Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C1-13-07
Baltimore, Maryland 21244-1850

Center for Medicare
Medicare Plan Payment Group

Date: April 5, 2012

To: All Part D Plan Sponsors

From: Cheri Rice, Director
Medicare Plan Payment Group

Subject: Draft Medicare Part D DIR Reporting Requirements for 2011

In the attached document, "Draft Medicare Part D DIR Reporting Requirements for 2011," the Centers for Medicare & Medicaid Services (CMS) provides proposed guidance for Part D sponsors on reporting direct and indirect remuneration (DIR) data for contract year (CY) 2011.

Part D sponsors are required to report DIR data associated with the Medicare Prescription Drug Benefit at the plan benefit package (PBP) level (i.e., "summary level") on the Summary DIR Report to CMS within six months of the end of the coverage year 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 (i.e., "detailed level") in the Detailed DIR Report to support 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.

This proposed guidance incorporates the following changes and clarifications from the Summary and Detailed DIR reporting requirements for contract year 2010:

1. We are providing guidance for both Summary and Detailed DIR reporting requirements in one guidance document. Likewise, the Summary 2011 DIR Report, Detailed 2011 DIR Report, and supporting 2011 DIR submission information applicable to both reports, will be due by 11:59 PM PT on Friday, June 29, 2012.

2. Part D sponsors must report all DIR associated with the Medicare prescription drug benefit in both the Summary and Detailed DIR Reports, and not limit the DIR reported to prescription drug events accepted for the 2011 Part D payment reconciliation. Thus, the DIR data reported on both the Summary and Detailed DIR Reports will be based on the same 2011 coverage year experience. Per 42 CFR 423.308, DIR is any and all rebates, subsidies, or other prices concessions from any source (including manufacturers, pharmacies, enrollees, or any other person) that serve to decrease the cost incurred by the Part D sponsor). This definition is not

limited to accepted prescription drug events but includes any DIR associated with purchases under the Medicare prescription drug benefit.

3. All applicable DIR received for Part D plan expenditures incurred for the contract year must be reported on the Summary and Detailed DIR Reports, including DIR associated with rejected PDE records. If a rejected PDE record is for a Part D drug expenditure, the associated DIR must be reported on the Summary and Detailed DIR Reports. This language supersedes the language found in Section V, subsection E., titled "DIR Associated with Rejected PDE Records" in the June 6, 2011, HPMS memorandum titled "Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report."

4. We have included additional details to our discussion of bona fide service fees, including a four-pronged test, to help Part D sponsors distinguish bona fide service fees from DIR.

5. We have added a column to the Summary DIR Report titled "PBM Incentive Payments." Part D sponsors may pay incentive or bonus payments to entities that provide pharmacy benefits management (PBM) services to Part D sponsors (for which we use the shorthand term of PBM) for performing administrative services such as negotiating rebates and drug prices as well as increasing generic utilization. These incentive or bonus payments represent an increase in the administrative fees paid by the Part D sponsor to their PBM and are not considered DIR. These payments must be reported in the PBM Incentive Payments column of the Summary DIR Report. As we do not collect non-DIR fields on the Detailed DIR Report, this change does not impact the Detailed DIR Report.

6. Section 6005 of the ACA requires Part D sponsors to report PBM spread amounts for retail pharmacies and for mail order pharmacies. Thus, CMS has divided the "PBM Spread" column from the Summary 2010 Report into two columns: one titled "PBM Spread Amounts for Retail Pharmacies" and another titled "PBM Spread Amounts for Mail Order Pharmacies."

Deadlines and Contact Information

CMS will accept comments on this proposed guidance until **Wednesday, April 25, 2012**. We particularly solicit comment on the changes and clarifications outlined above. We will review comments received and post the final CY 2011 DIR reporting requirements in May 2012. Comments may be submitted electronically to DIR_Reporting_Reqts@cms.hhs.gov or mailed to:

Ilina Chaudhuri
Centers for Medicare & Medicaid Services
7500 Security Boulevard C1-13-07
Baltimore, Maryland 21244

Questions about the policies in this guidance may be submitted to DIR_Reporting_Reqts@cms.hhs.gov.

Part D sponsors can begin to submit the 2011 DIR Submission Information, Summary 2011 DIR Report, and Detailed 2011 DIR Report on Friday, June 1, 2012. The deadline for submissions is **11:59 PM PT on Friday, June 29, 2012**. This deadline applies to all Part D sponsors, including non-calendar year Employer/Union-only Group Waiver Plans (EGWPs). Program of All Inclusive Care for the Elderly (PACE) organizations reporting $0 in all Summary DIR categories in the Summary 2011 DIR Report must submit the 2011 DIR Submission Information and Summary 2011 DIR Report, but are not required to submit a Detailed 2011 DIR Report. PACE organizations reporting a non-zero value in any column in the Summary DIR Report must submit the 2011 DIR Submission Information, Summary 2011 DIR Report, and Detailed 2011 DIR Report.

Because this is the first time for reporting Summary and Detailed DIR data during the same submission window, we strongly encourage Part D sponsors to submit early during the submission window to assure a complete, accurate, and successful submission by the reporting 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.

Draft Medicare Part D DIR Reporting Requirements for 2011

Table of Contents

I. INTRODUCTION

A. Purpose

The purpose of this document is to explain CMS' DIR reporting requirements for the Summary and Detailed 2011 DIR Reports. This document provides the format in which data will be submitted, explains the data elements to be reported by Part D sponsors at PBP and 11-digit NDC levels, and establishes reporting timeframes. CMS' 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 calculate these payments using "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 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 Patient Protection and Affordable Care Act (Public Law 111–148) (ACA), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (Public Law 111–152) (HCERA), imposes an aggregate annual fee on certain manufacturers of branded prescription drugs. The aggregate annual fee in 2013 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 fee amount to be paid by each manufacturer. Please refer to Section 9008 of the Patient Protection and Affordable Care Act (Public Law 111–148) for a definition of brand drugs. Sales dollar amounts are reported at the 11-digit NDC level and must be reduced by rebates and other price concessions.

C. Overview of 2011 DIR Reporting Process

Except for certain PACE organizations, Part D sponsors must prepare and submit the 2011

Submission Information, Summary 2011 DIR Report, and Detailed 2011 DIR Report to CMS for all of the Part D PBPs that they offered in 2011, even if they have no DIR to report for contract year 2011. PACE organizations that are reporting $0 in all Summary DIR categories in the Summary DIR Report are not required to submit a Detailed 2011 Report.

For PBPs and 11-digit NDCs with zero or negative DIR to report for contract year 2011, the Part D sponsor must include a brief explanation in the "Additional Comments" or "Comments" columns. CMS reviews the descriptions in the "Additional Comments" and "Comments" fields associated with zero and negative values. If the explanation is not sufficient, CMS will outreach to the sponsor requesting a more detailed description. We review the "Additional Comments" field on the Summary DIR Report. We also review the "Comments" field on the Detailed DIR Reports when reporting zero and negative DIR amounts.

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 2011 Submission Information and upload the Summary or Detailed 2011 DIR Reports as many times as they choose until 11:59 pm PT, on Friday, June 29, 2012. CMS will use only the DIR reported on the most recently uploaded Summary and Detailed Report in the June submission window in our reviews. Sponsors can access their latest submissions via the Health Plan Management System (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. For instructions on how to view or change your contact information, please see March 26, 2012 "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. 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:
http://www.cms.hhs.gov/EmployerRetireeDrugSubsid/Downloads/20090112RebateGuidancePaper.pdf.

II. DEFINING DIRECT AND INDIRECT REMUNERATION (DIR)

Per the regulations at 42 CFR 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 Point of Sale (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 Summary and Detailed 2011 DIR Reports 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 pages 7-15 in the June 6, 2011, HPMS memorandum titled "Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report", and the following clarification of Section V, subsection E., titled "DIR Associated with Rejected PDE Records." We clarify that it is inappropriate for a Part D sponsor to exclude from the DIR report DIR associated with rejected PDE records. If a rejected PDE record is for a Part D drug expenditure, the associated DIR must be reported on the Summary and Detailed DIR Reports.

III. 2011 DIR SUBMISSION INFORMATION

The first step to the 2011 DIR reporting process is ensuring that plan sponsor information in HPMS is up-to-date. For instructions on how to view or change your contact information, please see March 26, 2012 "Annual Request for Part D Payment Reconciliation Contact Information."

Next, Part D sponsors must complete the "2011 DIR Submission Information," for which Part D sponsors are required to provide 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 2011 DIR Submission Information must be completed for each contract and includes:

A. 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.

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 as part of the DIR Submission Information. For sponsors that needed no allocation methodologies because DIR was received from the manufacturers at the PBP and 11-digit NDC level, sponsors can make this selection from the dropdown menu. 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 selecting "Other allocation to the PBP level" or "Other allocation to the 11-digit NDC level" must provide comments, which must include an explanation of the entity applying the allocation methodology *and* a clear explanation of the methodology.

Sponsors must make one selection from the dropdown menu specifying an allocation methodology to the PBP level and one selection from the dropdown menu specifying an allocation methodology to the 11-digit NDC level. The options are as follows:

<u>Allocation Methodology to the PBP level</u>

- 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
- Other allocation to the PBP level (comments are required)

Allocation Methodology to the 11-digit NDC level

- 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 11-digit NDC level (comments are required)

Part D sponsors should allocate rebates for a specific drug to the plan and 11-digit NDC levels based on the actual utilization of that specific drug. Other allocation methodologies may be subject to additional validation. Table 2 provides examples of allocation methodologies and indicates whether they are generally considered reasonable for allocating rebates to the plan and 11-digit NDC levels. When considering an allocation methodology for rebates, Part D sponsors should consider whether the rebate dollars are appropriately allocated to each plan and 11-digit NDC given the drug costs associated with the rebatable drugs purchased under each plan.

Part D sponsors may also receive legal judgments or settlement amounts from lawsuits or other legal action, which 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 should be reported on the corresponding DIR Reports. Thus, for legal judgments or settlement amounts from lawsuits or other legal action 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 all other types of DIR. In this circumstance, please select the primary allocation methodology from the dropdown menu and explain the specific allocation methodology used for legal judgments or settlement amounts in the "Description of Allocation Methodology" found in the DIR Submission Information.

Table 2. Examples of Methodologies for Allocating Rebates to the Plan 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 plan or 11-digit NDC based on the number of units of the specific drug that were purchased under the plan 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 plans.
Based on Plan's Total Drug Spend	Rebate amounts received for multiple drugs are allocated to a plan or 11-digit NDC based on the total drug spend under the plan as a percent of the total drug spend under all of sponsor's Part D plans.	Yes	Approximates differences in utilization and spending on rebate eligible drugs across Part D plans.

Based on Plan's Brand Drug Spend	Rebate amounts received for multiple drugs are allocated to a plan or 11-digit NDC based on the total drug spend for brand drugs under the plan as a percent of the total drug spend for brand drugs under all of the sponsor's Part D plans.	Yes	Accounts for differences in utilization and spending on rebate eligible drugs across Part D plans.
Based on Total Drug Spend for Drugs in Preferred Brand Tier	Rebates received for multiple drugs are allocated to a plan or 11-digit NDC based on the total drug spend for drugs in the plan'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 plans.	Yes, if the sponsor only receives rebates for drugs in the preferred brand tier.	Accounts for differences in utilization and spending on rebate eligible drugs across Part D plans.
Based on Enrollment	Rebates received for multiple drugs are allocated to a plan or 11-digit NDC based on the number of beneficiaries enrolled in the plan as a percent of the total number of beneficiaries enrolled in all of the sponsor's Part D plans.	No	Does not sufficiently approximate differences in utilization and spending on rebate eligible drugs across Part D plans.
Based on Low-Income Subsidy (LIS) Enrollment	Rebates received for multiple drugs are allocated to a plan or 11-digit NDC based on the number of LIS beneficiaries enrolled in the plan as a percent of the total number of LIS beneficiaries enrolled in all of the sponsor's Part D plans.	No	Does not sufficiently approximate differences in utilization and spending on rebate eligible drugs across Part D plans.
Based on Billed Rebate Amounts	Rebates received for a specific drug are allocated to a plan or 11-digit NDC based on the rebate amounts billed to the pharmaceutical manufacturer for the specific plan and drug as a percent of the total rebate amount billed to the pharmaceutical manufacturer for all of the sponsor's Part D plans.	Yes	Appropriately accounts for differences in a specific drug's utilization across Part D plans.
Based on Number of Claims	Rebates received for multiple drugs are allocated to a plan or 11-digit NDC based on the number of claims under the plan as a percent of the total number of claims received under all of the sponsor's Part D plans. Thus, allocation is based on the total number of claims for all of the drugs rather than the number of claims received for each drug.	No	Does not sufficiently approximate differences in utilization and spending on rebate eligible drugs across Part D plans.

B. Description of Services Provided for Rebate Administration Fees: Part D sponsors must describe the services provided for the rebate administration fees reported as DIR as well as those reported as bona fide service fees. If this question is not applicable, Part D sponsors should enter "N/A".

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 should enter "N/A".

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 rebate administration fees and the allocation methodology used to determine this amount. If this question is not applicable, Part D sponsors should enter "N/A".

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 should enter "N/A".

F. Name of 2011 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 2011. If the Part D sponsor conducted claims processing and PDE record submission internally and did not contract with a PBM for these services, the Part D sponsor should indicate "Self" for this question.

G. Name of PBM(s) for Rebate Negotiation: 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 for 2011. Part D sponsors that conducted rebate negotiation and processing using their internal resources and did not contract with a PBM for these services should indicate "Self" for this question. If the Part D sponsor did not negotiate or process rebates, the Part D sponsor should enter "N/A" for this question.

H. Did PBM for Rebate Negotiation change from 2010 to 2011? Part D sponsors must indicate whether they contracted with a different PBM or entity in 2010 for the negotiation or processing of rebates. If the Part D sponsor did not negotiate or process rebates in 2010 and 2011, the sponsor should enter "N/A" for this question. If the Part D sponsor contracted with a PBM or other entity for the negotiation or processing of rebates in 2011 but not in 2010, the sponsor should enter "Yes" for this question. Similarly, if the sponsor contracted with a PBM or other entity for the negotiation or processing of rebates in 2010 but not in 2011, the sponsor should enter "Yes" for this question.

I. Were any of the plans in the contract owned by a different sponsor in 2010? Part D sponsors must indicate whether any of the plans in the contract were owned by a different sponsor in 2010. For any applicable plans, the sponsor must provide the plan ID, the name of the sponsor that owned the plan in 2010, and the contract number that the plan was under in 2010. If all of the plans in the contract were owned by a different sponsor in 2010, the sponsor may indicate "all plans in contract" instead of listing all of the plan IDs.

J. Did your parent organization acquire any of the plans in this contract during the 2011 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. Reason for Resubmission: When resubmitting the Summary DIR Report, Part D sponsors are required to provide an explanation for the resubmission of their DIR data.

VI. 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 level. DIR data must be summarized for each plan and reported in aggregate to include multiple drugs and price concessions.

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 field must be entered for each Part D plan as it will not be automatically generated. This field must be populated with 9 alpha-numeric characters.
DIR #1 – PBM Retained Rebates	For each Part D plan, this column represents the sum of all applicable PBM retained rebates and applicable rebate administration fees for a contract-plan. All rebates associated with the Medicare prescription drug benefit that are received by PBMs from pharmaceutical manufacturers and retained by the PBMs must be reported in this column. Please note that rebates PBMs have passed through to the Part D sponsor (and therefore, are not retained) are reported in column DIR #3, All Other Rebates. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal.
DIR #2 – Rebates Expected But Not Yet Received	Good faith estimates of rebate amounts that are expected for the applicable contract year, but have not yet been received are reported in this column. This column should not include rebate amounts that have been received by the sponsor prior to the latest submission of the DIR report unless the rebate amounts are received by the sponsor after the DIR data for the report are compiled. Part D sponsors are advised that the DIR data used to produce the DIR report should be reasonably current, reflecting at a minimum the DIR amounts received up to three months prior to the submission deadline. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal.
DIR #3 – All Other Rebates	All rebates associated with the Medicare prescription drug benefit are reported in this column with the exception of the rebate amounts reported in columns DIR #1 and DIR #2. Included in this column are rebate guarantee amounts from PBMs and rebates received from pharmaceutical manufacturers for Part D purchases, such as market share rebates. The actual rebate amounts received for rebates that were estimated and applied to the negotiated price at the point of sale are also reported in this column. Rebates that PBMs have received from pharmaceutical

Column Name	Column Description, Type, and Field Length
	manufacturers for Part D purchases and passed through to the Part D sponsor must also be included in this column. 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. Also reported in this column are rebates associated with Plan-to-Plan (P2P) claims. Under the current process for reimbursing P2P claims, the Part D sponsor actually incurring the Part D drug costs (the plan of record) does not have claim level data and therefore is unable to receive rebates for these claims. The submitting plan, however, may receive rebates for these claims and is required to report them to CMS. Rebates received by the submitting plan for P2P claims must be reported in this column. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal.
DIR #4 – Rebate Administration Fees Reported as DIR	Rebate administration fees amounts that do not meet the definition of a bona fide service fee and that are received in connection with the Medicare Part D program are considered DIR. These rebate administration fee amounts, including rebate administration fees received by PBMs, must be reported in this column of the Summary DIR Report. If the rebate administration fee exceeds fair market value, but otherwise meets the definition of a bona fide service fee (please refer to the description provided for "Rebate Administration Fees Reported as Bona Fide Service Fees" for additional guidance on the definition of a bona fide service), the differential between the rebate administration fee and fair market value must be reported in this column. The amounts reported in this column of the DIR Report are considered DIR and therefore, will be included in the Total DIR column. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal.
DIR #5 – Price Concessions for Administrative Services	Price concessions from pharmaceutical manufacturers for administrative services associated with the Part D benefit are reported in this column. This includes administrative services received by the Part D sponsor from pharmaceutical manufacturers at a cost below market value. The difference between the market value of the administrative service and the price paid by the Part D sponsor should be reported in this column. Also reported in this column are grants received by the Part D sponsor from pharmaceutical manufacturers for services and programs such as utilization management and medical education. Applicable price concessions for administrative services that are not associated with a specific drug must be reported in full in this column with no portion allocated for non-Part D Covered drugs. This DIR must fully accrue to the government and beneficiaries and cannot be kept by the Part D sponsor. Please note that PBM

Column Name	Column Description, Type, and Field Length
	retained rebates must be reported in column DIR #1, "PBM Retained Rebates", and are therefore not included in this column (DIR #5). This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal.
DIR #6 – Legal Settlement Amounts	Reported in this column are 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 2011. 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. Legal judgments or settlement amounts paid by the Part D sponsor which serve to increase the drug costs incurred by the sponsor for contract year 2011 must be reported in this column as a negative adjustment. Legal judgments or settlement amounts received by the Part D sponsor that serve to decrease the drug costs incurred by the sponsor for contract year 2011 must be reported as a positive adjustment. Legal fees associated with the lawsuit or legal action for each legal judgment or settlement amount received may be excluded from the amount reported on the Summary DIR Report for the applicable contract year up to the total amount of the judgment or settlement associated with the applicable lawsuit or legal action. For example, Sponsor A received a settlement amount of $500,000 for lawsuit A that impacted drugs costs for contract year 2008 and $100,000 for lawsuit B that impacted drug costs for contract year 2009. Sponsor A incurred $100,000 in legal fees for lawsuit A and $125,000 in legal fees for lawsuit B. Sponsor A would report $400,000 on the 2008 Summary DIR Report for Payment Reconciliation and $0 on the 2009 Summary DIR Report for Payment Reconciliation. Please note, however, that Part D sponsors cannot include legal fees associated with lawsuits or legal action in which the Part D sponsor is required to pay a judgment or settlement amount on the Summary DIR Report as a negative adjustment. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal.
DIR #7 – All Other Price Concessions from Manufacturers	All price concessions received from pharmaceutical manufacturers (either direct or indirectly) that cannot be categorized into columns DIR #1 though #6 and are associated with the Part D benefit are reported in this column. If all price concessions received from pharmaceutical manufacturers are captured in DIR #1 though #6, the value in this column will be zero. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal.
DIR #8 – Generic Dispensing Incentive Payments and	Reported in this column are generic dispensing incentive payments or adjustments made after the point of sale. Specifically, if a plan pays the pharmacy a prospective dispensing fee per event but recoups some of the fee if the pharmacy does not meet a target generic dispensing rate, the amount recouped by the plan must be reported to CMS as a positive adjustment that will reduce

Column Name	Column Description, Type, and Field Length
Adjustments	the drug costs of the Part D sponsor. Conversely, the sponsor should report payments made to the pharmacy after the point of sale as a negative adjustment. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal.
DIR #9 – Pharmacy Payment Adjustments	With the exception of adjustments to generic dispensing incentive payments and adjustments, which are reported in column DIR #8, applicable adjustments to pharmacy payments are reported in this column. These include penalties or pharmacy repayments stipulated in the Part D sponsor's contract with its network pharmacies that represent incorrect drug costs that were paid or reported by the Part D sponsor due to an error made by the pharmacy. For these types of pharmacy penalties, the portion of the penalty that is equivalent to the amount by which the drug costs paid by the Part D sponsor or reported to CMS on the PDE exceeds the correct drug costs must be reported as DIR in this column. Applicable pharmacy adjustments that reduce the total payments made to the pharmacy should be reported as a positive adjustment that will serve to reduce the plan's drug costs. Applicable pharmacy adjustments that increase the total payments made to the pharmacy should be reported as a negative adjustment that increases the plan's drug costs. Amounts credited to the Part D sponsor by the pharmacy due to beneficiary cost-sharing that exceeds the gross drug cost are also reported in this column, if these payments are not already reflected in the covered plan paid (CPP) amounts reported on the PDE data. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal.
DIR #10 – Risk Sharing Arrangement Payments and Adjustments	Gains or losses that the Part D sponsor may receive as a result of risk sharing arrangements with entities other than CMS that are permissible under the Part D rule are reported in this column. Risk sharing amounts received from other parties 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. Examples of other parties include, but are not limited to, accountable care organizations, other sponsors, and PBMs. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal.
DIR #11 – All Other DIR	All applicable DIR (as well as adjustments to DIR) that is not reported in the previous columns DIR #1 through 10 must be included in this column. PBM penalty payments or repayments that have not been submitted on adjusted PDE records are also included in this column. In cases where a PBM penalty represents incorrect drug costs that were paid or reported by the Part D sponsor due to an error made by the PBM, the portion of the penalty that is equivalent to the amount by which the drug costs paid by the plan or reported to CMS on the PDE exceed the correct drug costs should be reported as DIR. Any PBM manual

Column Name	Column Description, Type, and Field Length
	adjustments or PBM penalty amounts reported in this column must be explained in the "Additional Comments" column. DIR included in this column that is not associated with a specific drug must be reported in full on the Summary DIR Report with no portion allocated to non-Part D covered drugs. This DIR must fully accrue to the government and beneficiaries and cannot be kept by the Part D sponsor. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal.
Other DIR Text Description	A description is required for **all** DIR reported in DIR # 11 for each Part D plan. Please indicate the type of price concession, the type of entity from (or to) that the Part D sponsor is collecting (or paying) the amount (e.g., pharmacy or PBM), and the associated dollar amount is required in this column for each price concession or DIR adjustment included in column DIR #11 – All Other DIR. This field must be left blank if there is no dollar amount reported in column DIR #11. This field is a character field and may contain up to 4,000 characters.
Total DIR	This field represents the sum of all DIR reported for Part D plan and is automatically generated. It does not include amounts reported in the following columns: Rebate Administration Fees Reported as Bona Fide Service Fees, All Other Bona Fide Service Fees, and PBM Spread Amounts for Retail and Mail Order Pharmacies. If reporting zero total DIR dollars for a specific Part D plan, Part D sponsors must provide a short explanation in the "Additional Comments" column of the Summary DIR Report. This field is numeric and may contain up to 15 digits before the decimal and 2 digits after the decimal.
Rebates at POS?	If the Part D sponsor applied (estimated) rebates to the negotiated price at the point of sale in the applicable contract year, the Part D sponsor must enter "Y" in this column for each applicable Part D plan. Otherwise, the Part D sponsor should enter "N" in this column or leave it blank to indicate that rebates were not applied to the negotiated price at the point of sale. This field may be left blank or populated with one character.
Rebate Administration Fees Reported as Bona Fide Service Fees	For each Part D plan, this column represents the sum of all rebate administration fees considered bona fide service fees. Rebate administration fees that meet the definition of a bona fide service fee and are received in connection with the Medicare Part D program must be reported in this column of the Summary DIR Report. This includes rebate administration fees received by PBMs that are not passed through to the Part D sponsor. If the rebate administration fee exceeds fair market value, but otherwise meets the definition of a bona fide service fee, the differential between the rebate administration fee and fair market value must be reported in column DIR #4-Rebate Administration Fee Reported as DIR. Bona fide service fees are not considered DIR,

Column Name	Column Description, Type, and Field Length
	therefore **the amounts reported in the column titled "Rebate Administration Fees Reported as Bona Fide Service Fees" 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. Bona fide service fees are fees that Part D sponsors or subcontractors of Part D sponsors (such as PBMs) receive from pharmaceutical manufacturers for bona fide services, and are not considered price concessions that reduce the drug costs incurred by the Part D sponsor and are not considered DIR. Bona fide service fees must meet 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. We follow Medicare Part B's guidance in interpreting the first three elements of the bona fide service fee definition. For the first two elements, that the fee must be paid for a bona fide, itemized service that is actually performed on behalf of the manufacturer and that the manufacturer would otherwise perform or contract for the service **in** the absence of the service arrangement, the bona fide service encompasses any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs. Services "on behalf of" the manufacturer include both those the manufacturer has the capacity to perform, and those that can only be performed by another entity. The element of "fair market value" means expenses that generally would have been paid for by the manufacturer at the same rate had these services been performed by other or similarly situated entities. We believe manufacturers are well-equipped to determine the most appropriate, industry-accepted method for determining fair market value of drug distribution services for which they contract. For the fourth element, a fee may 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 Part D sponsor takes title to the drug. Similarly, a fee may 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. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the

Column Name	Column Description, Type, and Field Length
	decimal.
All Other Bona Fide Service Fees	Any bona fide service fees that are received in connection with the Medicare Part D program and are not included in rebate administration fees must be reported in this column. Please refer to the description provided for "Rebate Administration Fees Reported as Bona Fide Service Fees" for additional guidance on the definition of a bona fide service. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal.
PBM Incentive Payments	Part D sponsors may pay incentive or bonus payments to PBMs for performing administrative services such as negotiating rebates and drug prices as well as increasing generic utilization. These incentive or bonus payments represent an increase in the administrative fees paid by the Part D sponsor to their PBM and are not considered DIR. Any amounts reported in this column must be explained in the "Additional Comments" column. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal.
PBM Spread Amounts for Retail Pharmacies	The aggregate amount of the difference between the amount paid 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, and not the PBM spread for each retail pharmacy. These amounts are for all drug costs under the Part D program, and thus include both covered and non-covered drugs under the Part D program. If sponsors use pass-through pricing, this value should be zero. The PBM Spread Amounts for Retail Pharmacies are not considered DIR because they do not serve to change the drug cost paid by Part D sponsors at the point of sale. Therefore, the amounts reported in this column of the Summary DIR Report will not be included in the Total DIR column. In addition, these amounts will not be excluded from allowable reinsurance costs and allowable risk corridor costs when CMS calculates reinsurance and risk sharing payments during the Part D payment reconciliation process. PBM Spread Amounts for Retail Pharmacies are confidential and shall not be disclosed by CMS, except in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs for the purposes of complying with Section 6005 of the ACA or to carry out Part D program functions. For a negative value, enter a minus sign and the value for the field. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal.

Column Name	Column Description, Type, and Field Length
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, and not the PBM spread for each mail order pharmacy. These amounts are for all drug costs under the Part D program, and thus include both covered and non-covered drugs under the Part D program. If sponsors use pass-through pricing, this value should be zero. The PBM Spread Amounts for Mail Order Pharmacies are not considered DIR because they do not serve to change the drug cost paid by Part D sponsors at the point of sale. Therefore, the amounts reported in this column of the Summary DIR Report will not be included in the Total DIR column. In addition, these amounts will not be excluded from allowable reinsurance costs and allowable risk corridor costs when CMS calculates reinsurance and risk sharing payments during the Part D payment reconciliation process. PBM Spread Amounts for 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 complying with Section 6005 of the ACA or to carry out Part D program functions. For a negative value, enter a minus sign and the value for the field. This field is numeric and may have up to 12 digits before the decimal and 2 digits after the decimal.
Additional Comments	Additional notes or comments on the data provided in columns DIR #1 - DIR #11 are included in this column. For example, sponsors must provide a short explanation if: reporting zero or negative total DIR dollars for a specific Part D plan; for any PBM manual adjustments or PBM penalty amounts reported in column DIR #11-All Other DIR; and if any amounts are reported in the "PBM Incentive Payments" column. Part D sponsors must provide a description for any risk sharing arrangement amounts reported in column DIR #10. If the Part D sponsor, or its PBM, receives bona fide service fees from pharmaceutical manufacturers other than rebate administration fees, which are reported in the column titled All Other Bona Fide Service Fees, a short description must be reported in this column. This field is a character field and may contain up to 4,000 characters.

B. Description of Columns in the Detailed DIR Report

DIR data must be summarized for each PBP and reported in aggregate for each 11-digit NDC to include multiple drugs and price concessions. The Detailed DIR Report contains two

columns of DIR dollars. The column titled "Rebate Dollars" must be a sum of the values reported in columns #1 through #3 in the Summary DIR Report for the same coverage year. The column titled "All Other DIR (i.e. non-rebate DIR)" must be a sum of columns #4 through #11 in the Summary DIR Report for the same coverage year. DIR data for brand and generic drugs must be reported in the Detailed DIR Report.

Column Name	**Column Description, Type, and 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 field must be entered for each Part D PBP as it will not be automatically generated. This field must be populated with 9 alpha-numeric characters.
11-digit NDC	Enter the 11-digit National Drug Code in this field. This number must be entered as exactly 11 digits with no dashes (e.g., 55555000102)
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 will include all rebates classified under columns #1-3 on the Summary 2011 DIR Report. For each 11-digit NDC, provide the total rebate dollars. This field is numeric and may have up to 12 digits before the decimal and 3 digits after the decimal.
All Other DIR (i.e. non-rebate DIR)	Report total non-rebate DIR in this column. The All Other DIR column will include DIR provided in columns #4-11 on the Summary 2011 DIR Report. For each 11-digit NDC, provide the total amount of non-rebate DIR. This field is numeric and may have up to 12 digits before the decimal and 3 digits after the decimal.
Comments	If reporting zero in **both** "Rebate Dollars" and "All Other DIR" for a specific 11-Digit NDC, Part D sponsors must provide a short explanation in the "Comments" column of the Detailed DIR Report. If reporting negative dollars in **either** Rebate Dollars or All Other DIR for a specific 11-Digit NDC, Part D sponsors must provide a short explanation in the "Comments" column of the Detailed DIR report. This field is a character field and may have up to 4,000 characters.

C. Summary 2011 DIR Report Formal and Layout (With Example Values)

Contract-Plan	DIR #1 – PBM Retained Rebates	DIR #2 – Rebates Expected But Not Yet Received	DIR # 3 – All Other Rebates	DIR #4 Rebate Administration Fees Reported as DIR	DIR # 5 – Price Concessions for Administrative Services	DIR #6 - Legal Settlement Amounts	DIR #7 - All Other Price Concessions from Manufacturers	DIR #8 – Generic Dispensing Incentive Payments and Adjustments	DIR # 9 – Pharmacy Payment Adjustments
S####-001	27500.25	7000.00	137500.65	9000.00	2000.00	0.00	0.00	-3500.50	-4500.00
S####-002	0.00	250.00	12000.76	1500.00	1500.25	5000.00	1000.00	-500.00	-1550.00
S####-003	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

(…columns continued for Summary DIR Report Template…)

DIR # 10 – Risk Sharing Arrangement Payments and Adjustments	DIR # 11 – All Other DIR	Other DIR Text Description	Total DIR	Rebates at POS?	Rebate Administration Fees Reported as Bona Fide Service Fees	All Other Bona Fide Service Fees	PBM Incentive Payments	PBM Spread Amounts for Retail Pharmacies	PBM Spread Amounts for Mail Order Pharmacies	Additional Comments
6000.00	0.00		181000.40	Y	27,150.06	0.00	0.00	137500.65	50000.00	DIR #10-Received $6000 from risk sharing arrangement with physicians for prescription drug costs.
-2250.77	1500.00	1. DIR for PBM penalty: $1500.00	18450.24		1867.54	0.00	1000.00	12000.76	0.00	DIR #6-Received $5000 net of legal fees in manufacturer legal settlement. DIR #10-Paid $2250.77 to physicians due to risk sharing arrangement for prescription drug costs. DIR #11- Received $1500 from PBM due to error in applying step therapy requirements.
0.00	0.00		0.00		0.00	0.00	0.00	0.00	0.00	No DIR due to very low membership, no claims with associated DIR.

D. Detailed 2011 DIR Report Formal and Layout (With Example Values)

Contract-Plan	11-digit NDC	Rebate Dollars	All Other DIR (i.e. non-rebate DIR)	Comments
S1234-001	55555000101	30000.000	5000.000	
S1234-001	44444000102	11000.000	900.000	
S1234-001	33333000101	1725.000	725.000	
S1234-001	22222000101	0.000	0.000	Generic drug, no rebates received.
S1234-002	<Blank>	0.000	0.000	PBP was active with no enrollment.

E. Steps for Submitting 2011 DIR Submission Information and DIR Reports

We will list the pathways in HPMS for submitting DIR data in the final guidance.

F. Attestations of DIR Related Data

After CMS marks the Submission Information and DIR Reports as "accepted" in HPMS, 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 certify in the attestations 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.

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.

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

G. Resubmitting Summary DIR Reports for Prior Coverage 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. 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.

i. Reporting changes to 2006, 2007 and 2008 DIR

To report a change or error in the DIR amounts reported for contract years 2006, 2007 and 2008, sponsors may not simply upload updated DIR reports. Instead, they must submit a reopening request. The reopening request must be submitted in time for CMS to review the request and grant resubmission of the DIR report during the resubmission window which begins on June 1, 2012 and ends at 11:59 PM PT on June 29, 2012. If the reopening request is granted, then sponsors would be notified to resubmit an updated DIR report (using the 2006, 2007, and/or 2008 report template, as appropriate). The reopening request must be sent to StrategicHealthSolutions, LLC at PartDPaymentReview@Strategichs.com. 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" may be required to submit an updated 2008 DIR Report for Payment Reconciliation: Summary Report (Summary 2008 DIR Report) if they have not already done so. Please see the March 26, 2012 memo titled "Reopening of the 2008 Part D Payment Reconciliation and DIR" for additional details.

ii. Reporting changes to 2009 DIR

To report a known change or error in the DIR amounts reported for contract year 2009, Part D sponsors must submit an updated DIR Report using the 2009 report template during the DIR submission period from June 1, 2012 through 11:59 PM PT on June 29, 2012 in HPMS. 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.

To report a change or error in the DIR amounts reported for contract year 2009 after the current submission period that ends on June 29, 2012, Part D sponsors must submit a reopening request. CMS will review the updated DIR Reports as well as PDE data to make a determination on whether the sponsor's final Part D payment determinations will be reopened. If the reopening request is granted, then sponsors would be notified to resubmit an updated DIR report using the 2009 report template. The reopening request must be sent to StrategicHealthSolutions, LLC at:
PartDPaymentReview@Strategichs.com.

iii. Reporting changes to 2010 DIR

To report a known change or error in the DIR amounts reported for contract year 2010, Part D sponsors must submit an updated DIR Report using the 2010 report template during the DIR submission period from June 1, 2012 through 11:59 PM PT on June 29, 2012 in HPMS. 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.

To report a change or error in the DIR amounts reported for contract year 2010 after the

current submission period that ends on June 29, 2012, Part D sponsors must submit an updated DIR Report using the 2010 report template during the 2012 DIR submission period in 2013.

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. 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 consider only those sponsors who have submitted a reopening request.

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

Scenario	Sponsor Action
Part D sponsor must report a change or error in DIR amounts for contract year 2006, 2007, or 2008	Part D sponsor must submit a reopening request. If the reopening request is granted, then sponsors would be notified to resubmit an updated DIR report (using the 2006, 2007, and/or 2008 report template, as appropriate).
Part D sponsor must report a change or error for contract year 2009 or 2010 prior to submission period elapsing for contract year 2011 (i.e., before June 29, 2012)	Part D sponsor must submit an updated DIR Report (using the 2009 or 2010 report template, as appropriate) during the DIR submission period in June 2012 in HPMS. 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.
Part D sponsor must report a change or error in DIR amounts for contract year 2009 after submission period has elapsed for contract year 2011 (i.e., after June 29, 2012)	Part D sponsor must submit a reopening request. If the reopening request is granted, then sponsors would be notified to resubmit an updated DIR report using the 2009 report template.
Part D sponsor must report a change or error in DIR amounts for contract year 2010 after submission period has elapsed for contract year 2011 (i.e., after June 29, 2012)	Part D sponsors must submit an updated DIR Report using the 2010 report template during the 2012 DIR submission period in 2013. 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.

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 StrategicHealthSolutions, LLC (Strategic) at: PartDPaymentReview@Strategichs.com. Please see the May 8, 2008 HPMS memo, "The Part D Reopenings Process and the Part D Appeals Process" for additional guidance regarding how to submit a reopening request. When completing the reopening spreadsheet, please update the

spreadsheet header to reflect the appropriate benefit year for which you are requesting a reopening. 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.