FOR PAYMENT RECONCILIATION

The following instructions explain how to access the DIR module within HPMS. More detailed instructions are provided in the "Helpful Hints" documents under the "Documentation" section.

1. Enter DIR Submission Information
    a. Go to the DIR Submission Information page using the following pathway: HPMS Homepage > Plan Bids > DIR Reporting > Dashboard Contract Year 2024 > Submission > DIR Submission Info.
    b. For each contract, provide a response for each question or enter "N/A" as applicable. If the 2024 DIR Report for Payment Reconciliation was previously submitted, provide a reason for resubmitting the DIR Report. Refer to the DIR Submission Info Helpful Hints document for additional instructions.
2. Download DIR Report Template (for Summary and Detailed DIR Reports)
    a. Go to the DIR Download page using the following navigation path: HPMS Homepage > Plan Bids > DIR Reporting > Dashboard Contract Year 2024 > Submission> Download Templates.
    b. Download the DIR Summary and Detailed Report Templates.
3. Enter data into DIR Report Template to create new DIR Report
    a. Refer to the Summary DIR Reporting Helpful Hints and Detailed DIR Reporting Helpful Hints documents for the instructions for populating, saving the Reports, and uploading the Reports.
    b. If you receive any error messages when attempting to upload the report, make corrections to the DIR Report, save the file, and attempt to upload again.
    c. 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.
4. Verify data has successfully completed the unload process
    a. Go to the DIR Unload Status Report using the following navigation path: HPMS Homepage > Plan Bids > DIR Reporting > Dashboard Contract Year 2024 > Reports > select either Summary DIR Unload Status Report or Detailed DIR Unload Status Report.
    b. Check the "Unload Status" column. Once it says "Successful," the DIR data will be available to view in HPMS.
5. Review DIR Report saved in HPMS
    a. Go to the DIR Download page using the following navigation path: HPMS

Homepage > Plan Bids > DIR Reporting > Dashboard Contract Year 2024 > Reports > select either Summary DIR Data Report or Detailed DIR Data Report.

b. Review the submission information and Summary DIR values in the Summary DIR Data Report saved on HPMS.
c. Review the Detailed DIR values in the Detailed DIR Data Report.
d. If there are any errors, make corrections to the DIR Report, save the file, and upload the corrected DIR Report. If you are unable to resolve the errors, contact the HPMS Help Desk.