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Center for Medicare
Medicare Plan Payment Group

Date: August 24, 2011

To: All Part D Plan Sponsors

From: Cheri Rice, Director
Medicare Plan Payment Group

Subject: Draft Medicare Part D Detailed 2010 DIR Reporting Requirements

CMS is providing proposed guidance for Part D sponsors to report detailed direct and indirect remuneration (DIR) data at the plan benefit package (PBP) level in the Detailed 2010 DIR Report.

Under section 9008 of the Affordable Care Act (ACA), as amended by the Health Care and Education Reconciliation Act (HCERA), CMS must report to the Secretary of the Treasury Part D prescription drug sales by National Drug Code (NDC) according to a calculation methodology that requires Part D sponsors to report ingredient cost net of rebates, discounts, or other price concessions provided by certain manufacturers. Each manufacturer's share of the annual fee is based on its annual sales of branded prescription drugs under specified government programs, including Medicare Part D. To calculate each manufacturer's share of the annual fee, CMS must provide the Secretary of the Treasury with data on Medicare Part D branded prescription drug sales, net of DIR, at the NDC level.

To date, we have collected aggregate DIR data from Part D sponsors. To fulfill our responsibilities under section 9008, we will collect DIR information at the NDC level from Part D sponsors beginning with contract year 2010. As a result, starting with contract year 2010, there are two components to DIR reporting: 1) DIR Reporting Requirements for Payment Reconciliation: Summary Report (guidance on these requirements was released June 6, 2011) and 2) the Detailed 2010 DIR Report. DIR for PDEs with dates of service in 2010 should be reported for both components, regardless of when sponsors actually received the DIR.

In the Detailed DIR report, Part D sponsors will be responsible for providing price concession data at the 11-digit NDC level for each PBP within each contract. Because the marketing category determination of drug products is not consistent among plans, CMS believes collecting DIR information at the 11-digit NDC level on all covered Part D drugs is necessary to account for all branded prescription drugs identified by Treasury for purposes of section 9008 of the ACA.

In 2012, CMS will collect both components to DIR reporting for contract year 2011, the Summary Report and the Detailed DIR Report, during one submission period.

Deadlines and Submission Information

CMS will accept comments on this proposed guidance until **Wednesday, September 14, 2011**. Comments may be submitted electronically to DIR_Reporting_Reqts@cms.hhs.gov. We will review the comments received and then post the Final Medicare Part D Detailed 2010 DIR Reporting Requirements.

Part D sponsors can begin to submit the Detailed 2010 DIR report on November 15, 2011. The deadline for submitting the report is 11:59 PM PT on **Thursday, December 15, 2011**.

Further Information

Questions regarding this guidance may be submitted to DIR_Reporting_Reqts@cms.hhs.gov.

I. INTRODUCTION

Section 1860D-15(f)(1)(A) of the 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 for the purposes of determining reinsurance payments and risk sharing. Each year, we finalize guidance explaining these reporting requirements. Consistent with section 1860D-15(d)(2)(A), CMS payments to a Part D sponsor are conditioned upon the provision of this requisite data.

Section 9008 of the ACA, as amended by section 1404 of the HCERA, imposes an aggregate annual fee on certain manufacturers of branded prescription drugs. The aggregate annual fee in 2012 will be $2.8 billion and will be paid by manufacturers or importers with aggregate gross receipts from branded prescription drug sales over $5 million to specified government programs, including Medicare Part D.

CMS is required to provide dollar amounts of sales of branded prescription drugs under the Medicare Part D program on a yearly basis to the Secretary of the Treasury in order to determine the amount of the fee 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.

The purpose of this document is to provide an overview of CMS' proposed DIR reporting requirements for the Detailed 2010 DIR Report. This document provides the format in which data will be submitted, explains the data elements to be reported by Part D sponsors at the distinct PBP level (i.e., data will be reported at the 11-digit NDC level for each PBP offered under each Part D contract), and the established reporting timeframes. CMS' goal is to ensure a common understanding of DIR reporting requirements.

II. Defining Direct and Indirect Remuneration (DIR)

Per 42 C.F.R. 423.308, DIR is any and all rebates, subsidies, or other price concessions from any source (including manufacturers, pharmacies, enrollees, or any other person) that serve to decrease the costs incurred by the Part D sponsor (whether directly or indirectly) for the Part D drug. Thus, DIR includes discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, and coupons. DIR also includes goods in kind, free or reduced-price services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal action, and other price concessions or similar benefits. However, price concessions that are not considered to directly or indirectly impact drug costs incurred by the Part D sponsor are not included in DIR. Please see Table 1 below for examples of remuneration that are and are not considered DIR.

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
PBM retained rebates	Remuneration for administrative services (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 POS	Rebate amounts received by long term care (LTC) pharmacies
Prompt pay discounts from pharmacies	Claims data
Pharmacy payment adjustments	
Risk sharing amounts	

The definitions of what does and does not constitute DIR for the Detailed 2010 DIR Report mirror those previously provided for the 2010 DIR Report for Payment Reconciliation: Summary Report. For definitions of Remuneration Considered DIR and Remuneration Not Considered DIR, please refer to the June 6, 2011, HPMS memorandum titled "Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report".

The key difference between the Detailed DIR Report and the DIR Report for Payment Reconciliation: Summary Report is that the information included in the Detailed DIR report is provided in two categories (Rebates and All Other DIR) at the 11-digit NDC level for covered Part D drugs.

III. DIR Included on the Detailed 2010 DIR Report

Part D sponsors must report DIR associated with drug sales under Medicare Part D on the Detailed 2010 DIR Report at the 11-digit NDC level. DIR that is not generated from the sponsor's Medicare Part D book of business should not be included on this report. CMS will

reduce the total branded prescription drug sales amounts under Medicare Part D that are reported to the Secretary of the Treasury by the DIR included on the Detailed 2010 DIR Report.

Accurate and complete DIR data are necessary for compliance with section 9008 of the ACA. Data reported on the Detailed 2010 DIR Report are subject to audit. Part D sponsors are required to maintain records of all related transactions, claims, contracts, and other materials. Please note that misrepresentations or omissions in the DIR data provided to CMS may result in federal civil action and/or criminal prosecution.

IV. SUBMISSION ELEMENTS

Part D sponsors must submit their DIR data at the 11-digit NDC level for each covered Part D drug and for each PBP on the Detailed 2010 DIR Report. As with the 2010 DIR Report for Payment Reconciliation: Summary Report, all DIR received for Part D claims with dates of service within the 2010 benefit year should be reported in the Detailed 2010 DIR report. The Detailed 2010 DIR report must include all covered Part D drugs. The deadline for submitting this report is **11:59 pm PT on Thursday, December 15, 2011.** This deadline applies to all Part D sponsors, including non-calendar year Employer/Union-only Group Waiver Plans (EGWPs).

A. Detailed 2010 DIR Report

The Detailed 2010 DIR Report template will be made available for download from HPMS in November 2011. The navigation path for accessing the template will be provided in the finalized guidance. This report will be downloadable to an MS Excel spreadsheet in the format shown in Section V: Detailed 2010 DIR Report Format and Layout (With Example Values). Part D sponsors must complete and upload to HPMS the Detailed 2010 DIR Report for each of their Part D PBPs (including non-calendar year Employer/Union-only Group Waiver Plans). In order to upload successfully, **Part D sponsors must use the actual downloaded MS Excel spreadsheet.** The uploaded file must be named "DIR_NDC_2010.ZIP" and the contents of the zip file must be named "DIR_NDC_2010.TXT". Only one tab delimited text file per zip file is permitted.

Please note that the contract number and plan ID for each Part D PBP will need to be entered as an alphanumeric value, e.g., S0001-001. The values in this field must be entered for each Part D PBP as they will not be automatically generated.

Part D sponsors must prepare and submit the Detailed 2010 DIR Report to CMS for all of the Part D PBPs that they offered in 2010, even if they have no DIR to report for contract year 2010. For PBPs with zero or negative DIR to report for contract year 2010, the Part D sponsor must include a brief explanation in the column "Comments", shown above in Section II: Detailed 2010 DIR Report Format and Layout (With Example Values).

Sponsors may upload the Detailed 2010 DIR Report as many times as they choose until 11:59 pm PT, on Thursday, December 15, 2011. CMS will only use the DIR reported on the most recently uploaded Detailed Report in our reviews and to fulfill section 9008 reporting requirements.

CMS will review the DIR data submitted. DIR reports that have been reviewed and accepted by CMS will receive an "accepted" status in HPMS. If CMS identifies a potential error, CMS will contact the Part D sponsor. Part D sponsors will be able to view the status of submitted DIR reports within HPMS. The exact navigation path will be provided in the finalized guidance.

For technical assistance, Part D sponsors can contact the HPMS Help Desk at either 1-800-220-2028 or hpms@cms.hhs.gov. For other questions regarding the Detailed 2010 DIR Report, sponsors can e-mail DIR_Reporting_Reqts@cms.hhs.gov.

B. Allocation Methodology

Some Part D sponsors may receive or record their DIR at the sponsor or contract level. Also, Part D sponsors may not receive or record their DIR at the 11-digit NDC level. In these cases, the Part D sponsor must allocate their DIR to the PBP and 11-digit NDC level by applying reasonable allocation methodologies. Reasonable allocation methodologies to allocate DIR to the PBP level are described further in the guidance, dated June 6, 2011, titled "Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report."

A description of all allocation methodologies used, whether used to report DIR at the PBP and/or 11-digit NDC level, must be submitted by the Part D sponsor in HPMS when uploading the Detailed 2010 DIR Report. For sponsors who needed no allocation methodologies because DIR was received from the manufacturers at the PBP and 11-digit NDC level, sponsors can restate this in the description field. The description must include an explanation of the entity applying the allocation methodology *and* a clear explanation of the methodology. Part D sponsors are expected to maintain internal documentation of all methods used to allocate DIR and CMS may follow-up with sponsors to better understand the allocation methodology selected.

Sponsors may make more than one selection from the dropdown menu, which may include:

- No allocation method needed to the PBP level. DIR was received from the manufacturer at the PBP level.
- Allocation to the PBP level based on Actual Drug Utilization
- Allocation to the PBP level based on Plan's Total Drug Spend
- Allocation to the PBP level based on Plan's Brand Drug Spend
- Allocation to the PBP level based on Total Drug Spend for Drugs in Preferred Brand Tier
- Allocation to the PBP level based on Billed Rebate Amounts
- No allocation method needed to the 11-digit NDC level. DIR was received from the manufacturer at the 11-digit NDC level.
- Allocation to the 11-digit NDC level based on Actual Drug Utilization
- Allocation to the 11-digit NDC level based on Plan's Total Drug Spend
- Allocation to the 11-digit NDC level based on Plan's Brand Drug Spend
- Allocation to the 11-digit NDC level based on Total Drug Spend for Drugs in Preferred Brand Tier
- Allocation to the 11-digit level based on Billed Rebate Amounts

- Other allocation to the PBP/11-digit NDC level

C. Attestation of Data Relating to Detailed DIR Data

Part D sponsors will be required to submit an attestation, "Attestation of Data Relating to 11-digit NDC Level DIR Data." 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 certify in this attestation and maintain documentation 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.

Additional guidance regarding the submission of the Attestation of Data Relating to Detailed DIR Data will be provided at a later date.

V. DETAILED 2010 DIR REPORT FORMAT AND LAYOUT (WITH EXAMPLE VALUES)

Contract-Plan	11-digit NDC	A. Rebate Dollars	B. All Other DIR (i.e., non-rebate DIR)	C. Comments
S1234-001	55555000101	30000.00	5000.00	
S1234-001	44444000102	11000.00	900.00	
S1234-001	33333000101	1725.00	725.00	
S1234-001	22222000101	0.00	0.00	Generic drug, no rebates received.
S1234-002	<Blank>	0.00	0.00	PBP was active with no enrollment.

VI. REPORTING ELEMENTS

In the Detailed DIR Report, Part D sponsors will be responsible for reporting total "Rebate Dollars" and "All Other DIR" at the 11-digit NDC level. Part D sponsors are advised that the DIR data used to produce the Detailed DIR report should be reasonably current, reflecting at a minimum the DIR amounts received up to three months prior to the submission deadline.

File Record Layout: Detailed 2010 DIR Report

Field Name	Field Type	Field Length	Field Description
Contract-Plan	Character	9	Contract number and plan ID, e.g. S0001-001. This number must be entered as an alphanumeric value and must be entered as one letter followed by the four digit contract number, a dash, and the three digit plan ID. The values in this field must be entered for each Part D PBP as it will not be automatically generated.
11-digit NDC	Number Required	11	Enter the 11-digit National Drug Code in this field. This number must be entered as exactly 11 digits with no dashes (e.g., 55555000102)
A. Rebate Dollars	Number Required	12 digits before the decimal and 2 digits after	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 will include all rebates classified under columns #1-3 on the 2010 DIR Report for Payment Reconciliation: Summary Report. Refer to the June 6, 2011, HPMS memorandum referenced in this guidance. For each 11-digit NDC, provide the total rebate dollars.
B. All Other DIR (i.e., non-rebate DIR)	Number Required	12 digits before the decimal and 2 digits after	Report total non-rebate DIR in this column. The All Other DIR column will include DIR provided in columns #4-11 on the 2010 DIR Report for Payment Reconciliation: Summary Report. Refer to the June 6, 2011, HPMS memorandum referenced in this guidance. For each 11-digit NDC, provide the total amount of non-rebate DIR.
C. Comments	Character	4000	If reporting zero or negative Rebate or All Other DIR dollars for a specific Part D PBP, Part D sponsors must provide a short explanation in the "Comments" column of the Detailed DIR Report.