DEPARTMENT OF HEALTH & HUMAN SERVICES
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**MEDICARE PLAN PAYMENT GROUP**

**Date:** May 30, 2018

**To:** All Part D Plan Sponsors

**From:** Jennifer Harlow, Deputy Director
Medicare Plan Payment Group

**Subject:** Final Medicare Part D DIR Reporting Requirements for 2017

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) 2017.

Part D sponsors are required to report DIR data associated with the Medicare Prescription Drug Benefit at the plan benefit package (PBP) level ("summary level") on the Summary DIR Report to CMS for the purposes of the 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.

## DIR Submission Deadlines

Part D sponsors can begin to submit the 2017 DIR Submission Information, Summary 2017 DIR Report, and Detailed 2017 DIR Report on Friday, June 1, 2018. The deadline for submissions is **11:59 PM PT on Tuesday, July 31, 2018**. 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) plans.

The resubmission window for sponsors to submit an updated Summary DIR Report for contract years 2013, 2014, 2015, and 2016 will be July 1 through July 31, 2018. This July 31, 2018 deadline also applies to all Part D sponsors, including calendar year and non-calendar year EGWPs and PACE plans.

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 submit 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 the Health Plan Management System (HPMS). Sponsors are strongly encouraged to use these documents when completing the 2017 DIR Submission Information, Summary 2017 DIR Report, and Detailed 2017 DIR Report. There is also a "Helpful Hints" document for "Troubleshooting Text File Uploads," which may be helpful when uploading the reports into HPMS.

**Responses to Comments on the "Proposed Medicare Part D DIR Reporting Requirements for 2017"**

On April 17, 2018, CMS released proposed guidance for Medicare Part D sponsors on reporting DIR data for CY 2017. Comments on the proposed guidance were accepted through May 4, 2018. Provided below is an overview of the comments received and our responses to them.

COMMENT: A few commenters felt a 30-day data submission window opening shortly after the final reporting guidance is released does not allow enough time to make necessary system changes and provide accurate DIR Reports. Commenters recommended CMS extend the submission window.

RESPONSE: As noted above, we will allow a two month submission window for 2017 DIR Reports that begins June 1, 2018 and ends at 11:59 PM PT on July 31, 2018. We encourage sponsors to submit their Reports as early during the submission period as possible to ensure a complete, accurate, and successful submission by the deadline. Please note that very large files are not processed immediately. Timely reporting is critical to timely final payment reconciliation.

COMMENT: A commenter requested that CMS modify the templates provided for the Summary and Detailed DIR Reports to allow headers to be copied and pasted.

RESPONSE: We have made the requested change; the headers to the templates for the Summary and Detailed DIR Reports can now be copied and pasted.

COMMENT: A few commenters asked CMS to confirm that the information disclosed by Part D sponsors in the DIR reports will be kept confidential, stating that CMS should not voluntarily make this information publicly available or disclose it pursuant to a Freedom of Information Act (FOIA) request.

RESPONSE: CMS will comply with the applicable statutory provisions that limit the use or disclosure of information collected in the Summary and Detailed DIR Reports.

COMMENT: One commenter urged CMS not to require Part D sponsors to disclose any information that is not necessary for calculating total DIR. The commenter was particularly concerned with CMS requiring

disclosure of terms of sponsors' contracts with other private parties and the potential for the public release of such confidential information.

RESPONSE: All of the information that we require sponsors to report in the Summary and Detailed DIR Reports is necessary to calculate total DIR and ensure accurate plan payments. The information in addition to the dollar values required allows CMS to verify that all forms of remuneration are being accounted for and reported accurately—i.e., as DIR vs. a PDE adjustment, in full, for each plan and NDC, etc.—and any payment rules, such as PDE reporting and pass-through pricing requirements, are properly applied. The additional information sponsors report also allows CMS to ensure that we are capturing all forms of remuneration a sponsor might receive, especially as payment arrangements evolve and grow in complexity, and are doing so in a manner that allows us to validate the data once received. Moreover, as stated above, CMS will comply with all applicable statutory provisions that limit the use or disclosure of information collected in the Summary and Detailed DIR Reports.

COMMENT: Commenters requested information on the Paperwork Reduction Act (PRA) package that covers DIR reporting.

RESPONSE: The OMB control number for the PRA package for DIR reporting is 0938-0964. We have added the control number to the Summary and Detailed DIR Upload Helpful Hints documents for ease of reference.

COMMENT: Several commenters expressed concern about the new requirement for sponsors to provide the manufacturer rebate amounts corresponding to each type of rebate received in the DIR #3C column of the Summary DIR Report. The commenters suggested that sponsors may not all currently be billing manufacturers and collecting rebates in a manner that supports reporting at this level of detail, making accurate reporting operationally challenging. Commenters requested that CMS delay implementing the requirement.

RESPONSE: We appreciate the input received on this topic. We believe this requirement to be valuable for verifying the accuracy of the data reported and overseeing the Part D program and, thus, are finalizing it for CY 2017 as proposed. We expect sponsors to calculate the values associated with each rebate type using a reasonable allocation methodology if they do not bill and collect rebates in this manner, while continuing to build operational capacity for more precise reporting in future years if they do bill and collect rebates in this manner.

COMMENT: A few commenters asked CMS to provide definitions of the various rebate types listed under column DIR #3C of the Summary DIR Report.

REPSONSE: Please see the revised description for column DIR #3C for definitions of the various rebate types.

COMMENT: One commenter contended that the expectation for sponsors to provide rebate information at the level of detail now required under column DIR #3C of the Summary DIR Report conflicts with CMS allowing sponsors to use a reasonable allocation methodology for plan and/or NDC-level reporting.

RESPONSE: Sponsors are allowed to use a reasonable allocation methodology to report DIR at the plan and/or NDC level when the DIR is not collected at the plan and/or NDC level, respectively. For sponsors that do not receive rebate information from manufacturers or their PBMs broken down by type, we will allow the use of a reasonable allocation methodology to calculate the value associated with each rebate type, as needed for column DIR #3C.

COMMENT: A few commenters asked for definitions of the various rebate types provided for column DIR #3C of the Summary DIR Report.

RESPONSE: We have added descriptions for the various rebate types in the description for column DIR #3C below.

COMMENT: One commenter requested further explanation for what is required in the DIR #8C and DIR #9C columns of the Summary DIR Report, especially in regards to what is meant by "if relevant to the price concessions [or incentive payments] calculation."

RESPONSE: We expect Part D sponsors to describe the reason that a price concessions was received from or incentive payment was paid to a pharmacy. If the reason is performance related, we expect the sponsor to detail the metric(s) by which pharmacy performance was assessed.

The following are examples of acceptable responses for the DIR #8C column:

- "Performance-based price concessions. Metrics: generic dispensing rate, adherence rate for non-insulin diabetes medications, adherence rate for statins."
- "Performance-based price concessions. Metrics for specialty pharmacies: high risk medication rate, audit performance/error rates. Metrics for other pharmacies: generic dispensing rate, adherence rate for RAS antagonists."
- "Per-claim transaction fees."

An acceptable response for the DIR #9C column should look similar to the examples provided above for the DIR #8C column, but with the amount identified as an "incentive payment" instead of a "price concession" if necessary.

COMMENT: One commenter recommended that CMS require pharmacy DIR to be further broken out by pharmacy type, e.g., specialty and mail order, in the Summary DIR Report.

RESPONSE: We appreciate the comment and will take into consideration when developing guidance for future years.

COMMENT: One commenter recommended that CMS require Part D sponsors to provide an explanation with documentation for why pharmacy DIR reported could not be reasonably determined at the point of sale.

RESPONSE: We appreciate the comment and will take the recommendation into consideration when developing guidance for future years.

COMMENT: One commenter pointed out that the descriptions for the Summary DIR Report columns DIR #8 and DIR #9 could be construed as guidance on what can or cannot be reasonably determined at the point of sale, and thus what is and is not required to be included in the negotiated price.

RESPONSE: The purpose of this document is to provide Part D sponsors guidance on how they must report DIR, not on which pharmacy price concessions can or cannot be reasonably determined at the point of sale.

COMMENT: A couple of commenters requested clarification on the 60-day overpayment reporting requirement as it relates to DIR reporting and the April 6, 2018 HPMS memorandum, "Reopening Process and Updates to the PDE/DIR-related Overpayment Reporting."

RESPONSE: Part D sponsors have a 60-day deadline to report and return overpayments. Pursuant to 42 CFR 423.360(d)(2), a Part D sponsor must return identified overpayments in a manner specified by CMS. Prior to the global reopening for the year in which the overpayment occurs, the DIR-related overpayment is returned to CMS when the Part D sponsor submits corrected DIR data to rectify the overpayment.[1] DIR data cannot be submitted year-round and may only be resubmitted when the window for resubmitting prior years' DIR data is open. The window for submitting previous years' DIR data is typically open in July. Since not all DIR-related overpayments will be discovered within 60-days of the July resubmission window, in order for the Part D sponsor to be compliant with the 60-day requirement, the sponsor must notify CMS, via email to its Reconciliation Support Contractor, of the sponsor's intent to submit revised DIR data to correct a DIR-related overpayment. This email must be sent within 60 days of the overpayment being identified.

COMMENT: One commenter believed the June 1, 2017 HPMS memorandum, "Updates to the Reopening Request Spreadsheet" to be out of date and recommended that CMS instead make reference to the April 6, 2018 HPMS memorandum, "Reopening Process and Updates to the PDE/DIR-related Overpayment Reporting."

RESPONSE: The June 1, 2017 memorandum is not out of date; we continue referring sponsors to it for guidance on how to submit a reopening request. CMS references the June 1, 2017 memorandum in two

[1] For information related to overpayments identified after the data submission deadline for the global reopening for the contract year in which the overpayment occurs, see the April 6, 2018 HPMS memorandum, "Reopening Process and Updates to the PDE/DIR-related Overpayment Reporting."

places in the DIR reporting requirements guidance, once under the heading "Reporting Changes to 2012 DIR" and again when discussing changes to DIR for contract years prior to 2013 and after July 31, 2018, changes to DIR for contract year 2013.

Per the April 6, 2018 HPMS memorandum, if a sponsor has new or corrected PDE or DIR data to submit after the respective reopening submission deadlines, the sponsor may request a reopening consistent with the current process outlined in the June 1, 2017 HPMS memorandum. As the deadline for the 2012 reopening was in 2017 and the deadline for DIR submission for the 2013 reopening is July 31, 2018, if sponsors have changes to DIR data prior to contract year 2013, or for the 2013 contract year after the DIR submission deadline, they should submit a reopening request consistent with the June 1, 2017 memorandum.

COMMENT: Some commenters requested that CMS increase the character limit for certain comment fields, such as DIR #11C of the Summary DIR Report, to allow for more meaningful comments when necessary.

RESPONSE: We have increased the character limits for columns DIR #3C and DIR #11C to 1,500 characters.

COMMENT: One commenter asked whether a manufacturer administrative fee that does not exceed fair market value but is passed on in its entirety to the sponsor, would be considered DIR.

RESPONSE: Administrative fees charged to manufacturers must be reported as DIR only to the extent that they exceed fair market value or if they do not qualify as bona fide service fees.

Bona fide service fees, as defined at 42 CFR 423.501, are fees paid by a manufacturer to an entity that meets 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.

All of these conditions must be met for a fee to be considered a bona fide service fee. Therefore, if, as stated in the question, the fair market value fee is passed on in its entirety to the sponsor, it does not qualify as a bona fide service fee and thus must be reported as DIR in the DIR #4 column of the Summary DIR Report and the All Other DIR column of the Detailed DIR Report.

COMMENT: One commenter suggested that the examples of remuneration that are and are not considered DIR provided in Table 1 of section II of this document be updated to reflect more current arrangements.

RESPONSE: We appreciate the commenter's concerns and will consider updates to the table, as appropriate, in future years.

COMMENT: A few commenters requested clarification on why CMS broadened the scope of the "Rebates to POS?" column of the Summary DIR Report to require sponsors to also indicate whether they applied any other price concessions, in addition to or instead of manufacturer rebates, to the negotiated price at the point of sale.

RESPONSE: The requirement for this field was expanded in order to acknowledge the possibility that Part D sponsors might be applying, as they are able to under current law, concessions other than rebates at the point of sale and reporting such amounts in the "Estimated Rebates at Point-of-Sale" (ERPOSA) field of the PDE record. We use a sponsor's input in the Rebates at POS field of the DIR Report to ensure net DIR is being accurately calculated, taking POS price concession amounts reported on the PDE into account, for payment reconciliation purposes. We are finalizing expanding the scope of the "Rebates to POS?" column in order to ensure that all plans that apply price concessions at the POS, and report a value in the ERPOSA field of the PDE record, are appropriately flagged when calculating net DIR . This change should not require sponsors to adjust PDEs already submitted or revise existing contracts.

## Contact Information

For technical assistance and questions regarding the download or upload of the DIR Reports, 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 DIR_Reporting_Reqts@cms.hhs.gov.

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Attachment

## FINAL MEDICARE PART D DIR REPORTING REQUIREMENTS FOR 2017

# I. INTRODUCTION

## A. Purpose

The purpose of this document is to explain CMS's DIR reporting requirements for the Summary and Detailed 2017 DIR Reports. This document provides the format in which data must be submitted, explains the data elements to be reported by Part D sponsors at the PBP and 11-digit NDC levels, and establishes reporting timeframes. CMS's goal is to ensure a common understanding of DIR reporting requirements.

## 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 (SSA) requires Part D sponsors to fully disclose to CMS any information necessary for carrying out the payment provisions of Part D, including the calculation of reinsurance and risk-sharing. Therefore, Part D sponsors are required to report drug costs and DIR associated with the Medicare prescription drug benefit to CMS. Each year, we issue guidance explaining these reporting requirements. Consistent with section 1860D-15(d)(2)(A) of SSA, CMS's payments to a Part D sponsor are conditioned upon the provision of this 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 in 2018 will be $4.1 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. The Detailed DIR Report is required as part of this effort.

## C. Overview of DIR Reporting Process

Part D sponsors must prepare and submit the DIR Submission Information, Summary DIR Report, and Detailed DIR Report to CMS for all of the Part D PBPs that they offered in 2017, even if they have no DIR to report for contract year 2017.

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 2017 DIR Submission Information and upload the Summary and/or Detailed 2017 DIR Reports as many times as necessary until 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 March 16, 2018 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.

## D. DIR Reporting for PACE Organizations

PACE organizations reporting $0 in all Summary DIR categories in the Summary 2017 DIR Report must submit the 2017 DIR Submission Information and the Summary 2017 DIR Report, but are not required to submit a Detailed 2017 DIR Report. PACE organizations reporting a non-zero value in any column in the Summary DIR Report must submit the 2017 DIR Submission Information, Summary 2017 DIR Report, and Detailed 2017 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.

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 |
| Dispensing incentive payments to pharmacies after the point of sale (POS) that are not included in the negotiated price | Rebate amounts received by long term care (LTC) pharmacies |

| Remuneration Considered DIR | Remuneration Not Considered DIR |
|---|---|
| Prompt pay discounts from pharmacies that are not included in the negotiated price | Claims data |
| Post-POS pharmacy payment adjustments that are not already included in the negotiated price | |
| Risk-sharing amounts | |

## III. DIR SUBMISSION INFORMATION

As the first step in the DIR reporting process, Part D sponsors must ensure that sponsor information in HPMS is up to date. For instructions on how to view or change your contact information, please see the March 16, 2018 HPMS memorandum titled "Annual Request for Part D Payment Reconciliation Contact Information."

Next, Part D sponsors must complete the 2017 DIR Submission Information Report, providing additional information at the contract level regarding their DIR and PDE data. This step must be completed prior to uploading the Summary and Detailed DIR Reports. The 2017 DIR Submission Information Report must be completed for each contract and includes:

### A. Allocation Methodology

Part D sponsors are required to 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. To satisfy the reporting requirements, such Part D sponsors must 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 must be submitted by the sponsor in HPMS as part of the 2017 DIR Submission Information Report.

CMS has identified several reasonable allocation methodologies (see below) and requires that Part D sponsors select the applicable option from a dropdown menu when reporting the allocation methodology used. Sponsors must 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 must 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 receive rebates and therefore have no 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 them 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 received from the manufacturer 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 Rebate Amounts
7. This PACE Organization does not receive rebates; 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 received from the manufacturer 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 level based on Billed Rebate Amounts
7. This PACE Organization does not receive rebates; 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 manufacturer rebate amounts 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 DIR 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 must 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 must 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 are required to 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 Plan's Total Drug Spend | Rebate amounts received for multiple 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. | Yes | Approximates differences in utilization and spending on rebate eligible drugs across Part D PBPs. |

| Allocation Methodology | Description | Considered Reasonable? | Explanation |
|---|---|---|---|
| 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 Rebate 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. |
| 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 | No | Does not sufficiently approximate differences in utilization and |

| Allocation Methodology | Description | Considered Reasonable? | Explanation |
|---|---|---|---|
| | 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. | | 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. Description of Services Provided for Administrative Service Fees from Manufacturers

Part D sponsors must describe the services provided for administrative service fees received by sponsors or their PBMs from drug manufacturers. The description should address fees reported on the Summary DIR Report under the DIR #4 column when greater than fair market value and as bona fide service fees otherwise (see the applicable column descriptions in Section IV below for additional information). If this question is not applicable, Part D sponsors must enter "N/A." Sponsors are not permitted to leave this field blank. CMS will confirm that an appropriate description is entered in this field if any non-zero dollar amount is entered in either of the two rebate administration fee related fields on the Summary DIR Report.

## C. Description of Legal Settlement Amounts

Part D sponsors must provide a description of any legal judgment or settlement amounts, including the source or recipient of the judgment or settlement amount and the services or drugs at issue. If this question is not applicable, Part D sponsors must enter "N/A." Sponsors are not permitted to leave this field blank. CMS will confirm that an appropriate description is entered in this field if any non-zero dollar amount is entered in the "Legal Settlement Amounts" column of the Summary DIR Report.

## D. Description of Services Provided for Other Bona Fide Service Fees

Part D sponsors must describe the services provided for any bona fide service fees that are not related to rebate administration and the PBP- or NDC-level allocation methodology used to determine the amount of such fees allocated to the PBP or 11-digit NDC. If this question is not applicable, Part D sponsors must enter "N/A." Sponsors are not permitted to leave this field blank.

## E. Description of Risk-Sharing Arrangement(s)

Part D sponsors must describe all risk-sharing arrangements. If this question is not applicable, Part D sponsors must enter "N/A." Sponsors are not permitted to leave this field blank. CMS will confirm that an appropriate description is entered in this field if any non-zero dollar amount is entered in the "Risk-Sharing Arrangement Payments and Adjustments" column of the Summary DIR Report.

## F. Name of 2017 Claims Processing PBM(s)

Part D sponsors must provide the name of any PBM or other entity with which the sponsor contracted for the processing of claims or submission of PDE records for 2017. 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 must indicate "Self" for this question. Sponsors are not permitted to leave this field blank.

## G. Did PBM for Rebate Negotiation or Processing change from 2016 to 2017?

Part D sponsors must indicate whether they contracted with a different PBM or entity in 2017 for the negotiation or processing of rebates than they contracted with in 2016. If the sponsor did not negotiate or process rebates in 2016 and 2017, the sponsor must 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 2017 but not in 2016, the sponsor must enter "Yes" for this question. Similarly, if the sponsor contracted with a PBM or other entity for the negotiation or processing of rebates in 2016 but not in 2017, the sponsor must enter "Yes" for this question. Sponsors are not permitted to leave this field blank.

## H. Name of 2017 PBM(s) for Rebate Negotiation or Processing

Part D sponsors must provide the name of any PBM or other entity with which the Part D sponsor contracted for the negotiation or processing of rebates in 2017. Part D sponsors that conducted rebate negotiation or processing using their internal resources and did not contract with a PBM for these services must indicate "Self" for this question. If the Part D sponsor did not negotiate or process rebates, the sponsor must enter "N/A" for this question. Sponsors are not permitted to leave this field blank.

## I. Were any of the plans in the contract owned by a different sponsor in 2016?

Part D sponsors must indicate whether any of the plans in the contract were owned by a different sponsor in 2016. For any applicable plans, the sponsor must provide the plan ID, the name of the sponsor that owned the plan in 2016, and the contract number that the plan was under in 2016. If all of the plans in the contract were owned by a different sponsor in 2016, the sponsor may indicate "all plans in contract" instead of listing all plan IDs.

## J. Did your parent organization acquire any of the plans in this contract during the 2017 contract year?

Part D sponsors must indicate whether any of the plans in the contract were acquired mid-contract year. For any applicable plans, the sponsor must provide the plan ID, the name of the sponsor that previously owned the plan, and the contract number that the plan was under prior to the sponsor's acquisition of the plan.

## K. Explanation for Resubmission

When resubmitting the Summary or Detailed DIR Report for 2017 due to a plan or CMS discovered data error, Part D sponsors are required to 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 are advised that the DIR data used to produce the Summary and Detailed DIR Reports must be reasonably current, reflecting, at a minimum, the DIR amounts received up to three months prior to the submission deadline. Part D sponsors also must 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 must 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 requirements.

Unless specified otherwise, the numerical values reported under most of the columns in this Report must be positive. All mandatory fields must be filled out; none may be left blank.

| 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.<br><br>This field must be populated with 9 alpha-numeric characters. |

| Column Name | Column Description, Type, and Field Length |
|---|---|
| DIR #1 – PBM Retained Rebates | DIR Type: Manufacturer Rebates<br><br>Entity From: Drug Manufacturer<br><br>Exclusions: Do not include any manufacturer rebates passed through to the Part D sponsor, which must be reported in the DIR #3 column. Do not include any rebates expected but not yet received in this column, which must be reported in the DIR #2 column. Do not include any rebate administration fees, which must 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.<br><br>Additional Details:<br>Include all manufacturer rebates associated with the Medicare prescription drug benefit retained by the PBM and not passed through to the sponsor.<br><br>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.<br><br>This field is limited to 500 characters. |
| DIR #2 – Rebates Expected But Not Yet Received | DIR Type: Manufacturer Rebates<br><br>Entity From: 1. Drug Manufacturer, 2. PBM<br><br>Exclusions: Do not include any manufacturer rebates reported in the DIR #1 column. Do not include any other types of DIR.<br><br>Additional Details:<br>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.<br><br>All rebate guarantee amounts expected but not yet received from PBMs must 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 must be reported in this column.<br><br>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 are required when DIR #2 is negative.<br><br>This field is limited to 500 characters. |

| Column Name | Column Description, Type, and Field Length |
|---|---|
| DIR #3 – All Other Rebates | DIR Type: Manufacturer Rebates<br><br>Entity From: 1. Drug Manufacturer, 2. PBM<br><br>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 must be reported under the DIR #2 column. Do not include any other types of DIR from any other sources.<br><br>Additional Details:<br>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.<br><br>*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.<br><br>*Estimated Rebates at 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 are also required to report the actual rebate amounts for these estimated rebates on the Summary DIR Report. CMS will subtract the amounts reported in the Estimated Rebates at the POS 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.<br><br>*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 must be reported in this column.<br><br>*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 must be reported in this column.<br><br>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. |

| Column Name | Column Description, Type, and Field Length |
|---|---|
| DIR #3C – All Other Rebates *(Additional Comments)* | Additional comments are required. 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.<br><br>Identify the option(s) from the list below that best describe the reason(s) for the rebates reported in the DIR #3 column:<br>A. Formulary access/Tier placement rebates (e.g.., rebates received for inclusion of a drug on the plan's formulary or favorable tier placement)<br>B. Market share target rebates (e.g., rebates received for the plan/plan sponsor/PBM achieving a specified share of a drug's sales, or when one manufacturer's product comprises a specified percentage of the plan's/plan sponsor's/PBM's drug utilization within a specific class)<br>C. Volume target rebates (e.g., rebates received for the plan/plan sponsor/PBM purchasing a specified volume of a manufacturer's product)<br>D. Price inflation rebates (e.g., rebates received for a drug when its price increases above a specified threshold)<br>E. Rebate guarantee amount – from PBM (e.g., payment received from PBM to account for the difference between a contractually-guaranteed rebate amount and the rebate amount actually received)<br>F. Other rebates<br><br>The comment in this column must indicate the applicable selection(s) and the value(s) associated with the applicable selection(s). For example, if options A and D apply, the comment here would be: "A. $2,245,262 D. $4,685,794."<br><br>If the "Other" option (Option F) is selected, the Part D sponsor must 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 here would be: "A. $2,245,262 D. $4,685,794 F. $245,000 for a value-based arrangement."<br><br>This field is limited to 1,500 characters. This field must not be left blank. |
| DIR #4 – Administrative Service Fees Reported as DIR | DIR Type: Fees<br><br>Entity From: 1. Drug Manufacturer, 2. PBM<br><br>Exclusions: Do not include any bona fide service fees. Do not include any other types of DIR.<br><br>Additional Details:<br>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 is to be reported in this column. The amount reported in this column is considered DIR and, therefore, must be included in the Total DIR column. |

| Column Name | Column Description, Type, and Field Length |
|---|---|
| | The fee amounts included here must 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 reported here.<br><br>*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 must be reported in this column. The remaining portion must instead be reported in the Bona Fide Service Fees column of the Summary DIR Report and is not considered DIR.<br><br>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 are required 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.<br><br>This field is limited to 500 characters. |
| DIR #5 – Price Concessions for Administrative Services | DIR Type: Price Concessions and Grants<br><br>Entity From: Drug Manufacturer<br><br>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 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.<br><br>Additional Details:<br>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.<br><br>Also reported in this column are grants from pharmaceutical manufacturers for services and programs such as utilization management and medical education.<br><br>Applicable price concessions for administrative services that are not associated with a specific drug must be reported in full in this column, |

| Column Name | Column Description, Type, and Field Length |
|---|---|
| | inclusive of any amount 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.<br><br>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 #5C – Price Concessions for Administrative Services *(Additional Comments)* | Additional comments are required when DIR #5 is greater than zero in order to specify the administrative services for which the price concessions were provided. The comment must be structured according to the guidelines that follow.<br><br>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:<br>A. Utilization management<br>B. Medical education<br>C. Medication monitoring/Medication therapy management<br>D. Other<br><br>The comment in this column must indicate the applicable selection(s) and the value(s) associated with the applicable selection(s). For example, if options A and C apply, the comment here would be: "A. $2,000 C. $3,500."<br><br>If the Other option (Option D) is selected, the Part D sponsor must 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."<br><br>This field is limited to 500 characters. |
| DIR #6 – Legal Settlement Amounts | DIR Type: Legal Settlement Amounts<br><br>Entity From or To: Any<br><br>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 2017. Do not include any other types of DIR.<br><br>Additional Details:<br>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 2017 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.<br><br>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 must 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 |

| Column Name | Column Description, Type, and Field Length |
|---|---|
| | the sponsor—the value must be reported in this column as a positive adjustment.<br><br>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 2017. 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 2017 DIR Report—$400,000 for lawsuit A and $0 for lawsuit B.<br><br>Please note, however, that Part D sponsors cannot 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).<br><br>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)* | This field is optional.<br><br>This field is limited to 500 characters. |
| DIR #7 – All Other Price Concessions from Manufacturers | DIR Type: Price Concessions and Grants<br><br>Entity From: 1. Drug Manufacturer, 2. PBM<br><br>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.<br><br>Additional Details:<br>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.<br><br>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 #7C – All Other Price Concessions from Manufacturers *(Additional Comments)* | Additional comments are required when DIR #7 is a non-zero value. Describe the nature of all other price concessions reported in the DIR #7 column.<br><br>This field is limited to 500 characters. |

| Column Name | Column Description, Type, and Field Length |
|---|---|
| DIR #8 – Amounts Received from Pharmacies | DIR Type: Price Concessions, Fees, and Payment Adjustments<br><br>Entity From: Pharmacy<br><br>Exclusions: Do not include any DIR from entities other than pharmacies. Exclude any pharmacy payment adjustments applied at the POS and all post-POS incentive payments *to* pharmacies and positive adjustments *to* pharmacy payments, which must be reported in the DIR #9 column. Do not include other types of DIR.<br><br>Additional Details:<br>Reported in this column is any sum *received by* a PBM or Part D sponsor (directly or indirectly through the PBM) from 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). Include any amounts received and retained by PBMs (i.e., those not passed through to the sponsor).<br><br>Specifically, if a sponsor or its PBM pays a pharmacy a specified amount for a prescription event but recoups some of the payment after the event, if, for instance, the pharmacy has failed to meet performance standards set under a performance-based payment arrangement, the amount recouped by the sponsor or its PBM must be reported in this column as positive DIR, if it is not otherwise included in the negotiated price, as it reduces the drug costs of the Part D sponsor or the PBM.<br><br>Examples of adjustments to be reported in this field include any reconciliation amount that accounts for differences between the contracted rate and the higher adjudicated rate received by the pharmacy at the POS and contingent incentive 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 must only be reported in this column if they reduce the Part D sponsor's or PBM's costs and are not otherwise included in the negotiated price. If the adjustments serve to increase costs, they must be reported later in the Summary DIR Report.<br><br>This column must also include per-claim administrative fees collected, not paid, by a Part D sponsor or PBM from pharmacies *after* the POS that are not included in the negotiated price. Examples of such fees include, but are not limited to, preferred pharmacy fees, fees related to extended supply rates, etc.<br><br>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)* | This field is required 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.<br><br>The following are examples of acceptable responses: |

| Column Name | Column Description, Type, and Field Length |
|---|---|
| | • "Performance-based price concessions. Metrics: generic dispensing rate, adherence rate for non-insulin diabetes medications, adherence rate for statins."<br>• "Performance-based price concessions. Metrics for specialty pharmacies: high risk medication rate, audit performance/error rates. Metrics for other pharmacies: generic dispensing rate, adherence rate for RAS antagonists."<br>• "Per-claim transaction fees."<br><br>This field is limited to 500 characters. |
| DIR #9 – Amounts Paid to Pharmacies | DIR Type: Incentive Payments and Payment Adjustments<br><br>Entity To: Pharmacy<br><br>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.<br><br>Additional Details:<br>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).<br><br>Specifically, if a sponsor or its PBM pays a pharmacy a bonus payment after the POS, the amount paid by the sponsor or its PBM must be reported in this column as negative DIR, if it is not otherwise included in the negotiated price, as it serves to increase the drug costs of the Part D sponsor or its PBM.<br><br>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 must 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.<br><br>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. |
| DIR #9C – Amounts Paid to Pharmacies *(Additional Comments)* | Additional comments are required 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.<br><br>The following are examples of acceptable responses:<br>• "Performance-based incentive payments. Metrics: generic dispensing rate, adherence rate for non-insulin diabetes medications, adherence rate for statins." |

| Column Name | Column Description, Type, and Field Length |
|---|---|
| | • "Performance-based incentive payments. Metrics for specialty pharmacies: high risk medication rate, audit performance/error rates. Metrics for other pharmacies: generic dispensing rate, adherence rate for RAS antagonists."<br>• "Per-claim transaction fees."<br><br>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<br><br>Entity From or To: Any Non-Pharmacy<br><br>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 must be reported in the DIR #3 column. Do not include any pharmacy payments, fees, or adjustments, which must be reported in the DIR #8 or DIR #9 columns. Do not include any PBM penalty or repayment related to PBM error, which must be reported in the DIR #11 column.<br><br>Additional Details:<br>This field must include any gains or losses that are attributable to drug costs that the Part D sponsor may receive or pay as a result of risk-sharing arrangements with entities other than CMS and that are permissible under the Part D regulations and other applicable laws. 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 must determine and report as DIR only the portion specifically related to Part D drug costs.<br><br>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.<br><br>Risk-sharing amounts received must be reported in this column as a positive adjustment. Risk-sharing amounts credited to other parties must be reported in this column as a negative adjustment.<br><br>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 #10C – Risk-Sharing Arrangement Payments and Adjustments *(Additional Comments)* | Additional comments are required 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.<br><br>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.<br><br>This field is limited to 500 characters. |

| Column Name | Column Description, Type, and Field Length |
|---|---|
| DIR #11 – All Other DIR | DIR Type: Any<br><br>Entity From or To: Any<br><br>Exclusions: Do not include any DIR reported in the preceding columns (DIR #1 through DIR #10). All rebate guarantee amounts received must be reported in the DIR #3 column.<br><br>Additional Details:<br>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.<br><br>One example of DIR that must 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.<br><br>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 must 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.<br><br>DIR that is not associated with a specific drug, must be reported in full in this column, including any amount 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.<br><br>The All Other DIR field cannot be used to report claim level adjustments; the sponsor must submit an adjusted PDE record to account for any change in drug costs paid on specific claims or groups of claims. Thus, in most cases, Part D sponsors will 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 must not be reported as DIR since the PDE record has been adjusted to reflect the appropriate gross drug costs.<br><br>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 are required 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 |

| Column Name | Column Description, Type, and Field Length |
|---|---|
| | adjustments or PBM penalty amounts reported in column DIR #11 must be explained in this column.<br><br>This field is limited to 1,500 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).<br><br>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 are required when Total DIR reported is zero or negative. Provide an explanation of why the specific Part D PBP has no DIR or negative DIR.<br><br>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 must enter "Y" in this column for each applicable Part D PBP. Otherwise, the sponsor must enter "N" in this column to indicate that no such rebates or other price concessions were applied to the negotiated price at the POS.<br><br>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 must be either received directly and retained by a Part D sponsor, or received directly and retained by a PBM.<br><br>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:<br>1) The fee must be paid for a bona fide, itemized service that is actually performed on behalf of the manufacturer;<br>2) The manufacturer would otherwise perform or contract for the service in the absence of the service arrangement;<br>3) The fee represents fair market value; and<br>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.<br><br>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.<br><br>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 |

| Column Name | Column Description, Type, and Field Length |
|---|---|
| | entities. Manufacturers must 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 shall include, at a minimum, assumptions, methodology, and rationale used to determine fair market value.<br><br>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.<br><br>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.<br><br>*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 must be reported in the DIR #4 column of the Summary DIR Report. The remaining portion must instead be reported in this column and is not considered DIR.<br><br>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 calculates final reinsurance and risk corridor payments during the Part D payment reconciliation process.<br><br>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 are required 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.<br><br>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.<br><br>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.<br><br>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 |
|---|---|
| PBM Incentive Payments *(Additional Comments)* | Additional comments are required when the amount of PBM Incentive Payments reported is non-zero. Describe the factor motivating the PBM incentive payments. The comment must be structured according to the guidelines that follow.<br><br>Identify the option(s) from the list below which best describe why the PBM incentive payments that are reported were made:<br>A. Rebate threshold<br>B. Total drug costs savings threshold<br>C. Generic dispensing rate<br>D. Dispensing fees savings<br>E. Other<br><br>The comment in this column must indicate the applicable selection(s) and the value(s) associated with the applicable selection(s). For example, if options A and C apply, the comment here would be: "A. $1,000 C. $5,000."<br><br>If the Other option (Option E) is selected, the Part D sponsor must 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."<br><br>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," must be reported in this column of the Summary DIR Report. We emphasize that sponsors must report aggregate values for all PBM spread amounts, not the PBM spread for each retail pharmacy.<br><br>The value reported here must be for all covered drug costs under the Part D program, excluding spreads for drugs not covered under the Part D program.<br><br>If sponsors use pass-through pricing to pay PBMs, this value must be zero. Sponsors that use lock-in pricing to pay PBMs must report in this column the difference between the lock-in price and the price ultimately received by the pharmacy.<br><br>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.<br><br>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. |

| Column Name | Column Description, Type, and Field Length |
|---|---|
| | 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," must be reported in this column of the Summary DIR Report. We emphasize that sponsors must report aggregate values for all PBM spread amounts, not the PBM spread for each mail order pharmacy.<br><br>The value reported here must be for all covered drug costs under the Part D program, excluding spreads for drugs not covered under the Part D program.<br><br>If sponsors use pass-through pricing to pay PBMs, this value must be zero. Sponsors that use lock-in pricing to pay PBMs must report in this column the difference between the lock-in price and the price ultimately received by the pharmacy.<br><br>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 costs when CMS calculates reinsurance and risk-sharing payments during the Part D payment reconciliation process.<br><br>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.<br><br>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" must 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)" must 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 claims 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.<br><br>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).<br><br>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.<br><br>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 must 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 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 2017 DIR Report will include all rebates reported under columns #1-3 on the Summary 2017 DIR Report.<br><br>For each 11-digit NDC with utilization, provide the total rebate dollars for all Part D plan expenditures incurred during contract year 2017. 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 must be reported on the Detailed DIR Report.<br><br>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 2017 DIR Report will include DIR reported in columns #4-11 on the Summary 2017 DIR Report.<br><br>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 2017 must 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 must be reported on the Detailed DIR Report.<br><br>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. |

| Column Name | Column Description, Type, and Field Length |
|---|---|
| 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.<br><br>If reporting a negative amount in either the Rebate column or All Other DIR column for a specific 11-Digit NDC, Part D sponsors must 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 must provide a comment. If a Contract-Plan has no NDCs with utilization and leaves the 11-digit NDC field blank, the Part D sponsor must provide a short explanation in this column as well.<br><br>This field is a character field and may have up to 4,000 characters. |

## C. Steps for Submitting 2017 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

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. Per 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 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, 42 CFR 423.360.

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, 2007, 2008, 2009, 2010, and 2011*

CMS does not generally require Part D sponsors to report changes or errors in DIR for contract years 2006 through 2011. However, we continue to require Part D sponsors to report changes for these years that arise from fraud or similar fault. Although these years are outside the look-back period under 42 CFR 423.360, 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 outside of these provisions, including outside of the look-back period.

#### *ii. Reporting changes to 2012 DIR*

To report a change or error in the DIR amounts reported for contract year 2012, sponsors may not simply upload updated Summary DIR Reports. Instead, they must 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 2013 DIR*

To report a known change or error in the DIR amounts reported for contract year 2013, Part D sponsors must submit an updated Summary DIR Report in HPMS using the 2013 Report template during the DIR resubmission period from July 1, 2018 through 11:59 PM PT on July 31, 2018. The resubmission window will open for all Part D sponsors to resubmit the Summary DIR Report for contract year 2013. If a sponsor does not need to resubmit a report, please disregard any email notifications sent out regarding the resubmission window.

**The July 2018 resubmission window will be the last opportunity for sponsors to submit an updated Summary DIR Report for the reopening of the 2013 Part D payment reconciliation. Sponsors should access their 2013 Summary DIR Report to verify the data that will be used in the 2013 Part D payment reopening.**

Any Part D sponsor that was previously notified of audit findings and observations through the Office of Financial Management (OFM) regarding the "One-Third Audits" is required to submit an updated 2013 DIR Report for Payment Reconciliation: Summary Report (Summary 2013 DIR Report) if they have not already done so. If a sponsor fails to update the Summary DIR Report based upon audit findings, CMS may take compliance actions. Any sponsor that submitted a 2013 reopening request that included DIR should also submit an updated 2013 Summary DIR Report if the sponsor has not done so already.

To report a change or error in the DIR amounts reported for contract year 2013 after the submission period that ends on July 31, 2018, Part D sponsors must submit a reopening request.

### *iii. Reporting changes to 2014, 2015, and 2016 DIR*

To report a known change or error in the DIR amounts reported for contract years 2014, 2015, and 2016, Part D sponsors must submit an updated Summary DIR Report in HPMS using the 2014, 2015, and 2016 Report template, as appropriate, during the DIR resubmission period from July 1, 2018 through 11:59 PM PT on July 31, 2018. 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 report a change or error in the DIR amounts reported for contract years 2014, 2015, or 2016 after the current submission period that ends on July 31, 2018, Part D sponsors must submit an updated Summary DIR Report using the 2014, 2015, or 2016 report template, as appropriate, during the 2018 DIR reporting cycle in the summer of 2019.

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 a 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* |
|---|---|
| Part D sponsor must report a change or error for contract year 2012 | This scenario can be initiated by the Part D sponsor or by CMS. If the Part D sponsor believes it must resubmit DIR for contract year 2012, the sponsor must submit a reopening request. If the reopening request is granted, then the sponsor would be notified to resubmit an updated DIR Report (using the 2012 Report template).<br><br>CMS may also contact Part D sponsors with instructions and submission deadlines for resubmitting DIR for contract year 2012. |

| Scenario | Sponsor Action* |
|---|---|
| Part D sponsor must report a change or error for contract year 2013 | Part D sponsor must submit an updated Summary DIR Report using the 2013 Summary Report template during the DIR resubmission period from July 1, 2018 through 11:59 PM PT on July 31, 2018 in HPMS. |
| Part D sponsor must report a change or error for contract years 2014, 2015, or 2016 during July 2018 | Part D sponsor must submit an updated DIR Report (using the 2014, 2015, or 2016 Summary Report template, as appropriate) during the DIR resubmission period from July 1, 2018 through 11:59 PM PT on July 31, 2018 in HPMS. |
| Part D sponsor must report a change or error in DIR amounts for contract year 2013 after July 31, 2018 | Part D sponsor must submit a reopening request. If the reopening request is granted, then sponsor would be notified to resubmit an updated DIR Report using the 2013 Summary DIR Report template. |
| Part D sponsor must report a change or error in DIR amounts for contract years 2014, 2015, or 2016 after July 31, 2018 | Part D sponsor must submit an updated Summary DIR Report using the 2014, 2015, or 2016 Report template, as appropriate, during the DIR submission cycle in summer of 2019.<br><br>Part D sponsors also have the option to request that CMS, at its discretion, reopen and revise the sponsor's final Part D payment determinations to reflect their reported changes in DIR. |
| No change to the total DIR previously reported to CMS | Part D sponsors are not required to submit an updated DIR Report for any year if there has been no change to the total DIR previously reported to CMS. 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 and 42 CFR 423.360.

For contract years prior to 2013 and for changes or errors in DIR amounts for contract year 2013 reported after July 31, 2018, CMS will review all submitted reopening requests and make a determination on whether the sponsor's final Part D payment determinations will be reopened. Reopening requests must be submitted to the Reconciliation Support Contractor at: PartDPaymentSupport@acumenllc.com. Please see the June 1, 2017 HPMS memorandum titled "Updates to the Reopening Request Spreadsheet," for additional guidance regarding how to submit a reopening request. Please note that the reopening process requires substantial CMS preparation and resources. Therefore, it may take some time to receive a determination regarding a request for reopening from CMS. In addition, Part D sponsors should not expect the reopening to be performed immediately after receiving a decision to reopen.

For changes or errors in DIR amounts for contract years 2014, 2015, or 2016, CMS will review all submitted reopening requests, however, note that CMS will perform a global reopening of these contract years approximately four years after sending the reports and/or payments associated with the initial reconciliation for each contract year. For more information see the April 6, 2018 HPMS memorandum, "Reopening Process and Updates to the PDE/DIR-related Overpayment Reporting."

## 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 > Contract Year 2017 > DIR Submission Info.
    b. For each contract, provide a response for each question or enter "N/A" as applicable. If the 2017 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 > Contract Year 2017 > (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 > Contract Year 2017 > DIR 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 > Contract Year 2017 > DIR 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.