DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-16-16
Baltimore, Maryland 21244-1850

Center for Beneficiary Choices
Medicare Plan Payment Group

April 27, 2006

NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)

Today, the Centers for Medicare & Medicaid Services (CMS) issued an updated version of the PDE Instructions: Requirements for Submitting Prescription Drug Event Data. This document contains a few clarifications and minor updates from the previous version posted in January and it is available on our website at http://www.cms.hhs.gov/DrugCoverageClaimsData/RxDrugEventDataGuidance.asp#TopOfPage The changes are as follows:

- In Sections 3 and 6, we updated the document to reflect the correct number of key fields (seven).

- In Section 7.4.1, we appended a new instruction as a note to Table 7A. In the exceptional case where Co-pay > Gross Drug Cost under an enhanced alternative plan, only one calculation is appropriate to determine enhanced alternative cost sharing and NPP Amount when mapping to the defined standard benefit. NPP Amount = (Plan-Paid at POS – CPP Amount).

- In Section 8, we clarify that Medicaid or other payments to subsidize the cost sharing of low-income residents of the U.S. territories under a waiver or grant approved under §1860D-42(a) of the Social Security Act are considered incurred costs for purposes of TrOOP accumulation. These subsidies count towards TrOOP and therefore should be reported in the field Other TrOOP Amount on the PDE record. Note that all other Medicaid payments on behalf of beneficiaries do not count towards TrOOP as is the case with most other government funded programs.

- In Section 10, we added material that clarifies and incorporates the agency's policy for determining low income cost sharing for Level III beneficiaries enrolled in zero deductible plans or in plans with deductibles that are less than the statutory amount ($50 in 2006). This material parallels the Q&As issued on this topic by CMS on February 10th and April 19th.

We will continue to work with plans and other entities to refine and clarify our PDE rules and to answer questions. Please continue to reference these Instructions, review the Training Materials posted on the website of our Customer Service and Support Center (CSSC) at http://www.csscoperations.com/new/pdic/pdd-training/pdd-training.html, and utilize the support staff available to assist you at CSSC. The online PDE training material is a source of additional examples and is the only source of certain material such as report formats and editing rules.

Questions concerning the updated instructions may be addressed to Ann Marshall at (ann.marshall@cms.hhs.gov) or Sandra Anderson at (sandra.anderson@cms.hhs.gov).

/s/
Thomas E. Hutchinson
Acting Director
Medicare Plan Payment Group

INSTRUCTIONS: REQUIREMENTS FOR SUBMITTING PRESCRIPTION DRUG EVENT DATA

April 26, 2006

INSTRUCTIONS: REQUIREMENTS FOR SUBMITTING PRESCRIPTION DRUG EVENT DATA

Table of Contents

Introduction

i. Background

ii. Overview of contents

Section 1. Data Submission Requirements

1.1 Prescription Drug Event (PDE) record

1.2 Audit Trails

1.3 Drug Data Processing System (DDPS)

1.4 Data submission requirements for payment and reconciliation

1.4.1 Data submission during the coverage year

1.4.2 Data submission at the end of the coverage year

1.5 Appeals

Section 2. Data Elements for PDE records

Section 3. Key fields to uniquely identify a PDE record

Section 4. PDE records with non-standard data format source

Section 5. Drug Coverage Status

Section 6. Adjustment/Deletion Process

Section 7. Enhanced Alternative Benefits

7.1 Definition

7.2 Identifying enhanced alternative benefits for exclusion from payment

7.3 Business Rules for Reporting Enhanced Alternative Drugs

7.4 Business Rules for Calculating and Reporting Enhanced Alternative Cost Sharing

Table 7A Reporting EACS

Table 7B Mapping to the defined standard benefit to calculate CPP versus EACS

7.5 PDE Examples

Section 8. True Out-of-Pocket (TrOOP) and Other Payers

8.1 What is TrOOP
8.2 Why TrOOP matters
8.3 What counts towards TrOOP
8.4 Plan accountability for TrOOP accounting
8.5 What CMS will do to assist plan TrOOP accounting and benefits coordination
8.6 PDE fields that report TrOOP information
Section 9. Retroactive changes in TrOOP
Table 9A Retroactive TrOOP Changes: Reported as Administered
Table 9B Retroactive TrOOP Changes: Reported as Adjustment Records
Section 10. Low-Income Cost-Sharing Subsidy (LICS)
10.1 Definition
Table 10A LICS Categories
10.2 Reporting requirements
10.3 PDE examples
Section 11. Direct and Indirect Remuneration (DIR)
11.1 Definition
11.2 Reporting requirements
Section 12. Reinsurance
12.1 Definition
12.2 Apportioning DIR to reinsurance costs
12.3 Calculating allowable reinsurance costs for reconciliation
Section 13. Risk-sharing (risk corridor payment adjustments)
13.1 Definition
13.2 Calculating risk-sharing payment adjustments for reconciliation
13.3 Limited risk plans
Section 14. Special instructions for PACE organizations
14.1 Two types of PACE plans
14.2 Rules for populating PDE fields
14.3 Arraying the costs of dual eligible enrollees
14.4 Arraying the costs of Medicare-only enrollees
Section 15. Special instructions for payment demonstration plans

15.1 Overview
15.2 Rules for populating PDE fields: flexible and fixed capitation options
15.3 Examples: flexible capitation option
15.4 Examples: fixed capitation option
15.5 Examples: MA rebate option
15.6 Payment reconciliation: flexible and fixed capitation options
Section 16. Special instructions for employer/union-only group waiver plans (EGWPs)
16.1 Background
16.2 Plan types
16.3 Tracking TrOOP and Gross Covered Drug Costs
16.4 Reinsurance
16.5 Risk sharing
Section 17. Medicare as Secondary Payer (MSP)
17.1 Background
17.2 Verifying and establishing MSP
17.3 Mistaken payment recovery
17.4 Populating the PDE record as MSP
17.5 MSP and progression through the Part D benefit
17.6 Reinsurance under MSP
17.7 Sample Q&As

Glossary of Acronyms

Introduction

i. Background

In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), amending the Social Security Act (herein referred to as "the Act") by adding Part D under Title XVIII. Under the new Medicare benefit, the Act allows Medicare payment to plans that contract with CMS to provide qualified Part D prescription drug coverage as described in 42 CFR §423.401. For simplicity in this paper, we use the term "plans" to refer to these entities that provide Part D benefits and that must submit claims data to CMS for payment calculations.

The Act provides four summary mechanisms for paying plans:

1. direct subsidies
2. premium and cost-sharing subsidies for qualifying low-income individuals (low-income subsidy)
3. federal reinsurance subsidies
4. risk sharing

As a condition of payment, all Part D plans must submit data and information necessary for CMS to carry out payment provisions (§1860D-15(c)(1)(C) and (d)(2) of the Act, and 42 CFR §423.322). This document describes how CMS will implement the statutory payment mechanisms by collecting a limited subset of data elements on 100 percent of prescription drug "claims" or events. We describe the required data submission per event, the mode and frequency of submission, and how the data will be used to make payment and conduct reconciliation. These requirements apply to all Part D plans as defined in §423.401 unless separate instructions are issued. PACE organizations, payment demonstration plans and employer/union-only group waiver plans should especially note Sections 14, 15, and 16 where we define special rules for submitting their data.

These instructions are the result of extensive communication and consultation both within and outside the agency. We have incorporated feedback from industry and other stakeholders obtained by both formal and informal means including the rulemaking process, Open Door Forums, and other consultation. In determining requirements, we applied four criteria:

1. Ability to pay plans timely and accurately under the four legislated payment mechanisms;
2. Minimal administrative burden on CMS, plans, and other entities including MA-PDs, PDPs, fallback plans, pharmacy benefit managers, pharmacies, and others;
3. Legislative authority; and
4. Validity and reliability of the data requested, to ensure that the information will be useful.

Much of the data, especially dollar fields, will be used primarily for payment. However, some of the other data elements such as pharmacy and prescriber identifiers will be used for validation of the claims as well as for other legislated functions such as quality

monitoring, program integrity, and oversight. In addition, we note that this paper only covers data collected on claims and does not cover data CMS may collect from plans through other mechanisms, for example monitoring plan formularies and beneficiary appeals.

ii. Overview of contents

Every time a beneficiary fills a prescription covered under Part D, plans must submit a summary record called the prescription drug event (PDE) record to CMS. The PDE record contains prescription drug cost and payment data that will enable CMS to make payment to plans and otherwise administer the Part D benefit. Specifically, the PDE record will include covered drug costs above and below the out-of-pocket threshold; distinguish enhanced alternative costs from the costs of drugs provided under the standard benefit; and will record payments made by Part D plan sponsors, other payers, and by or on behalf of beneficiaries. Plans must also identify costs that contribute towards a beneficiary's true-out-of-pocket or TrOOP limit, separated into three categories: low-income cost-sharing subsidy amounts paid by the plan at the point of sale (POS), beneficiary payments, and all TrOOP-eligible payments made by qualified entities on behalf of a beneficiary.

The submitted data components fit together to allow calculation of payment under the four legislated payment mechanisms. Specifically, CMS will use the data to reconcile low-income cost-sharing subsidy and reinsurance payments and to implement risk sharing between the plan and the federal government through risk corridor payment adjustments. In future years, the drug utilization data may be added to the risk adjustment model for the direct subsidy. CMS will also use PDE data to verify plan administration of TrOOP.

Section 1 defines a PDE record. Many electronic transactions take place between plans, pharmacies, and intermediaries when an enrollee fills a prescription. This process allows determination of patient cost sharing at the point of sale by plan adjudication of the claim, and drives eventual plan payment to the pharmacy. In Section 1, CMS defines the summary claim record plans must submit to CMS, which only contains information that is vital for payment (and, in a few instances, quality oversight or program integrity). We also lay out submission deadlines and rules that apply if a plan fails to provide timely, adequate data for payment or reconciliation.

Section 2 lists the data elements that are required on PDE records submitted to CMS. We provide brief definitions of each data element and how the data field shall be populated. Section 3 lays out a subset of these data elements that together will enable CMS to identify a unique PDE record. CMS needs to be able to identify unique events in order to process adjustments and deletions for PDE record corrections.

Section 4 deals with the issue of how plans will submit PDE records to CMS when claims originate in a non-standard format, for example beneficiary submitted paper claims and 837 claim formats. In a limited number of instances, plans will receive claims from non-standard sources that will not include enough data to populate all data elements listed in

Section 2. Since the plan will then have incomplete data to pass on electronically to CMS for payment, CMS will waive the requirement for the full set of data elements and instead rely on selected elements and accept certain default values. This section lists the minimum required data set for this exceptional circumstance.

Section 5 defines drugs that are covered under the statute's Medicare Part D benefit and/or the Plan Benefit Package (PBP) versus those that are not. Modifiers on PDE records will enable CMS to distinguish costs that must be included or excluded from payment and/or true out-of-pocket costs (TrOOP).

In Section 6, we describe the process for making adjustments and deletions to previously submitted PDE records. Section 7 discusses the mechanisms to identify enhanced alternative (EA) benefits on PDE records. Medicare does not pay for enhanced alternative benefits (cost-sharing fill-in or coverage of non-Part D drugs) that extend beyond that standard or basic benefit defined in the Act; these benefits must not be counted towards TrOOP, low-income subsidies, or reinsurance or risk corridor payments. Therefore, we have developed a schema for disaggregating the costs that are attributable to enhanced alternative coverage. Section 7 also provides key instructions and examples for populating PDE dollar fields in accordance with specific rules for mapping standard versus EA benefits.

In Section 8, we define TrOOP and the process plans must use to segment out the dollar amounts that must be counted towards TrOOP. We provide a brief overview of the TrOOP facilitator and COB contracts, and describe a schema for identifying payments that count towards TrOOP and those that do not. Section 9 discusses the process for adjusting PDE records for revisions in TrOOP accounting within a coverage year.

Section 10 explains the low-income cost-sharing subsidy (LICS) payment provision of the law. We define LICS and describe how CMS will pay plans interim amounts in 2006. We then lay out the methodology for tracking actual LICS expenditures on the PDE record as they are incurred by plans, so that interim payments and incurred amounts can be reconciled. Finally, we provide some examples of how to populate PDE records for LICS-eligible beneficiaries under different plan benefit packages.

Section 11 addresses the requirements of the Act that covered drug costs must be incurred and actually paid by the Part D sponsor, net of any direct or indirect remuneration that decreases the costs incurred by the Part D sponsor for the drug (§1860D-15(b)(2) and (e)(1)(b), 42 CFR §423.308). CMS must exclude such direct and indirect remuneration (referred to in this document as DIR) from allowable reinsurance and risk corridor costs. In Section 11, we define DIR and detail reporting requirements. This section is not a comprehensive discussion of DIR cost accounting; rather, we only address aspects that are intrinsic to reinsurance and risk corridor calculations.

Sections 12 and 13 are devoted to reinsurance and risk corridors. Previous sections describe many of the data elements and calculations that will ultimately be used to conduct final reconciliation and calculate risk sharing dollars as detailed in Sections 12

and 13. Section 12 defines reinsurance and describes how we will determine allowable reinsurance costs from PDE data for reconciliation against interim payments. We describe how CMS will allocate DIR dollars in reconciling reinsurance. Section 13 is devoted to defining risk corridors and explaining how we will calculate adjusted allowable risk corridor costs from PDE data for payment adjustment in reconciliation. We also discuss how we will allocate DIR dollars to risk corridor costs.

In Sections 14 and 15, we provide special rules pertaining to PACE organizations and payment demonstration plans. Section 16 contains special instructions regarding employer-sponsored plans with rules for PDE data submission by employer/union-only group waiver plans. Section 17 provides calculation and reporting rules for PDEs when Medicare is the secondary payer (MSP). We conclude the document with a glossary of acronyms.

Section 1. Data Submission Requirements

1.1 Prescription Drug Event (PDE) Record
For each dispensing event, the plan must submit a prescription drug event or PDE record. Most organizations or sponsoring entities will use a pharmacy benefit manager (PBM) or other third party administrator to process incoming claims from pharmacies. Claims typically undergo several rounds of transactions between these parties before the plan finally adjudicates a claim for payment. The PDE is a summary record that documents the final adjudication of a dispensing event. Section 2 lists the required set of data elements for all PDE records (15 data elements from the NCPDP billing transaction, 5 data elements from the NCPDP billing response transaction, and 17 data elements defined by CMS for purposes of administering Part D, for a total of 37 data elements).

1.2Audit Trails
The PDE record summarizes multiple transactions. The plan must maintain audit trails to PDE source data. CMS expects that the plan will be able to directly link any PDE to the individual claim transactions from which the PDE was extracted and replicate the summarization. All PDE data is expected to represent the service components as defined for coverage under a given data field. CMS intends to conduct audits of PDE data to ensure the accuracy of payment. CMS will publish further information on audit methodology at a later date.

1.3 Drug Data Processing System (DDPS)

The Drug Data Processing System (DDPS) is the information system that collects, validates, and stores PDE data received from plans or their designee.

DDPS Information Flow PDE records enter DDPS through the Prescription Drug Front-End System (PDFS) in a CMS defined record format. The PDFS initially performs format and face validity checks. Once the file has passed the front-end checks, it moves through the DDPS where detail level edits are performed and the data are stored.

1.4 Data submission requirements for payment and reconciliation
As a condition of payment, all Part D plans must submit data and information necessary for CMS to carry out payment provisions (§1860D-15(c)(1)(C) and (d)(2) of the Act, and 42 CFR §423.322). Plans may designate another entity to submit claims for them to CMS, but plans remain responsible for data submission and content as required under §423.505(k)(3). Note that data submission and payment recovery provisions apply even in the event of a change in ownership.

Plans must submit PDE records for events that fall within the coverage gap of the benefit, even if the plan makes no expenditure in this part of the benefit. Finally, note that by statutory definition, a coverage year corresponds to a calendar year (§1860D-15(b)(4)).

1.4.1 Data submission during the coverage year
In the first year of the benefit (2006), plans or a plan's designee must submit PDE records electronically to CMS according to the following schedule:

- Test file due to CMS by January 31, 2006
- First production file (actual records) due to CMS by the end of the first quarter (March 31, 2006)
- Thereafter, PDE records must be submitted to CMS electronically at least once a month.

Throughout the coverage year, CMS will monitor plan data submission levels to detect plans with submission volumes lower than expected. Low submission patterns often indicate technical or system problems. We will work with plans in an attempt to correct submission problems before the end of the year so they can meet reconciliation submission deadlines. However, the Act places ultimate responsibility on the plan to submit adequate data for payment.

1.4.2 Data submission at the end of the coverage year

PDE records, adjustments, or deletions that are received after the end of the fifth month of the subsequent coverage year will not be considered in reconciliation (§423.308). As prescribed in legislation, a coverage year corresponds to a calendar year. Thus, prescription drug claims including adjustments for all dates of service within calendar year 2006 must be submitted to CMS by May 31, 2007 in order to be processed for payment reconciliation.

Cost information (DIR, LICS, and risk corridor costs) is required within sixth months of the end of the coverage year (§423.343) in order to be considered for payment and reconciliation. Thus, DIR for all dates of service within calendar year 2006 must be submitted to CMS by June 30, 2007.

Late submission or submission of insufficient data to conduct reconciliation may result in payment recovery through a lump-sum recovery; by adjusting or ceasing monthly payments throughout the remainder of a coverage year; or by adjusting monthly payments in a subsequent year. These rules apply to all four types of Part D payment, including risk adjustment data although it is not discussed in this document. For requirements on submitting data for risk adjustment, see the Medicare Managed Care Manual Chapter 7 available at http://www.cms.hhs.gov/manuals/116_mmc/mc86c07.pdf.

- **LICS –** In 2006, since CMS is collecting cost data on LICS via PDE records instead of cost reports, Part D plans must provide documentation of LICS amounts on PDE records within the claims submission deadline (by the end of the fifth month of the next coverage year) to avoid recovery of interim amounts paid to plans for which no data are available.

- **Reinsurance –** If a Part D sponsor does not provide DIR data within six months of the end of the coverage year, CMS may recover interim monthly reinsurance payments for which no data are available.

- **Risk corridor payment –** For risk-sharing arrangements, if allowable costs submitted in the prescribed periods sum to less than 50 percent of the plan's target

amount, CMS will assume or impute that the entity's adjusted allowable risks corridor costs are 50 percent of the target amount (§423.343).

1.5 Appeals
As described in the final rule §423.350, Part D sponsors may appeal final payment decisions if the sponsor believes the payment methodology described in the final Part D rule and in interpretive guidance has not been applied correctly. Under no circumstances may this process be used to submit new payment information after established deadlines.

Section 2. Data Elements for PDE records

In this section, we list the required data elements that must be submitted on PDE records for payment. We employ the National Council for Prescription Drug Programs (NCPDP) industry standard whenever possible. Most data elements represent existing NCPDP fields where we employ the same definition and field values that are currently in use per the NCPDP version 5.1 drug claim standard. CMS has also drafted several new fields for data that are not currently collected on industry drug claims but that are necessary for us to pay plans in accordance with the new law. All fields are consistent with NCPDP formatting. It is not our intent to change NCPDP standards; the NCPDP format is developed independently from CMS.

This section defines each data element and its specific potential use for CMS's payment process:
1. Contract Number (Format cross reference - **BHD 3**)
This field contains the unique number CMS assigns to each contract that a Part D plan has with CMS. This data will be collected in the file header.

2. Plan Benefit Package (PBP) ID (Format cross reference - **BHD 4**)
This field will contain the unique number CMS assigns to identify a specific PBP within a contract. DDPS will utilize this data to ensure that each beneficiary's claims are being attributed to the appropriate PBP, i.e., the PBP in which the beneficiary is enrolled.

3. Claim Control Number (Format cross reference - **DET 3**)
This field is an optional, free-form field. It may be used by plans to identify unique events they have submitted to DDPS or for any other plan purpose. The data in this field will be reported back to a plan in the event a batch or individual record is rejected at some point in processing.

4. Health Insurance Claim Number (HICN) (Format cross reference - **DET 4**)
This field will contain the unique number that the Social Security Administration assigns to identify every Medicare beneficiary. For Railroad Retirement Board (RRB) beneficiaries, plans will use the RRB number in this field instead of a HICN. From here forward, when we refer to HICN, we mean HICN or RRB# as appropriate. Plans must use other identifiers as member numbers (e.g., for plan membership cards). Plans must then translate their member number or cardholder ID to the beneficiary's correct HICN.

All drug events submitted to DDPS must use the HICN, which ensures that DDPS assigns drug event data to the appropriate beneficiary. The HICN will also permit linkage of Part D drug event data to Parts A and B claims data, eligibility and enrollment data, and risk adjustment data.

5. Cardholder ID (Format cross reference - **DET 5**)
We will collect the plan-assigned number used to identify the beneficiary. This number verifies beneficiary identity and will be used to help plans map transactions to their databases and for program oversight functions.

6. Patient Date of Birth (DOB) (Format cross reference - **DET 6**)
Patient date of birth (DOB) is optional and will be used in conjunction with HICN and gender to verify beneficiary identity. It will be used as a cross-reference to ensure the event has identified the correct beneficiary.

7. Patient Gender (Format cross reference - **DET 7**)
Together with HICN and DOB (when reported), gender confirms the identity of the beneficiary.

8. Date of Service (DOS) (Format cross reference - **DET 8**)
Date of Service (DOS) is the date on which the prescription was filled. This field should **not** contain the date on which the plan pays for the services or subsequent adjustments to the original event.

9. Paid Date (Format cross reference - **DET 9**)
This field shall be populated with the date the plan originally paid the pharmacy for the prescription drug. (If the plan subsequently adjusts payment, the plan will report the original paid date in the adjustment PDE). Paid Date is a mandatory field for fallback plans, and is **optional** for all other plan types. CMS will use Paid Date to reconcile drug costs reported on PDE records to withdrawals for drug costs from the fallback plan's draw-down account.

The following two fields pertain to identifying the pharmacy where the prescription was dispensed:

10. Service Provider ID Qualifier (Format cross reference - **DET 13**)
This field indicates the type of provider identifier used in field 11 (Service Provider ID).

11. Service Provider ID (Format cross reference - **DET 14**)
This field identifies the pharmacy where the prescription was filled. This data helps CMS identify a unique prescription drug event (see Section 3). CMS will transition to use of the national provider identifier (NPI) when it is implemented. In the interim, this field will typically contain the NCPDP number, which all NCPDP billers are assigned. Some Part D service providers who submit in Non-Standard Format (e.g., home infusion, physicians when providing vaccines) will not have NCPDP numbers. For these providers, the UPIN, State License Number, federal Tax Identification Number (TIN) or

Employer Identification Number (EIN), or the default value of "PAPERCLAIM" will be the required identifier.

The following two fields pertain to identifying the prescriber:

12. Prescriber ID Qualifier (Format cross reference - **DET 21**)
This field indicates the type of identifier that is used in the Prescriber ID field.

13. Prescriber ID (Format cross reference - **DET 22**)
This field will contain the prescriber's unique identification number. CMS will transition to use of the national provider identifier (NPI) when it is implemented. In the interim, CMS requires use of a DEA number whenever it uniquely identifies the prescriber and is allowed by state law. In other cases, the prescriber's state license number or Unique Provider Identification Number (UPIN#) shall be used.

14. Prescription/Service Reference Number (Format cross reference - **DET 10**)
This field will contain the prescription reference number assigned by the pharmacy at the time the prescription is filled. It enables DDPS to identify a unique prescription drug event (see Section 3).

15. Product/Service ID (Format cross reference **- DET 12)**
This field identifies the dispensed drug using a National Drug Code (NDC). NDC will be reported in NDC11 format. In instances where a pharmacy formulates a compound containing multiple NDC drugs, the NDC of the most expensive drug shall be used.

DDPS will reject the following billing codes for legend and/or scheduled drugs: 99999999999, 99999999992, 99999999993, 99999999994, 99999999995, and 99999999996. If plans receive these codes from trading partners, the plan is responsible for reporting the NDC of the most expensive drug.

16. Compound Code (Format cross reference - **DET 17)**
This field will indicate whether or not the dispensed drug was compounded or mixed. This distinction will ensure that correct payments are made to the plan for mixed or compounded drugs. Plans may adjust the dispensing fee to include additional labor costs in the delivery of the compounded pharmaceutical item.

17. DAW/Product Selection Code (Format cross reference **- DET 18)**
This field will indicate the prescriber's instruction regarding substitution of generic equivalents or order to dispense the specific product written.

18. Quantity Dispensed (Format cross reference **- DET 19)**
This field indicates how many dosage units of the medication were dispensed in the current drug event (e.g., number of tablets, grams, milliliters, or other unit).

19. Days Supply (Format cross reference **- DET 20)**

This field indicates the number of days' supply of medication dispensed by the pharmacy and will consist of the amount the pharmacy enters for the prescription.

20. Fill Number (Format cross reference **- DET 15)**
This field indicates the number fill of the current dispensed supply.

21. Dispensing Status (Format cross reference **- DET 16)**
This field indicates how the pharmacy dispensed the complete quantity of the prescription. When the pharmacy partially fills a prescription, this field indicates a partial fill. When the full quantity is dispensed at one time, this field is blank.

When the pharmacy dispenses a partial fill, the plan has the option to submit two PDE records, one for the partial fill and a second for completion of the partial fill. If the plan prefers, the plan can defer PDE submission for a reasonable amount of time until the plan receives transactions for both the partial and complete fill. At that point, the plan may summarize the multiple transactions in a single PDE, reporting a blank in Dispensing Status.

22. Drug Coverage Status Code (Format cross reference **- DET 23)**
This field indicates whether or not the drug is covered under the Medicare Part D benefit and/or a specific PBP (see Section 5).

23. Adjustment/Deletion Code (Format cross reference **- DET 24)**
This field distinguishes original from adjusted or deleted PDE records so that the DDPS can adjust claims and make accurate payment for revised PDE records

24. Non-Standard Format Code (Format cross reference **- DET 25)**
This data element will be used by DDPS to identify PDE records that are compiled from non-standard sources. NCPDP is the standard format in which plans receive data from pharmacies. Section 4 identifies non-standard data sources in more detail and gives direction for compiling PDE records using data received in non-standard formats.

25. Pricing Exception Code (Format cross reference **- DET 26)**
This field indicates that the PDE reports an out-of-network or Medicare as Secondary Payer (MSP) service that is subject to unique pricing rules.

26. Catastrophic Coverage Code (Format cross reference **- DET 27)**
This field indicates that a beneficiary has reached the out-of-pocket (OOP) threshold or attachment point. At this point, catastrophic coverage provisions begin, namely reinsurance and reduced beneficiary cost sharing (see Section 8).

The following three data elements represent the amounts we will use from PDE records to determine costs that qualify for payment under the Medicare benefit:

27. Ingredient Cost Paid (Format cross reference **- DET 28)**

This field will contain the amount paid to the pharmacy for the drug itself. Dispensing fees or other costs shall not be included in this amount except as allowed on non-standard format claims as discussed in Section 4.

28. Dispensing Fee Paid (Format cross reference **- DET 29)**
This field will contain amounts paid to the pharmacy for dispensing the medication. Include only those activities related to the transfer of possession the drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead as delineated in the final rule §423.100 and the preamble to the rule. No other costs shall be included in this field. The fee may be negotiated with pharmacies at the plan or PBM level.

29. Total Amount Attributed to Sales Tax (Format cross reference **- DET 30)**
This field shall contain the sum of all amounts paid to the pharmacy to cover sales tax.

Under Part D, benefits change for both the plan and beneficiary when a beneficiary reaches the out-of-pocket (OOP) threshold or attachment point. To facilitate reconciliation and monitoring benefit provisions on either side of the threshold, two fields on every PDE record will report total costs for covered drugs (see Section 5) as falling above or below the OOP threshold. For a PDE where a beneficiary reaches the OOP threshold or attachment point, there may be costs on either side of the threshold. The fields will be populated as follows:

30. Gross Drug Cost Below Out-Of-Pocket Threshold (GDCB)
(Format cross reference **- DET 31)**
This field represents the gross drug cost (Ingredient Cost Paid + Dispensing Fee Paid + Total Amount Attributed to Sales Tax) paid to the pharmacy below the OOP threshold for a given PDE for a covered drug as defined in Section 5. For claims before a beneficiary has reached the attachment point, this field will list a positive dollar amount. For claims above the attachment point, this field will have a zero dollar value. For a claim on which the attachment point is reached, there will be a positive dollar amount in this field and there is likely to be a positive dollar amount in the GDCA field.

31. Gross Drug Cost Above Out-Of-Pocket Threshold (GDCA)
(Format cross reference **- DET 32)**
This field represents the gross drug cost (Ingredient Cost Paid + Dispensing Fee Paid + Total Amount Attributed to Sales Tax) paid to the pharmacy above the OOP threshold for a given PDE for a covered drug as defined in Section 5. For claims before a beneficiary has reached the attachment point, this field will list a zero dollar amount. For claims above the attachment point, this field will have a positive dollar value. For a claim on which the attachment point is reached, there is likely to be a positive dollar amount in this field and there will be a positive dollar amount in the GDCB field.

32. Patient Pay Amount (Format cross reference **- DET 33)**

This field lists the dollar amount the beneficiary paid that is not reimbursed by a third party (e.g., copayments, coinsurance, deductible or other patient pay amounts). This amount contributes to a beneficiary's TrOOP only when it is payment for a covered drug as defined in Section 5. Plans are responsible for ensuring that beneficiaries are charged amounts that are consistent with their benefit packages as approved in the bidding process.

Note: Payments actually made by a beneficiary shall be recorded in this field, and we expect amounts paid by friends or family to also be reported under Patient Pay Amount. However, other third party payments made on behalf of a beneficiary that contribute to TrOOP shall be reported in the Other TrOOP Amount or LICS fields, and payments that do not contribute to TrOOP shall be reported in the PLRO field.

The following three data elements distinguish sources of subsidized payments that may be made on behalf of beneficiaries to reduce their cost-sharing liability. DDPS separates beneficiary liability amounts into Patient Pay Amount and these three fields to allow distinctions that are important to TrOOP accumulation and risk corridor cost calculation:

33. Other TrOOP Amount (Format cross reference **- DET 34)**
This field records all qualified third party payments that contribute to a beneficiary's TrOOP, except for LICS and Patient Pay Amount. Examples include payments made on behalf of a beneficiary by qualified SPAPs, charities, or other TrOOP-eligible parties.

*Note: LICS amounts and payments by beneficiaries or friends or family, which count towards TrOOP, shall **not** be reported in this field; they are reported in the LICS and Patient Pay Amount fields. Also, the Other TrOOP field does **not** include payments by other parties that do not contribute to TrOOP; those amounts are reported in the PLRO field.*

34. Low-Income Cost-Sharing Subsidy Amount (LICS)
(Format cross reference **- DET 35)**
The Act provides for Medicare payments to plans to subsidize the cost-sharing liability of qualifying low-income beneficiaries at the point of sale (see Section 10). In accordance with statutory language, we refer to these amounts as Low-Income Cost-Sharing Subsidies or LICS amounts. The LICS field will contain plan-reported LICS amounts per drug event, so that CMS systems can reconcile prospective LICS payments made to plans with actual LICS amounts incurred by the plan at POS.

35. Patient Liability Reduction due to Other Payer Amount (PLRO)
(Format cross reference **- DET 36)**
This field takes into account coordination of benefits that results in reduced patient liability, excluding any TrOOP-eligible payers. This field shall contain amounts by which patient liability is reduced due to payments by other payers that do not participate in Part D and are not TrOOP-eligible (see Section 8). PLRO amounts are excluded from Part D payment, and the PLRO field documents these benefits so that CMS can exclude

them from risk corridor calculations and from TrOOP accumulation. Further instruction on populating the PLRO field is provided in Section 8.

*Note: This field should **not** include payments or other patient liability reductions due to coverage under qualified SPAPs or any other TrOOP-eligible third party payer. All TrOOP-eligible amounts should be reported in the Patient Pay Amount field (if paid by the beneficiary, family, or friends) or in Other TrOOP Amount (if paid by another qualified third party).*

To facilitate reconciliation, the following two fields report the net amount the plan has incurred on a PDE for standard or enhanced alternative benefits:

36. Covered D Plan Paid Amount (CPP) (Format cross reference **- DET 37)**
This field shall contain the net amount the plan paid for standard benefits (covered Part D drugs – see Sections 5, 7). In other words, the field reports the plan-paid amount for drugs with Drug Coverage Code = C. If Drug Coverage Code = E or O, the CPP field is zero. DDPS will use this field to facilitate reconciliation calculations, especially determining allowable risk corridor costs.

37. Non-covered Plan Paid Amount (NPP) (Format cross reference **- DET 38)**
This field shall contain the net amount paid by the plan for benefits beyond the standard benefit. Thus, this value includes all over-the-counter drugs, enhanced alternative drugs, and enhanced alternative cost-sharing amounts (see Sections 5, 7). The amount recorded in NPP is excluded from risk corridor payment and from TrOOP accumulation. DDPS may also use this data to assure that coverage provisions are in accordance with the approved plan benefit structure from its bid.

Section 3. Key fields to uniquely identify PDE record

Of the fields outlined above, we will use the following seven fields to identify a single unique prescription drug event. A change in any of the following seven fields indicates a different event:

HICN
Service Provider ID
Service Provider ID Qualifier
Prescription/Service Reference Number
Date of Service
Fill Number
Dispensing Status

We used the following rationale to identify the key fields. We included HICN because it is the basic beneficiary identifier in the Medicare program. In the majority of cases, the concatenation of Service Provider, Prescription/Service Reference Number and Fill

Number uniquely identify a prescription. Fill Number distinguishes original versus subsequent refills of the same prescription from the same pharmacy. We added Date of Service because some pharmacies report that they reuse prescription numbers. We added Dispensing Status to differentiate between a partial fill and the completion of partial fill. The industry concurred that the concatenation of these seven fields guarantees that we will uniquely identify a prescription. See Section 6 on the Adjustment/Deletion process for additional information about processing rules.

Section 4. PDE records with non-standard data format source

Since the pharmacy industry is highly automated, plans will almost always receive data electronically in NCPDP format. Therefore, we consider NCPDP 5.1 to be the standard data format for PDE record transactions. However, there are occasions when plans will receive claims in another data format that does not provide some of the information requisite for populating the full set of PDE data elements. For example, plans must accept X12 837 formatted claims from certain providers in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), but the current version of X12 does not disaggregate dispensing fee for populating the NCPDP Dispensing Fee Paid field. On this and other occasions when a plan receives input data from pharmacies in a non-standard format, plans will populate the Non-standard Data Format Code with one of four mutually exclusive values. These values are:

B – submitted by beneficiary
Example: a beneficiary purchases an emergency prescription at an out-of-network (OON) pharmacy and submits a receipt to the plan for reimbursement
X – submitted by provider in X12 format
Example: a home infusion pharmacy submits data in X12 format
P – submitted by provider on paper claim
Example: a physician office submits a hard-copy claim for a Part D covered vaccine or other Part D drug
Example: an I/T/U pharmacy faxes a claim to the plan
Example: a 340B pharmacy submits a paper claim to the plan
Blank – NCPDP

Plans shall make every attempt to populate a PDE record completely. CMS recognizes that claims submitted in non-standard data format may not include all data elements necessary to populate a PDE record and that additional processing to add contractual elements would be necessary to produce a PDE record. Therefore, DDPS will suspend certain edits and accept a reduced set of data elements for PDE records compiled from non-standard data sources according to the following instructions:

Optional fields – Prescriber ID Qualifier and Prescriber ID. **All other fields must be reported.**

Instructions for Ingredient Cost Paid, Dispensing Fee Paid, and Total Amount Attributed to Sales Tax – If the dispensing pharmacy does not disaggregate gross drug cost into these three cost components, the plan may report one dollar value for all three costs under the field Ingredient Cost Paid. However, plans must still populate Dispensing Fee Paid and Total Amount Attributed to Sales Tax with a value = zero; these are not optional fields. Also, any dispensing fee that is reported by the plan under Ingredient Cost Paid shall only consist of the dispensing service that is covered under Part D as defined in the final rule §423.100 and in the preamble to the rule (see Section 2, Data Elements for PDE records, Dispensing Fee Paid). Plans must ensure that PDE records compiled from infusion pharmacy claims or any other claims originating in X12 format comply with the Part D regulatory definition of dispensing fee and all other data elements.

Instructions for Fill Number, DAW, Compound Code, Service Provider ID, Prescription Service Reference Number, and Days Supply – If plans do not have source data to populate these fields, plans will use the following business rules to populate default values:

Fill number – default value is "00"
DAW – default value is "0-No Product Selection Indicated"
Compound Code – default value is "0-not a compound"
Service Provider ID – When a physician who is not registered with NCPDP dispenses a drug, the plan will report one of the following alternative values in lieu of the pharmacy's NCPDP (formerly NABP) number in the Service Provider ID field.

Service Provider ID	Service Provider ID Qualifier
UPIN	06
State License Number	08
Federal Tax ID	11
PAPERCLAIM	99

Prescription Service Reference Number – When not available, the plan must assign a unique reference number. A reference number must be unique for any given service provider/DOS combination.
Days Supply – default value = 000

DDPS will monitor submission rates of this reduced data set. We anticipate reviewing the volume of PDEs with non-standard data formats as a percentage of total PDEs. If this percentage is higher than expected, we will conduct further research and we may reconsider use of reduced data requirements for PDEs with source data in non-standard data formats.

Consistent with Section 1.2 Audit Trails, CMS expects a complete audit trail for any PDE compiled from claims that originate in non-standard data format.

Section 5. Drug Coverage Status

Under §1860D-2(e) of the Act, CMS can pay only for drugs that both meet the definition of a "Part D drug" and are approved for coverage under a specific PBP. **In this document, we use the term "covered" to refer to these drugs that a plan covers under its basic benefit.** Drugs that do not meet these criteria must be excluded from reinsurance subsidy (§1860D-15(b)(2)), risk corridor calculations (§1860D-15(e)(1)(B)), low-income cost-sharing subsidy (§1860D-14 and D-2), and true out-of-pocket costs or TrOOP (§1860D-2(b)(4)(C)(i)). In implementing these policies, we use the following terminology:

Part D drug – any prescription drug described in §1927(k)(2)(A) of the Act, a vaccine licensed under section 351 of the Public Health Service Act, a biological product described in §1927(k)(2)(B) of the Act, or insulin described in §1927(k)(2)(C) and medical supplies associated with the injection of insulin as allowed under §1860D-2(e)(1)(B). Except for smoking cessation drugs, Part D drugs must be prescribed for the purposes allowed under §1862(a) and §1927(d)(2) (e.g., reasonable and necessary guidelines, exclusion of drug classes used for weight loss or cosmetic surgery). Drugs cannot be billed as Part D drugs if they are already covered under Medicare Parts A or B as prescribed, dispensed, or administered (§1860D-2(e)(2)(B)).

- **Covered Part D drug** – a drug that meets the definition of a Part D drug and is also covered under a PBP. Includes Part D drugs covered under an exception, transition, grievance, appeal or other coverage determination process as described in regulation (42 CFR Subparts C and M). **We refer to these drugs as "covered drugs" because they are included in the basic benefit.**

- **Non-covered Part D drug** - A drug that meets the definition of a Part D drug but the PBP does not cover it, usually because it is off-formulary or the plan does not find it is reasonable and necessary.

Non-Part D drug – any prescription or over-the-counter drug that is not a Part D drug or that is already covered under Medicare Parts A or B as prescribed, dispensed, or administered. **In this document, we refer to these drugs as "non-covered" even though a plan may cover some of these drugs as a supplemental benefit or as part of OTC step therapy under an approved formulary.** Except for smoking cessation agents, these drugs are described under §1927(d)(2) (e.g., benzodiazepines, weight loss agents, cough and cold relief) and §1862(a) (e.g., drugs used in cosmetic surgery).

Plans shall only pay for covered Part D drugs ("covered drugs"), with the following exceptions:

1. Supplemental drugs - Enhanced alternative plans may decide to offer some non-Part D prescription drugs as part of their enhanced alternative benefit package (see Section 7.1).

2. OTC drugs employed in step therapy – A plan may cover an over-the-counter (OTC) drug when it is included in approved step therapy protocols that satisfy CMS formulary review. Plans must submit PDE records to DDPS for these drugs, but the drugs will be paid for under plan administrative costs as reported in the bid and will be excluded from other Part D payment calculations based on PDE records. Plans shall not charge any beneficiary cost sharing for formulary OTCs.

Plans are not required to submit claim denials on PDE records. However, they must submit PDE records for any drug they cover, distinguishing three coverage categories:[1]

C – Covered Part D drug ("covered drug")
E – Enhanced alternative drug, a non-Part D drug covered by a plan as a supplement to the standard Part D benefit ("non-covered drug")
O – OTC drug, covered by a plan in keeping with approved formulary step edits ("non-covered drug")

The following examples clarify use of the Drug Coverage Status field values:

Example 1 – A beneficiary presents a prescription for a 30 day supply of hydrochlorothiazide 50 mg tablet, 30 tablets. Hydrochlorothiazide 50 mg tablet is on the plan's formulary. The plan requires no approval steps to dispense or pay. Drug Coverage Status = C.

Example 2 – A beneficiary presents a prescription for a 30 day supply (30 capsules) for Sporonox 200 mg (itraconazole) Capsules. Itraconazole is on the plan's formulary with prior authorization required. The beneficiary's physician prescribed itraconazole because the beneficiary has onychomycosis, confirmed by histological test (KOH, PAS stain) or culture. Treatment is limited to six months in duration. The clinical information provided by the physician met the authorization requirements. Drug Coverage Status = C.

Example 3 – A beneficiary presents a prescription for a 10 day supply (10 tablets) of Dalmane 15 mg (flurazepam), a benzodiazepine agent. The beneficiary is enrolled to an enhanced alternative plan that offers flurazepam on its plan formulary as a supplemental drug. Medicare Part D does not cover benzodiazepines. However, the plan covers this class of drugs as a supplemental benefit, appropriate for short-term use in healthy beneficiaries under the age of 75. Drug Coverage Status = E.

Example 4 – A plan's approved step therapy protocol requires a beneficiary to fail an initial course of OTC Prilosec before the plan will cover a prescription for proton pump inhibitors (Nexium). A beneficiary presents a prescription for Nexium at the retail pharmacy. The plan informs the pharmacist that the beneficiary must meet a step edit with OTC Prilosec. The pharmacist speaks with

[1] We omitted the value = X that designated EA drugs funded using A/B dollars.

the physician and the physician authorizes the pharmacy to change therapy to OTC Prilosec. Drug Coverage Status = O.

Section 6. Adjustment/Deletion Process

An adjustment or deletion is any change reported after the original PDE record was submitted. Adjustments and deletion records can report data changes that are critical to Part D. For example, an adjustment record can update delayed reporting of secondary health insurance payments that reduce TrOOP. Alternatively, an adjustment record can update delayed reporting of secondary coverage that does count towards TrOOP, e.g. retroactive determination of low-income subsidy eligibility, qualified SPAP eligibility, or a payment by a charity. When prescriptions are not picked up by the beneficiary and a PDE has already been submitted, the plan must submit a deletion record.

The DDPS will use the Adjustment/Deletion Code to trigger adjustment/deletion processing. Adjustment/Deletion matching logic requires a nine-field match: the seven key fields (see Section 3), Contract Number (reported in the header), and Plan Benefit Package ID. We added Contract Number and PBP ID to reserve adjust/delete rights exclusively to the Contract Number and PBP that authored the original PDE record.

When DDPS receives a PDE record with Adjustment/Deletion Code = A (adjustment) or D (deletion), DDPS will search the database for a current active PDE record with matching values in Contract Number, Plan Benefit Package ID, HICN, Service Provider ID, Service Provider ID Qualifier, Prescription/Service Reference Number, Date of Service, Fill Number, and Dispensing Status. If the matching current active record is not found, DDPS will return an error message to the plan. DDPS will not assume that the plan submitted an original PDE incorrectly identified as an adjustment or a deletion. If the Adjustment/ Deletion Code = D (deletion), DDPS will inactivate the current active record. If the Adjustment/ Deletion Code = A (adjustment), DDPS will inactivate the current active record and identify the adjustment PDE as the current active record. DDPS will exclude inactivated PDE records from any subsequent calculations for the beneficiary, PBP or Contract.

Since key fields cannot be changed, there is only one mechanism to correct a key field. The plan will submit a deletion PDE for the record in error and submit a new PDE with corrected data elements. This logic has implications for partial fills. DDPS cannot support multiple partial fills. Dispensing Status, the field that documents partial fills (see Section 2), is a key field (see Section 3). DDPS will reject a PDE documenting a multiple partial fill as a duplicate. If a plan receives multiple partial fill transactions, the plan will submit an adjustment record that, in effect combines all partial fill events.

DDPS adjustment processing logic observes several hierarchies. Once a PDE record has been marked as inactive, it cannot be adjusted. If a replacement record is necessary, the plan must submit a new PDE record for the prescription event.

A second hierarchy applies to PDEs reporting partial and complete fills:

- Dispensing Status = 'P' or 'C' cannot follow a value = 'blank' – When a PDE with Dispensing Status = 'P' or 'C' indicating partial fill or completion of partial fill is on file, DPPS will not accept a deletion record with Dispensing Status = 'blank'
- Dispensing Status = 'blank' cannot follow 'P' or 'C' – When a PDE with Dispensing Status = blank is on file, DPPS will not accept a deletion record with Dispensing Status = 'P' or 'C'

Plans may take steps to minimize adjustment volume. There are several ways to minimize the number of adjustments:

- Plans can delay submission until they have finalized the data necessary to populate a PDE **but within the submission deadlines detailed in Section 1.3.1.** For example, a plan may decide to defer PDE submission for a period of time (e.g., 15 days) to allow sufficient time for the beneficiary to pick up the prescription. Most pharmacies wait 10 days or 2 weeks before returning "no pick-up" prescriptions to stock. Alternatively, plans may decide to defer PDE submission for one month if the plan expects an update in other insurance coverage.

- Second, plans may report PDEs as they administer the benefit (see Section 9).

Finally, note that a PDE record, which may be an original event, an adjustment or a deletion, reports the most recent information as of the date of submission. DDPS will use the file submission date on a given PDE record as its identifier. Because DDPS uses submission date to identify a PDE, only one original record, adjustment, or deletion of an event can be submitted per day.

Section 7. Enhanced Alternative Benefits

7.1 Definition

Under §1860D-1 and D-2 of the Act, all Part D plans are required to provide "standard" (§1860D-2(b)) or "basic alternative" (§1860D-2(c)) prescription drug benefits. However, plans have the option to provide additional benefits that exceed the actuarially equivalent value of (i.e. are supplemental to) the basic benefit (§1860D-2(a)(2)). We refer to these plans as enhanced alternative plans and we refer to these benefits as enhanced alternative benefits.[2] Enhanced alternative benefits, which the statute refers to as supplemental benefits, can take two forms (§1860D-2(a)(2)(A)(i-ii)):

[2] The Act uses the term "supplemental" to describe benefits that exceed the standard benefit and that are offered by enhanced alternative plans (§1860D-2(a)(2)). In this document, we only use the term "supplemental" in its statutory sense to refer to enhanced alternative benefits. In contrast to common industry practice, we use the term "other health insurance" (OHI) rather than "supplemental benefits" when referring to non-Part D third-party payers or benefits discussed in Section 8 (TrOOP and Other Payers).

1. Reduced cost sharing (reduced coinsurance, copays, deductible, and/or an increase in the initial coverage limit), that is, additional payments by the plan beyond those provided under the basic benefit (applies only to covered Part D drugs). We refer to this supplemental benefit as enhanced alternative cost sharing (EACS); and/or

2. Coverage of non-Part D drugs that require a prescription (e.g., benzodiazepines, barbiturates). Over-the-counter products are not allowed as enhanced alternative benefits.

Per §1860D-15(e)(4), Medicare does not pay for these enhanced alternative benefits; rather, plans fund them from other sources such as supplemental premiums (§1860D-13(a)(1)(C)), A/B rebate dollars from the MA bidding process (see 42 CFR §422.266), and/or the negative premium as described in the Announcement of Calendar Year (CY) 2006 Medicare Advantage Payment Rates (http://www.cms.hhs.gov/healthplans/rates/2006/cover.pdf).

The Act does not allow enhanced alternative benefits to be included in calculating the following amounts:

- Reinsurance subsidies (§1860D-15(b)(2))
- Risk corridor payment adjustments (§1860D-15(e)(1)(B))
- LICS (§1860D-14)
- TrOOP (§1860D-2(b)(4)(C)(i)).

7.2 Identifying enhanced alternative benefits for exclusion from payment

As previously described, Medicare does not cover benefits beyond the standard benefit; they must be excluded from payment. CMS uses three data fields in the Prescription Drug Event (PDE) record to identify EA benefits in order to make correct payments:

- Drug Coverage Status Code
- Covered D Plan Paid Amount (CPP)
- Non-covered Plan Paid Amount (NPP)

7.2.1 Drug Coverage Status Code

The value of "E" in the drug coverage status code indicates when payments are for an EA drug.

(E) Enhanced Alternative Drug – a non-Part D drug that is covered under a Part D plan's benefit package, also referred to as a non-covered or supplemental drug. Only EA plans can report a value of "E" in the drug coverage status field.

When Drug Coverage Status Code = E, the Drug Data Processing System (DDPS) automatically excludes the gross drug cost from reinsurance subsidies, allowable risk corridor costs, True Out-of-Pocket costs (TrOOP), and low income cost-sharing (LICS)

payment calculations. DDPS uses the Drug Coverage Status Code to exclude supplemental drugs from payment.

7.2.2 Covered D Plan Paid Amount (CPP)

Plans administering a standard benefit cannot offer supplemental benefits. When these plans report a covered drug, the plan-paid amount is reported in full in CPP, and NPP is zero. EA plans can offer EACS on covered drugs, cost-sharing assistance that exceeds the standard benefit amount. So, when an EA plan reports a covered drug, the plan-paid amount is split into the amount the plan would have paid under the Defined Standard benefit (which is CPP) and the amount the plan pays in EACS (which is reported in NPP). We refer to this process as "mapping to the Defined Standard benefit," and we further discuss the rationale for mapping and the business rules to apply it in Section 7.4.

7.2.3 Non-Covered Plan Paid Amount (NPP)

The NPP field is used for reporting plan-paid amounts for non-covered drugs (supplemental drugs and over-the-counter (OTC) drugs) and for EACS. **Note:** the dollar amount in NPP is mutually exclusive of the dollar amounts reported in the other payment fields: CPP, Patient Pay Amount, LICS, Other TrOOP Amount, and Patient Liability Reduction due to Other Payer Amount (PLRO). These six payment fields record six mutually exclusive types of payment. When the PDE reports a covered drug, the sum of these six payment fields is the total covered drug cost, also called the gross drug cost.

If a plan reports a value of "C" in the Drug Coverage Status field and a dollar amount in the NPP field, DDPS automatically excludes the dollar amount in NPP from risk corridor and TrOOP calculations because it is EACS.

7.3 Business Rules for Reporting Enhanced Alternative Drugs

As described above, EA drugs are identified using the drug coverage status code = E. The plan and the beneficiary pay the pharmacy according to the provisions of the plan benefit package (PBP). The full plan-paid amount is reported in NPP so that it is excluded from allowable reinsurance and risk corridor costs. There is never a CPP amount because all plan payments for EA drugs are excluded from Medicare payment. Finally, recall that no LICS is paid on supplemental drugs and no out-of-pocket or third party payments on these drugs count toward TrOOP. Therefore, the LICS Amount and Other TrOOP Amount always = $0.00 on a PDE that reports an EA drug.

7.4 Business Rules for Calculating and Reporting Enhanced Alternative Cost Sharing

Enhanced alternative cost sharing (EACS) is a key component in administering benefits and reporting PDEs. It is more complicated than reporting EA drugs. Reporting for EA drugs is straightforward because CMS uses the Drug Coverage Status Code with a value of "E" to identify EA drugs and exclude them from payment. But because EACS includes an amount the plan would have paid under a basic benefit and an additional amount the plan pays in extra cost-sharing assistance, CMS uses a slightly more complicated process

to partition the two amounts and exclude the supplemental cost-sharing from Medicare payment.

7.4.1 Mapping to the Defined Standard Benefit

PDE reporting must be consistent with bid information. EA bids have a standard component and an enhanced alternative component. To align PDE reporting with the standard component of the bid, CMS maps payments that include EACS to the defined standard benefit using special rules for reporting CPP and NPP amounts.

Note that all EACS amounts are for covered drugs, so both supplemental and standard benefits are being reported in the same PDE (unlike a PDE for an EA drug, which only includes supplemental benefits identified as such). The following section delineates the business rules that allocate covered drug costs for a PDE into covered and non-covered amounts paid by the plan. The amount associated with the defined standard benefit is reported in CPP. The amount associated with the EA benefit is classified as the supplemental cost-sharing assistance, referred to as EACS, and is reported in the NPP amount.

Tables 7B and 7C delineate how to calculate and report PDEs that have EACS, focusing on the data fields Patient Pay Amount, CPP and NPP with special rules for calculating CPP.

TABLE 7A – REPORTING EACS

STEP	DESCRIPTION	PDE FIELD
1	Report the amount paid by the beneficiary at Point of Sale (POS) in the Patient Pay Amount field.	Patient Pay Amount
2	Calculate the amount to report in the CPP field. • CPP is determined by the defined standard benefit, and will not necessarily be the same as the amount paid by the plan at POS. • CPP equals total covered drug cost multiplied by the applicable percentage for calculating the defined standard benefit (see Table 7C).	CPP
3	Determine EACS, which is the amount to report in the NPP field. • NPP equals total covered drug cost minus the sum of Patient Pay Amount, CPP, PLRO, Other TrOOP, and LICS.† • Alternatively, NPP also equals plan-paid at POS minus CPP. • EACS is reported in NPP.	NPP

† This calculation assumes that the sum of costs and payments for the PDE are equal. In the exceptional circumstance of beneficiary copay > gross drug cost, plans shall not use this calculation to determine NPP because the assumption is violated. Instead, plans shall use the alternate equation of NPP = Plan-Paid at POS minus CPP.

TABLE 7B – MAPPING TO THE DEFINED STANDARD BENEFIT TO CALCULATE CPP VERSUS EACS

RULE #	YEAR-TO-DATE (YTD) TOTAL COVERED DRUG COST	PERCENTAGE TO CALCULATE DEFINED STANDARD BENEFIT
1	≤ $250	0%
2	> $250 and ≤ $2,250	75%
3	> $2,250 and ≤ $5,100	0%
4	> $5,100 and ≤ OOP threshold	15%
5	> OOP threshold	Lesser of 95% or (Total Covered Drug Cost -$2/$5)

Note: For covered drug costs that fall above $5,100 but below the PBP's Out-of-Pocket (OOP) threshold, CMS maps to the 15 percent amount that the plan is at risk for under the standard portion of their bid (Rule #4). CMS only maps to 95 percent (15% risk payment plus 80% reinsurance payment) once the beneficiary crosses the OOP threshold of the EA plan, because reinsurance does not apply until the beneficiary crosses the OOP threshold (Rule #5).

The following patterns occur when costs are mapped to the defined standard benefit:

- When the plan pays more than what is covered in a given benefit phase under the defined standard benefit, the result is a positive EACS/NPP amount.

- When the plan and the defined standard benefit payment amounts happen to be the same, the result is a zero EACS/NPP amount.

- When the plan pays less than what is covered in a given phase under the defined standard benefit, the result is a negative EACS/NPP amount.

Definitions and terminology:

Total covered drug cost – the sum of Ingredient Cost Paid, Dispensing Fee Paid, and Total Amount Attributed to Sales Tax for a given PDE with Drug Coverage Status Code = C
Year-to-date (YTD) total covered drug cost – the sum of all total covered drug costs for a beneficiary to-date within a coverage year
Initial coverage period – the phase of the benefit above the deductible and at or below the initial coverage limit in the defined standard benefit
Enhanced coverage period – the phase of the benefit above the initial coverage limit in the defined standard benefit and up to and including the initial coverage limit in the EA plan. If the EA plan does not have an initial coverage limit, the enhanced coverage period extends up to the out-of-pocket threshold (TrOOP = $3,600).

7.5 PDE Examples

For purposes of illustration, these examples assume the simplest case. The beneficiary does not qualify for the low-income cost-sharing subsidy and the beneficiary has no other health insurance. (See Section 10.3 for examples on low-income cost-sharing subsidy eligible beneficiaries).

Plan A - EA Plan A retains the $250 deductible in the standard benefit but it eliminates the coverage gap and offers 25% cost sharing throughout the benefit until the beneficiary reaches catastrophic coverage. Because Plan A eliminates the coverage gap, a beneficiary does not reach the out-of-pocket threshold until YTD total covered drug costs equal $13,650.

Example 1 – The beneficiary's YTD total covered drug costs = $0. In Plan A's benefit structure, the beneficiary is in the deductible phase of the benefit. The beneficiary purchases a covered Part D drug for $100. Apply Rule #1.

YTD Total Covered Drug Cost ≤ $250 – Rule #1				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount (a) * 1	Plan Paid at POS (a) * 0	Covered D Plan Paid Amount (CPP) (a) * 0	EACS (a) - (b + d) or (c-d)
$100	$100	$0	$0	$0

Example 2 – The beneficiary's YTD total covered drug costs = $2,000. In Plan A's benefit structure, the beneficiary is in the initial coverage period. The beneficiary purchases a covered drug for $100. Apply Rule #2.

YTD Total Covered Drug Cost = $2000. – Rule #2				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount (a) * .25	Plan Paid at POS (a) * .75	Covered D Plan Paid Amount (CPP) (a) * .75	EACS (a) - (b + d) or (c-d)
$100	$25	$75	$75	$0

Example 3 – The beneficiary's YTD total covered drug costs = $3,000. In Plan A's benefit structure, the beneficiary is in the enhanced coverage period. The beneficiary purchases a covered drug for $100. Apply Rule #3.

YTD Total Covered Drug Cost = $3,000 - Rule #3				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount (a) * .25	Plan Paid at POS (a) * .75	Covered D Plan Paid Amount (CPP) (a) * 0	EACS (a) - (b + d) or (c-d)
$100	$25	$75	$0	$75

Example 4 – The beneficiary's YTD total covered drug costs = $6,000. In Plan A's benefit structure, the beneficiary is in the enhanced coverage period. The beneficiary purchases a covered drug for $100. Apply Rule #4. Note that above $5,100 of total covered drug cost, the amount reported in Covered D Plan Paid Amount is constrained to 15% of the total drug cost.

YTD Total Covered Drug Cost = $6,000 - Rule #4				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount (a) * .25	Plan Paid at POS (a) * .75	Covered D Plan Paid Amount (CPP) (a) * .15	EACS (a) - (b + d) or (c-d)
$100	$25	$75	$15	$60

Example 5 – The beneficiary's YTD total covered drug costs = $13,650. The beneficiary has reached $3,600 in true out-of-pocket costs, thus is in the catastrophic phase of the benefit where cost sharing is the greater of $2/$5 or 5%. The beneficiary purchases a covered drug for $100. Apply Rule #5.

YTD Total Covered Drug Cost = $13,650 - Rule #5				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount (a) * .05	Plan Paid at POS (a) * .95	Covered D Plan Paid Amount (CPP) (a) * .95	EACS (a) - (b + d) or (c-d)
$100	$5	$95	$95	$0

Plan B – EA Plan B alters cost sharing in the initial coverage period, offering tiered cost sharing (5% / 25% / 30%). (These amounts are only for purposes of illustration and are not necessarily representative of an actuarially equivalent benefit structure). Thus the initial coverage limit in this enhanced alternative plan is increased to $4,000.

Example 6 – The beneficiary's YTD total covered drug costs = $500. In Plan B's benefit structure, the beneficiary is in initial coverage phase of the benefit. The beneficiary purchases a covered drug in Tier 1 for $20. Apply Rule #2.

YTD Total Covered Drug Cost = $500 - Rule #2				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount (a) * .05	Plan Paid at POS (a) * .95	Covered D Plan Paid Amount (CPP) (a) * .75	EACS (a) - (b + d) or (c-d)
$20	$1	$19	$15	$4

Example 7 – The beneficiary's YTD total covered drug costs = $520. In Plan B's benefit structure, the beneficiary is in the initial coverage period. The beneficiary purchases a covered drug in Tier 2 for $100. Apply Rule #2.

YTD Total Covered Drug Cost = $520 - Rule #2				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount (a) * .25	Plan Paid at POS (a) * .75	Covered D Plan Paid Amount (CPP) (a) * .75	EACS (a) - (b + d) or (c-d)
$100	$25	$75	$75	$0

Example 8 – The beneficiary's YTD total covered drug costs = $620. In Plan B's benefit structure, the beneficiary is in initial coverage phase of the benefit. The beneficiary purchases a covered drug in Tier 3 for $250. Apply Rule #2.

YTD Total Covered Drug Cost = $620.00 - Rule #2				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount (a) * .30	Plan Paid at POS (a) * .70	Covered D Plan Paid Amount (CPP) (a) * .75	EACS (a) - (b + d) or (c-d)
$250.00	$75.00	$175.00	$187.50	-12.50

Plan C – EA Plan C extends the initial coverage period by $2,000 from the standard benefit limitation of $2,250 to $4,250. Plan C retains the standard benefit deductible and 25% cost sharing. Because Plan C extends the initial coverage period, beneficiaries do not reach the out-of-pocket threshold until total covered drug costs equal $6,600.

Example 9 – The beneficiary's YTD total covered drug costs = $3,000. In Plan C's benefit structure, the beneficiary remains in the enhanced coverage period. The beneficiary purchases a covered drug for $100. Apply Rule #3.

YTD Total Covered Drug Cost = $3,000 - Rule #3				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount (a) * .25	Plan Paid at POS (a) * .75	Covered D Plan Paid Amount (CPP) (a) * 0	EACS (a) - (b + d) or (c-d)
$100	$25	$75	$0	$75

Example 10 – The beneficiary's YTD total covered drug costs = $4,500. In Plan C's benefit structure, the beneficiary is in the coverage gap. The beneficiary purchases a covered drug for $100. Apply Rule #3.

YTD Total Covered Drug Cost = $4,500 - Rule #3				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount (a) * 1	Plan Paid at POS (a) * 0	Covered D Plan Paid Amount (CPP) (a) * 0	EACS (a) – (b + d) or (c-d)
$100	$100	$0	$0	$0

Example 11 – The beneficiary's YTD total covered drug costs = $6,000. In Plan C's benefit structure, the beneficiary is in the coverage gap. The beneficiary purchases a covered drug for $100. Apply Rule #4. Note that above $5,100 of total covered drug cost, the amount reported in Covered D Plan Paid Amount is constrained to 15%. Also see Example 4.

YTD Total Covered Drug Cost = $6,000 - Rule #4				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount (a) * 1	Plan Paid at POS (a) * 0	Covered D Plan Paid Amount (CPP) (a) * .15	EACS (a) - (b + d) or (c-d)
$100	$100	$0	$15	-$15

Example 12 – The beneficiary's YTD total covered drug costs = $6,600. The beneficiary has just entered the catastrophic phase of the benefit. The beneficiary purchases a covered drug for $100. Apply Rule #5.

YTD Total Covered Drug Cost = $6,600 - Rule #5				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount (a) * .05	Plan Paid at POS (a) * .95	Covered D Plan Paid Amount (CPP) (a) * .95	EACS (a) - (b + d) or (c-d)
$100	$5	$95	$95	$0

Note: If a plan decides to offer reductions in cost sharing beyond the standard benefit in the catastrophic phase of the benefit, the plan must calculate the normal beneficiary cost sharing and count the remainder of drug cost as Covered D Plan Paid Amount. As in cases below the out-of-pocket threshold, the difference between the actual plan paid amount and the Covered D Plan Paid Amount will be considered EACS and reported under Non-covered Plan Paid Amount.

Section 8. True Out-of-Pocket (TrOOP) and Other Payers

8.1 What is TrOOP

TrOOP is a pivotal concept in the Part D benefit. TrOOP is defined as incurred allowable costs that are paid by the beneficiary or by specified third parties on their behalf within the limits of the standard benefit, up to a legislatively specified out-of-pocket threshold or attachment point (§1860D-2(b)(4) of the Act). The out-of-pocket threshold is set at $3,600 for 2006 and will increase annually each subsequent year as directed by §1860D-2(b)(4)(A)(ii).

8.2 Why TrOOP matters

When a beneficiary has accumulated TrOOP costs that reach the out-of-pocket threshold, catastrophic coverage provisions begin for both the beneficiary (§1860D-2(b)(4)) and the

plan (D-15(b)). In the catastrophic phase of the benefit, beneficiaries incur lower cost-sharing amounts, and benefits provided by plans are eligible for reinsurance subsidies. Reinsurance subsidies are subsequently excluded from risk corridor calculations.

8.3 What counts towards TrOOP

In order to administer the Part D benefit, plans must differentiate between payments that are and are not included in TrOOP. Note that all TrOOP-eligible payments must be for covered Part D drugs (see Section 5).

- Payments made by beneficiaries count towards TrOOP, including out-of-pocket payments for differentials (e.g. mail order/retail, generic/brand or out-of-network differentials).
- Payments made by qualified third parties on a beneficiary's behalf count towards TrOOP.
- LICS Amounts count towards TrOOP (see Section 10).
- Payments by group health plans, insurers, government-funded health programs, and similar third party arrangements do not count towards TrOOP. *Note:* Medicaid cost sharing subsidies for residents of the U.S. territories that are funded under §1860D-42(a) of the Act count towards TrOOP. In all other circumstances, Medicaid is not a TrOOP eligible insurance.

The following chart identifies frequently occurring OHI payers by TrOOP status:

TrOOP-eligible	**Not TrOOP-eligible**
Qualified SPAPs	Governmental programs (VA, Black Lung, TRICARE, I/T/U, other)[1]
Qualified charities and PAPs	Workers' Compensation
Payments by family, friends, or other qualified entities or individuals on behalf of a beneficiary	Automobile/No-Fault/Liability Insurances
Low-income cost-sharing subsidies[2]	Group health plans

[1]Medicaid cost sharing subsidies for residents of the U.S. territories that are funded under §1860D-42(a) of the Act count towards TrOOP. In all other circumstances, Medicaid is not a TrOOP eligible insurance.
[2]Counts towards TrOOP but is not OHI (see Section 10)

8.4 Plan accountability for TrOOP accounting

Given the important consequences of TrOOP both to the patient and to the plan, the Act requires the Secretary to implement measures for coordination of benefits among other payers, referred to in this document as other health insurance or OHI (§1860D-23 and D-24). Part D plans shall be responsible for maintaining accurate accounting of TrOOP on a day-to-day basis and for coordinating benefits to that end.

8.5 What CMS will do to assist plans in the coordination of benefits and TrOOP

CMS is currently developing a TrOOP process within the NCPDP standards framework to facilitate accurate OHI billing, payment and reporting at the point of sale (POS). To support the TrOOP facilitation process, CMS will implement processes and systems to capture and document beneficiary specific OHI coverage for drugs. CMS will leverage

existing Medicare COB processes and systems and extend the capability for capturing and verifying beneficiary OHI drug coverage information. Working in collaboration with the industry, CMS's TrOOP facilitation process will integrate the validated OHI drug coverage information within the current stream of real-time transactions between the POS pharmacy, routing intermediaries, OHI payers and the Part D Plan. Beneficiary OHI drug coverage information will be made available to the Part D plans as part of the enrollment file exchange with CMS and will accommodate any OHI information the Part D plan has discovered through their own enrollment process, when the beneficiary is asked to provide OHI coverage information.

The following is a brief overview of the process:

1. A Part D beneficiary enters a pharmacy to fill a prescription. If the beneficiary does not have a card and does not know which Part D plan they are in, the pharmacy can execute an NCPDP E1 request transaction to determine plan enrollment. The E1 response will return enrollment information, including payer-specific information about any OHI drug coverage;
2. The pharmacy submits the claim to the Part D plan;
3. The Part D plan returns a response file to the pharmacy with payment information;
4. If necessary, the pharmacy will then generate a secondary claim to any other OHI payers via the TrOOP facilitator(s);
5. The OHI payer(s) will send a response back to the pharmacy routed through the TrOOP facilitator(s), and;
6. The TrOOP facilitator(s) will build an NCPDP N1[3] reporting transaction from the response and sends it to the appropriate Part D Plan;

Within the TrOOP facilitation process, the Part D plan, in combination with knowledge of its own adjudication, will have information necessary to report TrOOP-sensitive dollar fields in the PDE. In addition, the beneficiary will have the benefit of POS coordination of benefits, accurate and perhaps even reduced cash outlay at the POS, and more accurate TrOOP accounting.

8.6 PDE fields that report TrOOP information

Catastrophic Coverage Code - The Catastrophic Coverage Code values are dependent upon the level of TrOOP accumulation and hence, the beneficiary's status in the benefit. When the beneficiary crosses the threshold from the coverage gap to the catastrophic phase of the benefit, the PDE will report a value = A in the Catastrophic Coverage Code. Provided that the beneficiary's status in the benefit does not change within a coverage year, subsequent PDEs will report a value = C in the Catastrophic Coverage Code field. The Catastrophic Coverage Code field will be blank on other PDEs. In other words, a PDE with Catastrophic Coverage Code = blank indicates that the beneficiary is in the deductible phase, the initial coverage period, or the coverage gap.

[3] NCPDP is in the process of adopting revisions that were made to the N1 transaction to provide additional OHI information sufficient for Part D.

Drug Coverage Status Code - The Drug Coverage Status Code identifies covered drugs. TrOOP accumulations only include covered drugs (see Section 5).

Six payment fields - Six payment fields report TrOOP information. The dollar amounts reported in these fields are mutually exclusive:

- Patient Pay Amount
- Other TrOOP Amount
- Low-Income Cost-sharing Subsidy Amount (LICS)
- Covered D Plan Paid Amount (CPP)
- Non-covered Plan Paid Amount (NPP)
- Patient Liability Reduction due to Other Payer Amount (PLRO)

The chart below shows the impact of each dollar field on TrOOP accounting:

Field Name	**TrOOP Inclusion**	**TrOOP Exclusion**
Patient Pay Amount	**X**	
Other TrOOP Amount	**X**	
LICS	**X**	
NPP		**X**
CPP		**X**
PLRO		**X**

The following examples show how a plan would populate Patient Pay Amount, Other TrOOP, LICS, NPP, CPP, and PLRO. Assume that a pharmacy dispenses a $100 covered Part D drug with a $20 co-pay under the standard benefit:

Example	TrOOP Inclusions			TrOOP Exclusions			TrOOP Impact
	Patient Pay Amount	Other TrOOP Amount	LICS	NPP	CPP	PLRO	
Example 1: non-LICS beneficiary enrolled in basic plan, no OHI	20	0	0	0	80	0	+$ 20
Example 2: LICS beneficiary enrolled in basic plan, no OHI	3	0	17	0	80	0	+$ 20
Example 3: LICS beneficiary enrolled in basic plan, qualified SPAP or other TrOOP-eligible payer pays $3 co-pay	0	3	17	0	80	0	+$ 20
Example 4: non-LICS beneficiary enrolled in basic plan, beneficiary has OHI that pays Part D co-pay in full	0	0	0	0	80	20	$0
Example 5: non-LICS beneficiary enrolled in basic plan, beneficiary has OHI that pays $10 of the Part D co-pay	10	0	0	0	80	10	+$ 10
Example 6: non-LICS beneficiary enrolled in enhanced alternative plan. Supplemental benefit (funded by additional premium) reduces beneficiary co-pay by $5 for this particular drug.	15	0	0	5	80	0	+$ 15
Example 7: Very late in the plan year the pharmacy dispensed a drug per the scenario in example 1 and submitted a PDE. Subsequently the plan learned that the beneficiary did not pick up the prescription so the plan submitted a deletion record†	0	0	0	0	0	0	-$20

Note: TrOOP (True Out-Of-Pocket), LICS (Low-Income Cost-sharing Subsidy), NPP (Non-covered Plan Paid Amount), CPP (Covered Plan Paid Amount), PLRO (Patient Liability Reduction due to Other Payer Amount), OHI (Other Health Insurance), PDE (Prescription Drug Event).

†In example 7, we indicate -$20 TrOOP Impact to indicate that the TrOOP accumulator works as a counter and will reduce TrOOP by $20 when the deletion PDE record is received. We list zero in each dollar field because these fields are not counters, and the deletion record will indicate to CMS to reduce the dollar amounts of the original record to zero (see Section 6).

In summary the interaction between and among payment fields has a direct impact on TrOOP accounting:

> If a plan failed to report OHI payments and included the PLRO amount in the Patient Pay Amount field, TrOOP would be overstated.
>
> If a plan included EACS in the Patient Pay Amount field, TrOOP would be overstated.
>
> If a Plan included LICS dollars in the Patient Pay Amount field, TrOOP would be counted accurately, but the plan would not receive payment to which it is entitled for paying the LICS (see Section 9).

Section 9. Retroactive changes in TrOOP

As of year-end, aggregate PDE data must be consistent with year-end TrOOP balances maintained by the plan.[4] When plans have to deal with retroactive changes that alter TrOOP accounting, the plan has two choices. The plan may submit adjustments for each PDE that was affected by the retroactive changes or the plan may report as they administer the benefit, provided that PDEs accurately report TrOOP balances by the end of the coverage year. When a retroactive TrOOP change occurs, the plan may reinstate cost sharing until the beneficiary has paid back the TrOOP balance.

In Tables 9A-9B, we provide an example in which the plan learns about a retroactive change that affects TrOOP. In this scenario, the pharmacy notified the plan late about a prescription that was not picked up. This PDE deletion has important TrOOP impact. By the time the correction was identified, the beneficiary had entered the catastrophic phase of the benefit. This correction suspends catastrophic benefits including reduced beneficiary cost sharing. The plan must react in two ways. The plan must update its day-to-day TrOOP accounting and the plan must act accordingly to assure that PDEs reflect accurate TrOOP status by year-end. In order to update day-to-day TrOOP accounting, this plan decided to implement a TrOOP account receivable. The plan will not resume catastrophic benefit cost sharing until the beneficiary has repaid additional cost sharing equal to the value of the account receivable. The example includes sample PDE records for two scenarios, both when the plan reports PDEs as it administers the benefit and when the plan submits adjustments. In a complex case like this one, when a single beneficiary crosses the OOP threshold twice, we expect two PDEs with a Catastrophic Coverage Code value = A. Typically, a beneficiary reaches the OOP threshold only once in any

[4] Unlike some commercial insurance, Part D plans shall not carry forward negative TrOOP (or co-pay) balances from one coverage year to the next because Part D payment reconciliation must be calculated on a coverage year basis.

given coverage year, and we expect only one active PDE record with a Catastrophic Coverage Code value = A per coverage year.

Table 9A. Retroactive TrOOP Changes: Reported as Administered

This table is an example of a plan reporting retroactive changes in true out-of-pocket costs (TrOOP) to CMS according to how the plan administers the benefit (see Section 9). On June 7 the pharmacy notified the plan that the beneficiary did not pick up a 4/15 prescription. The plan had already submitted a PDE record and incremented TrOOP based on the 4/15 prescription. The 4/15 PDE deletion has important TrOOP impact because the beneficiary had entered the catastrophic phase of the benefit by the time the correction was identified. In order to update day-to-day TrOOP accounting, this plan decided to implement a beneficiary account receivable. The plan will resume 100% coinsurance until the beneficiary has repaid additional cost sharing equal to the value of the account receivable. The plan implemented the correction on June 7. PDEs with service dates 6/15, 6/30 and 7/15 show that the beneficiary paid 100% coinsurance. The 7/30 PDE shows that the beneficiary has paid back the receivable and re-entered catastrophic coverage. By the time the plan adjudicated the 8/15 PDE, the TrOOP balance had been corrected. Note that if this scenario had occurred late in the coverage year when the plan expected insufficient PDE volume to net out the account receivable, the plan's only option would be to submit adjustment PDEs and recover the overpayment directly from the beneficiary (see example 4).

Clm ID	DOS	Note	YTD Ingredient Cost + Dispensing + Sales Tax	YTD TrOOP	TrOOP Payback	Claim-level Ingredient Cost + Dispensing + Sales Tax	Plan Paid	Pt Paid	LICS	EACS	PLRO	Cat Cov Flag	Gross Drug Cost Below OOP Threshold	Gross Drug Cost Above OOP Threshold
1	1/15/2006	*a*	610.00	340.00		610.00	270.00	340.00	0.00	0.00	0.00		610.00	0.00
2	1/30/2006		1,220.00	492.50		610.00	457.50	152.50	0.00	0.00	0.00		610.00	0.00
3	2/15/2006		1,830.00	645.00		610.00	457.50	152.50	0.00	0.00	0.00		610.00	0.00
4	2/28/2006	*b*	2,440.00	940.00		610.00	315.00	295.00	0.00	0.00	0.00		610.00	0.00
5	3/15/2006		3,050.00	1,550.00		610.00	0.00	610.00	0.00	0.00	0.00		610.00	0.00
6	3/30/2006		3,660.00	2,160.00		610.00	0.00	610.00	0.00	0.00	0.00		610.00	0.00
7	4/15/2006-orig		4,270.00	2,770.00		610.00	0.00	610.00	0.00	0.00	0.00		610.00	0.00
8	4/30/2006		4,880.00	3,380.00		610.00	0.00	610.00	0.00	0.00	0.00		610.00	0.00
9	5/15/2006	*c*	5,490.00	3,619.50		610.00	370.50	239.50	0.00	0.00	0.00	A	220	390
10	5/30/2006		6,100.00			610.00	579.50	30.50	0.00	0.00	0.00	C	0.00	610
		d			**610.00**				0.00	0.00	0.00			
		e	-610.00			-610.00		-610.00					-610.00	
11	6/15/2006	*F*	5690.00		**410.00**	200.00	0.00	200.00	0.00	0.00	0.00		200.00	0.00
12	6/30/2006	*F*	5,890.00		**210.00**	200.00	0.00	200.00	0.00	0.00	0.00		200.00	0.00
13	7/15/2006	*F*	6,090.00		**10.00**	200.00	0.00	200.00	0.00	0.00	0.00		200.00	0.00
14	7/30/2006	*g*	6,290.00		**0.00**	200.00	180.50	19.50	0.00	0.00	0.00	A	10.00	190.00
15	8/15/2006		6,490.00			200.00	190.00	10.00	0.00	0.00	0.00	C	0.00	200.00

a Beneficiary crosses from deductible to initial coverage period. Beneficiary pays $250 deductible + $90 coinsurance (.25*(610-250)). Plan pays $270 (.75*(610-250))

b Beneficiary crosses from initial coverage period to coverage gap. Beneficiary pays initial coverage period coinsurance of $105 (.25 * (2250-1830) + coverage gap coinsurance of $190 (1.0* (610 - (2250-1830))). Plan pays $315 (.75 * (2250 - 1830))

c Beneficiary crosses from initial coverage period to coverage gap. Beneficiary pays coverage gap coinsurance of $220.00 (1.0 * (3600-3380)) + catastrophic coinsurance of $9.00 (.05 * (200 - (3600-3580))). Plan pays catastrophic $370.50 (.95 * (610 - (3600-3380)))

d On June 7 plan discovers that the beneficiary did not pick up 4/15 prescription. It submits a PDE deletion record for the 4/15 PDE and establishes a receivable account.

e Corrections

f Beneficiary re-enters coverage gap

g Beneficiary re-enters catastrophic coverage

Table 9B. Retroactive TrOOP Changes: Reported as Adjustments

This table is an example of a plan reporting retroactive changes in a beneficiary's true out-of-pocket (TrOOP) costs by submitting pertinent adjustment records to CMS (see Section 9). On June 7 the pharmacy notified the plan that the beneficiary did not pick up a 4/15 prescription. The plan had already submitted a PDE record and incremented TrOOP based on the 4/15 prescription. The 4/15 PDE deletion has important TrOOP impact because the beneficiary had entered the catastrophic phase of the benefit by the time the correction was identified. In order to update day-to-day TrOOP accounting, this plan decided to recover the TrOOP overpayment directly from the beneficiary. On June 7 when the plan discovers the error, the plan deletes the 4/15 PDE and submits adjustments for PDEs with service dates 4/30, 5/15 and 5/30. By the time the plan submits the 6/15 PDE, all corrections have been completed.

Clm ID	DOS	Note	YTD Ingredient Cost + Dispensing + Sales Tax	YTD TrOOP	Claim-level Ingredient Cost + Dispensing + Sales Tax	Plan Paid	Pt Paid	LICS	EACS	PLRO	Cat Cov Flag	Gross Drug Cost Below OOP Threshold	Gross Drug Cost Above OOP Threshold
1	1/15/2006	*a*	610.00	340.00	610.00	270.00	340.00	0.00	0.00	0.00		610.00	0.00
2	1/30/2006		1,220.00	492.50	610.00	457.50	152.50	0.00	0.00	0.00		610.00	0.00
3	2/15/2006		1,830.00	645.00	610.00	457.50	152.50	0.00	0.00	0.00		610.00	0.00
4	2/28/2006	*b*	2,440.00	940.00	610.00	315.00	295.00	0.00	0.00	0.00		610.00	0.00
5	3/15/2006		3,050.00	1,550.00	610.00	0.00	610.00	0.00	0.00	0.00		610.00	0.00
6	3/30/2006		3,660.00	2,160.00	610.00	0.00	610.00	0.00	0.00	0.00		610.00	0.00
7	*4/15/2006*		*4,270.00*	*2,770.00*	*610.00*	*0.00*	*610.00*	*0.00*	*0.00*	*0.00*		*0.00*	*0.00*
		d	3,660.00	2,160.00									
8	*4/30/2006*		*4,880.00*	*3,380.00*	*610.00*	*0.00*	*610.00*	*0.00*	*0.00*	*0.00*		*0.00*	*0.00*
		e	4,270.00	2,770.00	610.00	0.00	610.00	0.00	0.00	0.00		610.00	0.00
9	5/15/2006	*c*	*5,490.00*	*3,619.50*	*610.00*	*370.50*	*239.50*	*0.00*	*0.00*		*A*	*220.00*	*390.00*
		f	4,880.00	3,380.00	610.00	0.00	610.00	0.00	0.00	0.00		610.00	0.00
10	5/30/2006		*6,100.00*	*3,650.00*	*610.00*	*579.50*	*30.50*	*0.00*	*0.00*		*C*		*610.00*
		g, h	5,490.00	3,619.50	610.00	370.50	239.50	0.00	0.00	0.00	A	220.00	390.00
11	6/15/2006		5,690.00	3,629.50	200.00	190.00	10.00	0.00	0.00	0.00	C	0.00	200.00

a Beneficiary crosses from deductible to initial coverage period. Beneficiary pays $250 deductible + $90 coinsurance (.25*(610-250)). Plan pays $270 (.75*(610-250))

b Beneficiary crosses from initial coverage period to coverage gap. Beneficiary pays initial coverage period coinsurance of $105 (.25 * (2250-1830) + coverage gap coinsurance of $190 (1.0* (610 - (2250-1830))). Plan pays $315 (.75 * (2250 - 1830))

c Beneficiary crosses from coverage gap to catastrophic. Beneficiary pays coverage gap coinsurance of $220.00 (1.0 * (3600-3380)) + catastrophic coinsurance of $9.00 (.05 * (200 - (3600-3580))). Plan pays catastrophic $370.50 (.95 * (610 - (3600-3380)))

d Deleted PDE for 15-April-06 service date

e Adjusted PDE for 30-Apr-2006 service date

f Adjusted PDE for 15-May-2006 service date

g Adjusted PDE for 30-May-2006 service date

h Beneficiary re-enters catastrophic coverage

Section 10. Low Income Cost-Sharing Subsidy (LICS)

10.1 Definition

Section 1860D-14 of the Act provides for Medicare payments to plans to subsidize the cost-sharing liability of qualifying low-income beneficiaries, including plan premiums, deductibles, coinsurances, and late enrollment penalties. The statute divides these income-related subsidies into two categories: premium assistance and cost-sharing assistance. Premium subsidies are taken into account via other data streams and do not impose any PDE data reporting requirements on plans. However, LICS assistance is documented and reconciled using PDE data.

These cost-sharing subsidies, referred to as Low Income Cost-Sharing Subsidies (LICS), are applied at the point of sale (POS) and paid by the plan. CMS makes prospective LICS payments to plans to cover anticipated LICS at POS. The LICS payments plans make on behalf of beneficiaries at POS must be reported to CMS on PDE records. CMS will reconcile these actual paid amounts with the prospective payments.

Plans must implement business rules that apply LICS calculations to covered drugs and facilitate the accurate processing and timely submission of PDE records. Plans will adjudicate claims and report PDEs in accordance with the level of assistance for which the beneficiary is eligible. The table below outlines the four LICS assistance levels. LICS beneficiaries have continuous coverage for Part D covered drugs with one exception: Level III beneficiaries are assigned a $50 deductible that is indexed annually or, if less, the PBP deductible. They then have continuous coverage.

TABLE 10A LICS CATEGORIES

			Maximum LICS Beneficiary Cost Sharing, 2006			
LICS Level	**MBD Code**	**Income Category (% FPL)**	**Deductible**	**Initial Coverage Period**	**Coverage Gap**	**Catastrophic Phase**
I	2	≤100% and fbde	$0	$1-generic $3-brand	$1-generic $3-brand	$0
II	1	<135%, or >100% and fbde	$0	$2-generic $5-brand	$2-generic $5-brand	$0
III	4	<150%	$50	15%	15%	$2-generic $5-brand
Inst	3	Institutionalized fbde	$0	$0	$0	$0

Notes: MBD (Medicare Beneficiary Database); fbde (full benefit dual eligible); Inst (institutionalized).
To be eligible for LICS, beneficiaries must also pass certain asset tests. For a complete description of eligibility rules, see §1860D-14(a)(3)(D) and (E).
In general, there are two phases of low income cost sharing: the cost sharing that is assigned before catastrophic coverage and the cost sharing that is assigned during the catastrophic coverage period. Pre-catastrophic low income cost sharing begins when the beneficiary purchases his/her first Part D covered drug of the benefit year. The only exception is the Level III beneficiary in a plan with a deductible. These beneficiaries must first satisfy a deductible amount equal to the statutory amount or, if less, the plan deductible.
An MBD code of 0 (zero) means no LICS eligibility.
The values in this table are indexed annually as per §1860D-14(a)(4).

Generic also includes a preferred multiple source drug as defined in §1860D-2(b)((2)(D)(ii) of the MMA.

A **full-benefit dual eligible (fbde)** beneficiary is an individual who has prescription drug coverage for the month under a Prescription Drug Plan (PDP) or Medicare Advantage – Prescription Drug (MA-PD) plan and is determined eligible by the state for medical assistance under Title XIX of the Act (42 CFR 423.772).

For purposes of determining LICS level, an **institutionalized** beneficiary is a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for whom payment is made under Medicaid for a month (§1860D-14(a)(1)(D)(i)). When an individual enters such institution, community co-pay levels apply until the beneficiary has spent a continuous, full calendar month in the institution. The zero costing sharing provision only applies after a continuous stay of one calendar month.

Regardless of the plan type, the following rules for calculating and reporting LICS remain constant:

- LICS only applies to covered Part D drugs; the low-income beneficiary pays the same cost sharing for non-covered drugs as any other beneficiary under their benefit package.

- The categories in Table 10A apply to all LIS eligible individuals except for beneficiaries residing in the U.S. territories to whom different low income subsidy provisions apply. In addition, calculations of LICS for the PACE program are unique as laid out in Section 14.

- LICS always counts towards True Out-of-Pocket (TrOOP) costs.

- Supplemental benefits provided under the PBP are always applied before LICS is calculated.

- LICS rules in this Section apply to low-income subsidy beneficiaries in both basic and enhanced plans.

10.2 Reporting requirements

Section 1860D-14(c) of the Act mandates that the Secretary notify plans when a beneficiary is eligible for LICS; the plan must then provide for appropriate beneficiary cost sharing and also submit information to the Secretary reporting the amount of the reduction. Finally, the Secretary shall reimburse the plan periodically and timely for these amounts. In order to pay the plan accurately, CMS has defined a Low Income Cost-Sharing Subsidy (LICS) Amount field.[5] Plans will populate the LICS Amount field with the amount they pay the pharmacy at the point of sale for an eligible beneficiary's cost sharing.

In formula:

When Non-LI cost sharing > LI cost sharing, then
LICS Amount = Non-LI beneficiary cost sharing – LI beneficiary cost sharing

When Non-LI cost sharing ≤ LI cost sharing, then LICS Amount = zero†

Notes: Non-LI (non-low income subsidy eligible); LI (low income subsidy eligible).
†When non-LI cost sharing ≤ LI cost sharing, then the non-LI cost sharing is applied to the LI beneficiary and LICS Amount = 0.

We refer to this formula as the LICS Amount formula. The non-low income (non-LI) cost sharing is the amount due from a non-low income subsidy beneficiary for a given dispensing event under the plan benefit package. The low-income (LI) cost sharing is the maximum allowable amount due under the Act from a low-income subsidy beneficiary for that same dispensing event (see Table 10A) or, if less, the cost sharing under the plan benefit package. The difference between the non-LI and LI cost sharing is the amount subsidized by the plan at point of sale and ultimately by CMS.

- **Lesser Of Test:** In accordance with statutory and regulatory provisions, if the applicable LI cost-sharing amount is greater than the amount of cost sharing that would be due under the plan benefit package (standard or enhanced) for a

[5] The low-income cost-sharing subsidy is unique to Medicare. There is no NCPDP field to capture this information.

beneficiary who is not LI, the beneficiary is only responsible for the non-LI (lesser) cost-sharing amount. This logic, referred to as the Lesser Of test, shall be used to determine all LI co-pays and coinsurances as well as any deductible applicable to a Level III beneficiary.

Specifically, when PBP deductible < Level III deductible: The Part D final rule in §423.782(b)(2) states that low-income cost sharing for the Level III beneficiary is a 15% coinsurance "after the annual deductible under the plan." Accordingly, in the LICS Amount formula, the Level III cost sharing shall include whichever is less: the statutory Level III deductible or a lower deductible amount if provided under the plan benefit package. In practice, this means that the LICS Amount formula shall not include a Level III deductible amount that is greater than that under the PBP.

In sum, in the LICS Amount formula and the lesser of test:

- Include the entire Level III deductible when PBP deductible ≥ statutory Level III amount ($50 in 2006).
- Include a partial Level III deductible equal to the PBP amount if the PBP deductible is < the statutory Level III amount and > $0.
- Exclude the entire Level III deductible when the PBP has a deductible = $0.

These rules apply to low-income subsidy beneficiaries in both basic and enhanced plans. Also note that year to date (YTD) total covered drug cost, not TrOOP cost, satisfies deductibles in Part D. Therefore, if the YTD gross covered drug cost ≥ the Level III deductible amount, even if a third party payment or the lesser of test has reduced actual beneficiary liability below that amount, the beneficiary has met his/her Level III deductible.

- If a beneficiary has any other health insurance, whether TrOOP-eligible or not, the LICS Amount formula must use cost sharing amounts as calculated *before* any wrap-around coverage is applied. However, this rule does not apply when Medicare is a secondary payer (MSP). See Section 17 for MSP calculations.

10.3 PDE Examples

The following examples demonstrate how plans will populate the PDE fields Patient Pay Amount, LICS Amount and Other TrOOP Amount. They also illustrate how plans will identify TrOOP-eligible dollars at the PDE level. We show a variety of benefit permutations, summarized as follows:

LICS Examples in Section 10

Example #	Deductible amount	Plan type	Structure	Other TrOOP	Covered drug	EA drug
All Levels (I, II, III, Inst)						
1-4	≥ statutory Level III amount[1]	basic	tiered	—	X	—
5	≥ statutory Level III amount	basic	tiered	X	X	—
6	≥ statutory Level III amount	EA	tiered	—	X	—
7	≥ statutory Level III amount	EA	tiered	—	—	X
Level III						
8	≥ statutory Level III amount	basic	defined standard	—	X	—
9	< statutory Level III amount and > 0	basic	coinsurance	—	X	—
10	zero	basic	coinsurance	—	X	—
11	zero	EA	copay	—	X	—

[1]$50 in 2006

Examples 1-7 show calculating and reporting for all four assistance levels under two plans with a deductible amount ≥ the statutory level III amount ($50 in 2006). Examples 1-5 show reporting for a basic plan with a 5% generic/25% preferred brand/30% non-preferred brand tiered cost sharing structure. In examples 1-4, we show a PDE for each benefit phase and the beneficiary has no other health insurance. In example 5, a TrOOP- eligible third party makes a payment on behalf of the low-income beneficiary.

Examples 6 and 7 show sample data for a low-income subsidy beneficiary in an enhanced alternative plan (see Section 7) with the same deductible assumptions and a tiered benefit structure. Example 6 demonstrates how enhanced alternative plans will report enhanced alternative cost sharing. Example 7 demonstrates how enhanced alternative plans will report enhanced alternative (supplemental) drugs for LI beneficiaries.

Examples 8-11 illustrate calculating and reporting for Level III beneficiaries in plans with deductibles that are greater than, less than or equal to the statutory Level III amount ($50 in 2006). In example 8, we begin with a plan deductible that is ≥ the statutory amount such that the L-III beneficiary pays the full statutory amount. In example 9, the plan's deductible is < the statutory Level III amount but > 0 such that the L-III beneficiary pays a portion of the statutory amount. In example 10, the plan has no deductible so the L-III beneficiary does not pay any deductible and their 15% coinsurance provision begins with the first covered drug of the year.

Examples 8-10 are basic plans. We add example 11 to show that the calculating and reporting rules for Level III deductibles do not change for enhanced plans.

Note the following definitions:
Total Covered Drug Cost – the sum of Ingredient Cost Paid, Dispensing Fee Paid, and Total Amount Attributed to Sales Tax for a given PDE
Year-to-date (YTD) Total Covered Drug Cost – the sum of all Total Covered Drug Costs for a beneficiary to-date within a coverage year

Initial coverage period – the phase above the deductible and at or below the defined standard initial coverage limit
LICS – reports the difference between Patient Pay Amount for a non-LI beneficiary and the Patient Pay Amount for a beneficiary under an LICS subsidy

Example 1 – This is the first claim for each beneficiary. YTD Total Covered Drug Cost = $0 which places the beneficiary in the deductible phase of the benefit. The beneficiary purchases a covered drug in Tier 2 (preferred brand) for $50.

	(a)	(b)	(c)	(d)	(e)
Beneficiary Type	Total Covered Drug Cost (b)+(c)+(d)	Patient Pay Amount	LICS	Covered D Plan Paid Amount (CPP)	TrOOP Amount (b) + (c)
Non-LI	$50	$50	n/a	$ 0	$50
L-I	$50	$ 3	$47	$ 0	$50
L-II	$50	$ 5	$45	$ 0	$50
L-III	$50	$50†	$ 0	$ 0	$50
Institutionalized	$50	$0	$50	$ 0	$50

†L-III beneficiary satisfies deductible

Example 2 – The beneficiary's YTD total covered drug cost = $500 which places the beneficiary in the initial coverage period. The beneficiary purchases a covered drug in Tier 1 (a generic drug) for $5.

	(a)	(b)	(c)	(d)	(e)
Beneficiary Type	Total Covered Drug Cost (b)+(c)+(d)	Patient Pay Amount	LICS	Covered D Plan Paid Amount (CPP)	TrOOP Amount (b) + (c)
Non-LI	$5.00	$.25	n/a	$ 4.75	$.25
L-I	$5.00	~~$1.00*~~ $.25	$ 0.00	$ 4.75	$.25
L-II	$5.00	~~$2.00~~* $.25	$ 0.00	$ 4.75	$.25
L-III	$5.00	~~$.75~~* $.25	$ 0.00	$ 4.75	$.25
Institutionalized	$5.00	$0.00	$ .25	$ 4.75	$.25

*Lesser Of logic

Example 3 – The beneficiary's YTD total covered drug cost = $3,000 which places the beneficiary in the coverage gap. The beneficiary purchases a covered drug in Tier 3 (non-preferred brand) for $250.

	(a)	(b)	(c)	(d)	(e)
Beneficiary Type	Total Covered Drug Cost (b)+(c)+(d)	Patient Pay Amount	LICS	Covered D Plan Paid Amount (CPP)	TrOOP Amount (b) + (c)
Non-LI	$250	$250	n/a	$ 0	$250
L-I	$250	$3	$ 247	$ 0	$250
L-II	$250	$5	$ 245	$ 0	$250
L-III	$250.00	$37.50	$ 212.50	$ 0.00	$250.00
Institutionalized	$250	$0	$ 250	$ 0	$250

Example 4 – The beneficiary reaches the out-of-pocket threshold (equivalent to $3,600 in TrOOP in 2006) and enters the catastrophic phase of the benefit. The beneficiary purchases a covered drug in Tier 2 for $150.

	(a)	(b)	(c)	(d)	(e)
Beneficiary Type	Total Covered Drug Cost (b)+(c)+(d)	Patient Pay Amount	LICS	Covered D Plan Paid Amount (CPP)	TrOOP Amount (b) + (c)
Non-LI	$150.00	$7.50	n/a	$ 142.50	$7.50
L-I	$150.00	$0.00	$ 7.50	$ 142.50	$7.50
L-II	$150.00	$0.00	$ 7.50	$ 142.50	$7.50
L-III	$150.00	$5.00	$ 2.50	$ 142.50	$7.50
Institutionalized	$150.00	$0.00	$ 7.50	$ 142.50	$7.50

Example 5 – This example is a modification of Example 3. The low-income beneficiary receives assistance from a qualified SPAP. Note the difference between Patient Pay Amount and Other TrOOP Amount. The qualified SPAP assumes responsibility for the cost-share on behalf of the low-income beneficiary. Since qualified SPAPs are TrOOP-eligible payers, the amount paid by the SPAP is reported in the PDE field named Other TrOOP and the Patient Pay Amount is reduced to zero.

	(a)	(b)	(c)	(d)	(e)	(f)
Beneficiary Type	Total Covered Drug Cost (b)+(c)+(d)+(e)	Patient Pay Amount	LICS	Other TrOOP Amount	Covered D Plan Paid Amount (CPP)	TrOOP Amount (b)+(c)+(d)
Non-LI	$250	$250	n/a	$0	$0	$250
L-I	$250	~~$3~~ $0	$247	$3	$0	$250
L-II	$250	~~$5~~ $0	$245	$5	$0	$250
L-III	$250.00	~~$37.50~~ $0.00	$212.50	$37.50	$0.00	$250.00
Institutionalized	$250	$0	$250	$0	$0	$250

Example 6 – Assume that the low-income beneficiary enrolls in an enhanced alternative (EA) plan. Unlike the plan referenced in Examples 1-5, this plan may charge a supplemental premium from which it funds benefits that exceed the basic benefit (see Section 7). In this example, the EA plan reduces cost sharing from 25% in the standard benefit to 15%. The difference of 10% is enhanced alternative cost sharing. The beneficiary is in the initial coverage period of the benefit and purchases a covered brand drug for $100.

	(a)	(b)	(c)	(d)	(e)	(f)
Beneficiary Type	Total Covered Drug Cost (b)+(c)+(d)+(e)	Patient Pay Amount	LICS	EACS*	Covered D Plan Paid Amount (CPP)	TrOOP Amount (b)+(c)
Non-LI	$100	$15	n/a	$10	$ 75	$15
L-I	$100	$ 3	$12	$10	$ 75	$15
L-II	$100	$ 5	$10	$10	$ 75	$15
L-III	$100	$15	$ 0	$10	$ 75	$15
Institutionalized	$100	$ 0	$15	$10	$ 75	$15

*Reported in Non-covered Plan Paid Amount (NPP) field on the PDE record

Example 7 – The same EA plan referenced in example 6 also offers a supplemental drug benefit (see Section 5). The beneficiary out-of-pocket under this plan remains 15% since 10% of cost sharing is subsidized by the plan as EACS. The beneficiary is in the initial coverage period and purchases a supplemental drug for $100. The drug coverage status code = E. Low-income beneficiaries pay the same cost sharing on these supplemental drugs as any other beneficiary because low-income cost-sharing subsidies do not apply to supplemental drugs. Also note that beneficiary cost sharing for these drugs does not count towards TrOOP.

	(a)	(b)	(c)	(d)	(e)	(f)
Beneficiary Type	Total Covered Drug Cost (b)+(c)+(d)+(e)	Patient Pay Amount	LICS	Non-Covered Plan Paid Amount (NPP)	Covered D Plan Paid Amount (CPP)	TrOOP Amount (b)+(c)
Non-LI	$0	$15	n/a	$85	$ 0	$ 0
L-I	$0	$15	$ 0	$85	$ 0	$ 0
L-II	$0	$15	$ 0	$85	$ 0	$ 0
L-III	$0	$15	$ 0	$85	$ 0	$ 0
Institutionalized	$0	$15	$ 0	$85	$ 0	$ 0

Example 8 – Assume a Level III beneficiary in a defined standard plan with a $250 deductible. Their first two claims of the year have a negotiated price (gross drug cost) of $100 each and both are for covered drugs. In the lesser of test, we include a $50 deductible for the first claim in the calculation on the Level III side. After the $50 deductible is met, we apply the 15% coinsurance provision to the remaining drug cost in Claim 1 and to the total drug cost in Claim 2.

	(a)	(b)	(c)	(d)	(f)
Beneficiary Type/Claim	Total Covered Drug Cost (b)+(c)+(d)	Patient Pay Amount	LICS Amount	Covered D Plan Paid Amount (CPP)	TrOOP Amount (b)+(c)
Non-LI Claim 1	$100	$100	n/a	$0	$100
Non-LI Claim 2	$100	$100	n/a	$0	$100
L-III Claim 1	$100	$57.50[1]	$42.50	$0	$100
L-III Claim 2	$100	$15[2]	$85	$0	$100

[1]$57.50 = $50.00 + (0.15 * $50.00)
[2]$15.00 = 0.15 * $100.00

Example 9 – Assume a Level III beneficiary in a basic PBP in 2006 that has a $30 deductible then 25% coinsurance in the initial coverage period. We show the first two claims of the year for the beneficiary, applying the lesser of rule by including a $30 deductible (not $50) in the calculation on the Level III side. The negotiated prices are $25 for a generic drug in the first claim and $200 for the second claim; both are covered drugs.

	(a)	(b)	(c)	(d)	(f)
Beneficiary Type	Total Covered Drug Cost (b)+(c)+(d)	Patient Pay Amount	LICS	Covered D Plan Paid Amount (CPP)	TrOOP Amount (b)+(c)
Claim 1 Non-LI	$25	$25	n/a	$0	$25
Claim 2 Non-LI	$200	$53.75[1]	n/a	$146.25	$53.75
Claim 1 L-III	$25	$25[2]	$0	$0	$25
Claim 2 L-III	$200	$34.25[3]	$19.50	$146.25	$53.75

[1]$53.75 = $5 remaining deductible + (0.25*$195)
[2]L-III beneficiary pays $25 of the $30 PBP deductible
[3]$34.25 = $5 remaining deductible + (0.15*$195)

Example 10 – Assume a Level III beneficiary in a basic PBP with zero deductible and 25% cost sharing in the initial coverage period. This is the beneficiary's first claim of the year and the negotiated price (gross drug cost) is $100; it is a covered drug. In the lesser of test, we exclude any deductible from the calculation on the Level III side and only use 15% coinsurance. The L-III beneficiary receives the 15% coinsurance provision beginning with their first covered drug of the year.

	(a)	(b)	(c)	(d)	(f)
Beneficiary Type	Total Covered Drug Cost (b)+(c)+(d)	Patient Pay Amount	LICS	Covered D Plan Paid Amount (CPP)	TrOOP Amount (b)+(c)
Non-LI	$100	$25	n/a	$75	$25
L-III	$100	$15[1]	$10	$75	$25

[1]$15.00 = 0.15 * $100.00

Example 11 - Assume a Level III beneficiary who has paid a supplemental premium to enroll in an enhanced alternative plan. The plan has zero deductible and a copay of $25 for a $100 covered drug dispensed as the first claim of the year. We use the lesser of rule, including no deductible in the calculation on the Level III side; the beneficiary receives 15% coinsurance provision beginning with their first covered drug of the year. The calculations for LICS remain the same as in examples under basic plans. The only difference in calculating and reporting for the PDE record under this enhanced plan is that the gross drug cost is mapped to the defined standard benefit to determine CPP and NPP Amounts (see Section 7.4.1).

	(a)	(b)	(c)	(d)	(e)	(f)
Beneficiary Type	Total Covered Drug Cost (b)+(c)+(d)+(e)	Patient Pay Amount	LICS	Covered D Plan Paid Amount (CPP) (a) * 0	Non-covered Plan Paid Amount (NPP)	TrOOP Amount (b)+(c)
Non-LI	$100	$25	n/a	$0	$75	$25
L-III	$100	$15[1]	$10	$0	$75	$25

[1]$15.00 = 0.15 * $100.00

Section 11. Direct and Indirect Remuneration (DIR)

11.1 Definition

In order for covered drug costs to count towards allowable reinsurance or risk corridor costs, the Act and the final rule require the costs to be incurred and actually paid by the Part D sponsor, net of any direct or indirect remuneration which includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers from any source, including manufacturers, pharmacies, enrollees, or any other person, that would serve to decrease the costs incurred by the Part D sponsor for the drug (§1860D-15(b)(2) and (e)(1)(b), 42 CFR §423.308). We refer to all such direct or indirect remuneration as DIR. DIR must be excluded from allowable reinsurance and risk corridor costs (see Sections 12-13).

11.2 Reporting requirements

Some DIR may already be reflected in the amount paid (sum of ingredient cost, dispensing fee, plus applicable sales tax) at the point of sale. However, all DIR that is not factored into the point of sale price and thus is not reflected in the costs reported on the PDE must be reported to CMS separately. These DIR will be excluded from allowable costs.

Plans must report these DIR to CMS within six months of the end of the year. DIR dollars must be reported in full with no reduction for administrative cost or any other fees. Plans will submit DIR amounts to CMS in the following three categories:

1) DIR dollars for non-covered drugs as defined in Section 5;

2) DIR dollars for covered Part D drugs as defined in Section 5; and
3) Total DIR (the sum of 1 and 2).

Non-covered drugs are benefits beyond the standard benefit while covered Part D drugs constitute a plan's basic benefit. Distinguishing DIR dollars for drugs in these two categories enables CMS to calculate reinsurance and risk corridor payments net of DIR and based only on the basic benefit, in accordance with legislation.

Section 12. Reinsurance

12.1 Definition
Reinsurance is designed to reduce the risk of participating in the Part D program, where the federal government subsidizes 80 percent of covered Part D drug costs incurred and actually paid by the plan in the catastrophic phase of the benefit, net of DIR (§1860D-15(b)(2), §423.308). A beneficiary enters the catastrophic phase of the benefit after accumulating $3,600 in true out-of-pocket costs (see Section 8). The $3,600 limit in TrOOP costs is referred to as the out-of-pocket threshold or attachment point. The amount of $3,600 is specific to 2006 and increases annually each subsequent year as per §1860D-2(b)(4)(B)(i).

Thus, the reinsurance subsidy applies to drug costs accumulated after the beneficiary reaches the attachment point, net of DIR. We also apply other statutory exclusions based on plan type, covered Part D drug status, and enhanced alternative benefits. After these exclusions have been applied, we refer to the remaining costs used in final reconciliation as Allowable Reinsurance Costs (§1860D-15(b)(2)).

Plan level exclusions – CMS will not calculate reinsurance for fallback plans because they do not receive reinsurance and are instead paid allowable costs under the standard benefit (§1860D-15(e)(1)(B)). Private fee-for-service (PFFS) plans will receive reinsurance according to separately legislated parameters as per §1860D-21(d)(4) and as set forth in the Advance and Final Notices of Methodological Changes for Calendar Year (CY) 2006 Medicare Advantage (MA) Payment Rates (http://www.cms.hhs.gov/healthplans/rates/).

Excluding enhanced alternative costs related to non-covered drugs –Allowable Reinsurance Costs only include those costs above the OOP threshold that would have been paid under the basic prescription drug coverage (§1860D-15(b)(2)). Thus we will exclude all costs related to drugs that the statute specifies as non-covered from our calculation of Allowable Reinsurance Costs, i.e., all drugs that have Drug Coverage Status Codes of E or O (see Section 5).

12.2 Calculating allowable reinsurance costs for reconciliation
As in all other Part D payment reconciliation, reinsurance calculations will be carried out at the individual beneficiary level with costs aggregated up to the plan (PBP) level. To calculate allowable reinsurance costs, we will use the Gross Drug Cost Above the Out-of-Pocket Threshold (GDCA) and Catastrophic Coverage Code fields to identify all active PDE records for covered Part D drugs for beneficiaries who reached the attachment point.

We will aggregate each beneficiary's GDCA for PDEs with Catastrophic Coverage Codes = A or C. We will sum these at the plan level to determine the incurred reinsurance costs.

Next, we will apportion DIR to these incurred reinsurance costs by taking the ratio of costs above the out-of-pocket threshold to total covered drug costs then applying it to covered Part D DIR. We will subtract the DIR allocated to reinsurance costs (referred to as reinsurance DIR) from incurred reinsurance costs to derive the allowable reinsurance costs. Finally, we multiply the allowable reinsurance costs by 80 percent to determine the federal government liability.

In formula:
Reinsurance DIR = (Gross Drug Cost Above the Out-of-Pocket Threshold /Total Gross Drug Cost) * covered Part D DIR
Allowable reinsurance costs= (incurred reinsurance costs – reinsurance DIR)
Reinsurance payment = (allowable reinsurance costs*0.80)

Example
A plan had $1,000,000 in incurred reinsurance costs and total allowed costs of $6,100,000. Covered Part D DIR = $610,000.

Reinsurance DIR = ($1m/$6.1m)*$610,000 = $100,000
Allowable reinsurance costs = ($1m - $100,000) = $900,000
Reinsurance payment = ($900,000)*0.80 = $720,000

The resulting reinsurance payment amount ($720,000 in the example) will be reconciled with prospective reinsurance payment amounts made to plans during the coverage year (see Section 13).

Calculating and reconciling allowable reinsurance costs can also be considered as a 6-step process:

1. Plan level exclusions - We will use plan type to exclude drug data submitted by fallback and PFFS plans from allowable reinsurance cost processing.

2. In order to limit allowable reinsurance costs to basic prescription drug coverage we will use data in the Drug Coverage Status field, excluding PDE data reported as E or O.

3. To identify events with costs above the attachment point, we will sum GDCA (Ingredient Cost Paid + Dispensing Fee Paid + Total Amount Attributed to Sales Tax) reported on all PDE records with Catastrophic Coverage Code = C or A.

4. We will sum the beneficiary totals calculated in step 3 to derive the plan total.

5. We will apportion DIR to the reinsurance part of the benefit and subtract this portion (referred to as reinsurance DIR) to derive allowable reinsurance costs.

6. We will multiply the allowable reinsurance costs by 80 percent to determine the federal government liability for reconciliation.

Section 13. Risk sharing (risk corridor payment adjustments)

13.1 Definition
As provided in §1860D-15(e) of the Act, risk sharing is designed to limit exposure to unexpected expenses not already included in the reinsurance subsidy or taken into account through health status risk adjustment. The federal government and the plan share the profits or losses resulting from expenses for the standard benefit within defined symmetrical risk corridors around a target amount (see Figure 1), and risk sharing is most generous in the first two years of the program.

Risk corridors work by determining the difference between (a) the target amount (what a plan was actually paid through the direct subsidy plus enrollee premium related to the standardized bid amount) and (b) a plan's actual allowable costs not including administrative expenses.

A plan's actual allowable costs are limited to those costs actually incurred or paid by the plan and must subtract out any DIR (see Section 11). Also, if a plan provides supplemental coverage CMS takes into account how the presence of such coverage increases utilization beyond what it would be if the coverage were defined standard coverage. CMS will also subtract out enhanced alternative cost-sharing amounts, all federal reinsurance payments, low-income subsidy payments related to cost sharing, and beneficiary cost sharing including TrOOP-eligible payments made on the beneficiary's behalf.

Note: Risk corridor provisions do not apply to fallback plans (§1860D-11(g)(5)) or PFFS plans (§1860D-21(d)(5)), and reduced risk sharing is applied to limited risk plans as detailed in Section 13.3 below.

13.2 Calculating risk-sharing payment adjustments for reconciliation
As in all other Part D payment reconciliation, risk corridor calculations will be carried out at the individual beneficiary level with costs aggregated up to the plan (PBP) level. Calculating risk corridor payment adjustments can be considered as a 4-step process:

- Calculate the plan's target amount
- Calculate associated risk corridor thresholds
- Calculate adjusted allowable risk corridor costs
- Determine where costs fall with respect to the risk corridor thresholds, then calculate payment adjustment

Calculate the target amount (§1860D-15(e)(3)(B))
The first step in determining risk corridor payment adjustments is to establish a plan's target amount. The target amount is the plan's total direct subsidy payments plus total beneficiary premiums related to the standardized bid amount minus administrative costs.

In formula:

Target amount = (total direct subsidy payments + total beneficiary premiums related to the standardized bid amount) * (1.00 - administrative cost ratio), where:

- Total direct subsidy is the sum of all monthly direct subsidy amounts paid for the entire coverage year.
- Direct subsidy = (standardized bid * beneficiary risk adjustment factor) – beneficiary premium related to the standardized bid amount. Note that risk factors are calculated three times a year: initial calculation, mid-year correction, and final at year-end.
- The direct subsidy as used in this calculation will reflect all retroactive adjustments made based on changes in enrollment, relevant status (low income/long-term institutionalized), and final risk adjustment factors, for any month during the payment year.
- The total beneficiary premiums related to the standardized bid amount is the sum of all monthly basic beneficiary premiums for payment purposes plus any A/B rebate applied to the basic premium, for the entire coverage year. Beneficiary premiums include premiums due from enrollees or paid on their behalf, including low-income premium subsidies.
- Administrative cost ratio is calculated as follows from bid data: (Total Non-Pharmacy Expense + Gain/Loss) / Total Basic Bid

Example:

Total direct subsidy	$ 792,500
Total basic beneficiary premiums for payment purposes	$ 269,457
+ A/B rebate	$ 25,000
Target amount before administrative cost adjustment	$1,086,957
* (1 - Administrative cost ratio)	* 0.92
Target amount	$1,000,000

Note that CMS will have data to calculate the components that make up the target amount that will be used in reconciliation at the end of the year. For example, risk-adjusted direct subsidies that take into account any A/B rebates will be paid to plans monthly per beneficiary, and CMS will also know premium amounts and administrative costs. Beneficiary-level subsidies and premiums will be aggregated into plan-level data for reconciliation.

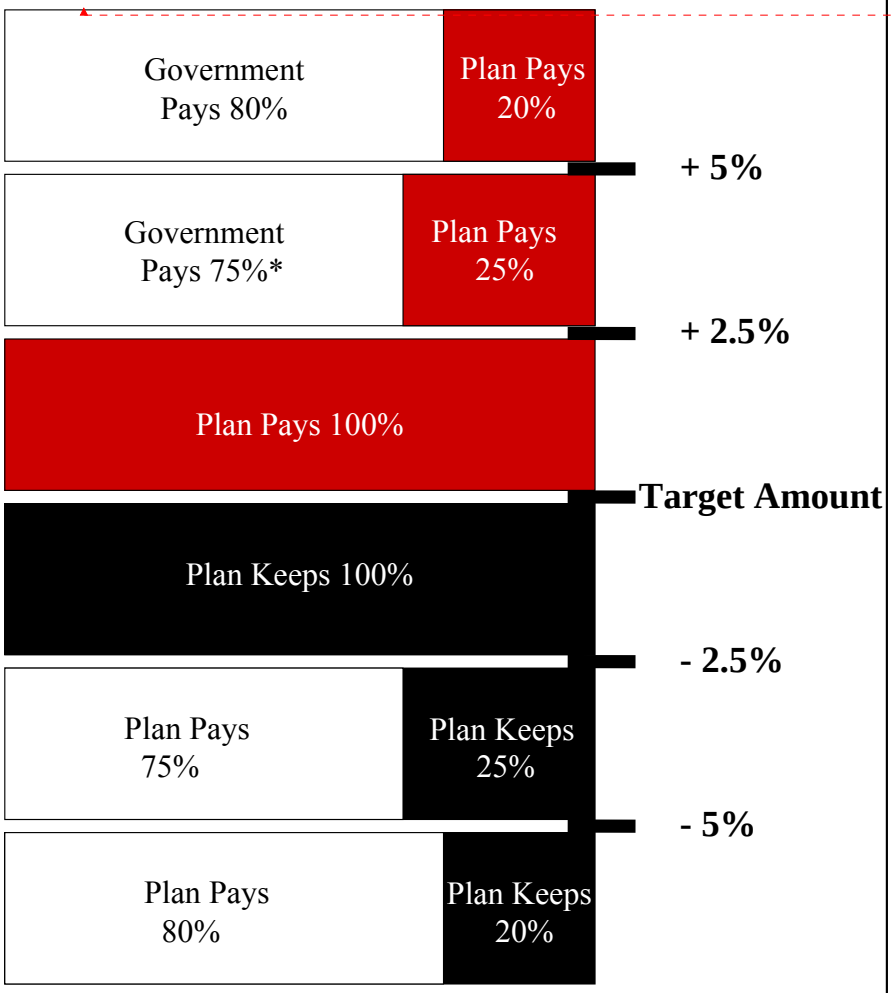
Calculate associated risk corridor threshold limits

Risk corridors are calculated based on the target amount plus or minus the threshold risk percentages associated with four symmetrical threshold limits. As illustrated below, in 2006 the first threshold upper limit is 102.5 percent of the target amount and the second threshold upper limit is 105 percent of the target amount; similarly, the first threshold lower limit is 97.5 percent of the target amount and the second threshold lower limit is 95 percent of the target amount. These percentages will be adjusted in future years according to legislation.

Example (target amount = $1,000,000):

The first threshold upper limit is $1,025,000 or $1,000,000 + (.025*$1,000,000)

Figure 1. Risk corridors for full risk plans, 2006 - 2007



Formatted: Font: 14 pt

The second threshold upper limit is $1,050,000 or $1,000,000 + (0.050*$1,000,000)
The first threshold lower limit is $975,000 or $1,000,000 – (.025* $1,000,000)
The second threshold lower limit is $950,000 or $1,000,000 – (0.050*$1,000,000)

***Note: The 75% changes to 90% if the conditions of the "60/60 rule" have been met.**

Calculate adjusted allowable risk corridor costs

CMS will calculate adjusted allowable risk corridor costs from PDE records as per §1860D-15(e)(1) of the Act. Adjusted allowable risk corridor costs include covered prescription drug costs actually incurred and paid by the plan within the limits of the standard benefit that are not covered by reinsurance payments or low-income cost-sharing subsidies, net of DIR. The term "actually paid by the plan" excludes coinsurance and copayments, LICS and EACS Amounts, and any payments by other health insurers or qualified entities.

Calculating adjusted allowable risk corridor costs can be considered as a 4-step process:

1. Include a plan's PDE records for covered Part D drugs, i.e. Drug Coverage Status value = C (see Section 5) and calculate allowable risk corridor costs for the basic benefit by summing CPP Amounts on those PDEs.
2. Exclude induced utilization vis-a-vis the standard benefit (applies only to enhanced alternative plans);
   Multiply result of formula above by (1.00 – induced utilization percentage)
3. Subtract plan-level reinsurance subsidy (see Section 12).
4. Subtract covered Part D DIR dollars (see Section 11) to determine adjusted allowable risk corridor costs.

Determine where costs fall with respect to the thresholds and calculate payment adjustment

If adjusted allowable risk corridor costs fall within 2.5 percent of the target amount (above or below it), there is no risk sharing of additional costs or "savings" compared to estimated (prepaid) amounts, so no payment adjustment will be made:

If adjusted allowable risk corridor costs > 97.5 percent and ≤ 102.5 percent of target amount, then no payment adjustment is made.

Example 1 (target amount = $1m and adjusted allowable risk corridor costs = $978,000):

No payment adjustment is made

Example 2 (target amount = $1m and adjusted allowable risk corridor costs = $1,005,000):

No payment adjustment is made

If adjusted allowable risk corridor costs are more than 2.5 percent outside the plan's target (above or below it), costs or savings will be shared in accordance with the following provisions:

If adjusted allowable risk corridor costs > 102.5 percent and ≤ 105 percent of target amount, then the government pays plan 75 percent of difference between adjusted allowable risk corridor costs and the 1st upper threshold limit. The plan covers remainder of costs.

Example (target amount = $1m and adjusted allowable risk corridor costs = $1,035,000):

Payment adjustment = 0.75*($1,035,000-$1,025,000) = $7,500 (government pays plan)

If adjusted allowable risk corridor costs > 105 percent of target amount, then the government pays plan the sum of 75 percent of difference between 2nd and 1st upper threshold limits and 80 percent of the difference between the adjusted allowable risk corridor costs and the 2nd upper threshold limit. The plan covers remainder of costs.

Example (target amount = $1m and adjusted allowable risk corridor costs = $1,063,000):

Payment adjustment = [0.75*($1,050,000-$1,025,000) + 0.80*($1,063,000-$1,050,000)] = $29,150 (government pays plan)

If adjusted allowable risk corridor costs < 97.5 percent and ≥ 95 percent of target amount, then the plan pays government back 75 percent of difference between 1st

lower threshold limit and the adjusted allowable risk corridor costs. The plan retains 25 percent.
Example (target amount = $1m and adjusted allowable risk corridor costs = $973,000):
Payment adjustment = 0.75*($975,000-$973,000) = $1,500 (plan pays back to government)

If adjusted allowable risk corridor costs < 95 percent of target amount, then the plan pays government back the sum of 75 percent of difference between 1st and 2nd lower threshold limits and 80 percent of the difference between the 2nd lower threshold limit and the adjusted allowable risk corridor. The plan retains the remaining amount.
Example (target amount = $1m and adjusted allowable risk corridor costs = $945,000):
Payment adjustment = [0.75*($975,000-$950,000) + 0.80*($950,000-$945,000)] = $22,750 (plan pays back to government)

The "60/60 Rule"
Note that in 2006 and 2007, the 75 percent risk sharing for adjusted allowable risk corridor costs between the first and second upper threshold limits will change to 90 percent (or the higher percentage if negotiated as a limited risk plan) if the following two conditions have been met:

1. At least 60 percent of Part D plans subject to risk sharing have adjusted allowable risk corridor costs for the Part D plan for the year that are above 102.5 percent of their target amount; and
2. Such plans represent at least 60 percent of part D eligible individuals enrolled in any prescription drug plan or MA-PD plan.

CMS often refers to this as the "60/60 rule." Note that condition 1 excludes employer-sponsored plans that elect the 28% subsidy but includes all employers that are contracted Part D plans.

13.3 Limited Risk Plans
PDPs assuming limited risk may be approved in geographic areas where access requirements for a PDP region have not otherwise been met. The statute requires that regions contain at least two qualifying plans offered by different entities, one of which must be a PDP; also, these plans must offer basic coverage or basic and supplemental benefits without any accompanying supplemental premium. In regions where access requirements are not met, the minimum number of limited risk plans needed to satisfy the requirements may be approved. Note that only PDPs may act as limited risk plans and that they must at least provide basic coverage (§1860D-11(f)(4)(A), 42 CFR §423.104(f)(2)). MA-PD plan sponsors may not assume reduced risk.

In making risk corridor payments to limited risk PDPs, we will apply the reduced risk provisions approved in their bids. In accordance with the statute, reduction in risk may be accomplished by 1) symmetrical increases in the federal risk percentages assumed within either risk corridor or 2) symmetrical narrowing of the risk corridors by reducing the

threshold risk percentages. As required under § 423.272(c)(2), CMS shall not approve any bid with a de minimis level of risk. In the preamble to the final rule, we stated that our definition of de minimis in this context was a level of risk that was 10% or less of the statutory level of risk. We clarified in the Advance Notice of Payment Methodological Changes for 2006 that this means the risk after modification cannot be less than 10% of the risk before the risk corridors were moved or federal risk percentages were increased. For example, the lowest reduction in terms of plan threshold risk percentages would be a reduction in the first corridor from 25% to 2.5% and a reduction in the second corridor from 20% to 2%. If risk were reduced by narrowing the corridors, the threshold limits could not be reduced below one-tenth of 2.5% or one-tenth of 5%.

Section 14. Special rules for PACE organizations

Because of several statutory provisions unique to the PACE program, PACE organizations (POs) have several different rules for submitting PDE data. In this section, we describe requirements particular to POs. Note that unless otherwise specified, POs are subject to all other instructions for submitting PDE data.

Section 14.1 Two types of PACE plans

Sections 1894(b)(1)(A)(i) and 1934(b)(1)(A)(i) of the Act preclude PACE organizations from charging PACE enrollees any form of cost sharing. This provision must be reconciled with the global provisions in the MMA that require beneficiary out-of-pocket expenditures. Therefore, CMS will classify all PACE enrollees in two groups, each with its own plan benefit package; the distinction is made according to whether or not a beneficiary is dual eligible. (For further detail, see the 45-Day and Final Payment Notices for 2006 at http://www.cms.hhs.gov/healthplans/rates/).

Dual eligible enrollees – The majority of PACE enrollees are dually eligible for Medicare and Medicaid. These beneficiaries will be enrolled in a plan benefit package that generally maps to the defined standard benefit. They will also be deemed eligible for the low-income subsidy (LIS) to cover most of the standard beneficiary cost sharing. In addition, under the provisions of section 1894(d)(2) of the Act CMS will cover the nominal cost sharing due from non-institutionalized low-income beneficiaries by paying POs an additional monthly capitated payment. For 2006, we will determine the capitation amount to be two percent of costs below the out-of-pocket (OOP) threshold in an approved bid. In this document, we refer to this amount as the "2% capitation." Note that this 2 percent capitation results in a slight deviation from the defined standard benefit at the OOP threshold for catastrophic coverage.

Because LICS payments count towards TrOOP, dual eligible enrollees may reach the OOP threshold and catastrophic coverage provisions. For PACE calculation purposes in 2006, the threshold will be reached at $5,204 in total drug spending, corresponding to $3,600 in TrOOP costs as per the Part D benefit. Between $5,100 and $5,204 in spending, the plan is at risk for 15 percent of allowable costs plus the 2 percent in capitation (for a total of 17%), and 83 percent of costs will be covered as LICS. After the OOP threshold is crossed (>

$5,204), reinsurance covers 80 percent of costs; risk is still shared around 15 percent of costs; and LICS covers 5 percent of cost sharing on behalf of the beneficiary (see Section 12).

Risk corridor calculations remain largely unchanged (see Section 13); CMS will share risk with the plan around 75 percent of adjusted allowable risk corridor costs in the initial coverage period and 15 percent of adjusted allowable risk corridor costs above the OOP threshold. However, the federal government will also share risk with plans on the 2 percent capitation. The formula for the target amount will be (direct subsidy + premium + 2% capitation). Note that since POs do not bid on the A/B component of the benefit, there is no A/B rebate to apply to the target amount.

Note that PACE organizations will not submit a bid for any non-covered benefits they may provide to dual eligible beneficiaries (e.g., non-Part D drugs). These benefits cannot be covered by a supplemental premium or by Medicare, so bidding does not apply to them. POs may – but are not required to – submit PDE records for these drug events with Drug Coverage Status Code = E or O.

Medicare-only enrollees – A small number of PO enrollees are only eligible for Medicare. These beneficiaries will be enrolled in an enhanced alternative (EA) plan in which the PO covers all enrollee cost sharing as enhanced alternative cost sharing (EACS). Since the EA benefit is primary to most wrap-around coverage and will cover all enrollee cost sharing, Medicare-only enrollees who are eligible for LIS will not use any cost-sharing subsidy although they will receive premium assistance.

Medicare-only enrollees will never reach the OOP threshold or the catastrophic coverage phase of the standard benefit, because no TrOOP-eligible payments will be made by them or on their behalf. Thus, reinsurance provisions do not apply. However, risk will be shared around adjusted allowable risk corridor costs using the calculations in Section 13.

Note that the enhanced alternative Medicare-only PACE plans will submit a bid and report PDE data for all supplemental benefits that are funded through a supplemental premium, namely the enhanced alternative cost sharing and any non-Part D covered drugs.

No PACE organization of either plan type shall assume reduced risk (§1860D-11(f)(4)(A), 42 CFR §423.104(f)(2)).

Section 14.2 Rules for populating PDE fields

For both plan types, POs will always report the following fields with zero dollar values:

- Gross Drug Cost Above the Out-of-Pocket Threshold (GDCA)
- Gross Drug Cost Below the Out-of-Pocket Threshold (GDCB)
- Patient Pay Amount
- Other TrOOP Amount
- Low-Income Cost-Sharing Subsidy (LICS)
- Patient Liability Reduction Due to Other Payer (PLRO)

Note: All dollar fields must be populated with a zero dollar value and submitted in PDE records, even if there is no positive amount to report.

The Catastrophic Coverage Code will always be blank.

Drug Coverage Status Code (DCS), Covered D Plan Paid Amount (CPP), and Non-covered Plan Paid Amount (NPP) shall be populated as follows:

- When DCS = C, the total drug cost must be reported in the Covered D Plan Paid field (CPP); NPP will always = zero.
- When DCS = E or O, the total drug cost must be reported in the Non-covered Plan Paid field (NPP); CPP will always = zero.
- In both instances, CMS will apply an edit to verify that the sum of Ingredient Cost Paid + Dispensing Fee Paid + Amount Attributed to Sales Tax = the summary dollar value in the CPP or NPP field.

CMS will then array the costs reported by the plan in CPP or NPP into the payment categories.

Section 14.3 Arraying the costs of dual eligible enrollees

YTD Total Covered Drug Cost	LICS	Reinsurance	2% capitation	CPP	NPP
DCS = C					
Below the OOP threshold†					
≤ $250	98%	n/a	2%	0%	0
> $250 and ≤ $2,250	23%	n/a	2%	75%	0
> $2,250 and ≤ $5,100	98%	n/a	2%	0%	0
> $5,100 and ≤ $5,204	83%	n/a	2%	15%	0
Above the OOP threshold†					
> $5,204	5%	80%	n/a	15%	0
When DCS = E or O	n/a	n/a	n/a	$0	All drug cost amounts reported in NPP

†In 2006, the threshold is reached at $3,600 in true out-of-pocket costs and will correspond to $5,204 in total covered drug spending for PACE organizations.

Section 14.4 Arraying the costs of Medicare-only enrollees

YTD Total Covered Drug Cost†	CPP	NPP
When DCS = C		
≤ $250	0%	100%
> $250 and ≤ $2,250	75%	25%
> $2,250 and ≤ $5,100	0%	100%
> $5,100	15%	85%
When DCS = E or O	0	100%

†No out-of-pocket threshold or catastrophic coverage is reached

Section 14.5 Examples

The following chart shows the calculations CMS will perform to array beneficiary costs into standard benefit categories for payment reconciliation.

		Dual Eligible PACE Program The Dual Eligible PACE Program has submitted PDEs for Beneficiary A for Covered Part D drugs that total $6,000				Medicare PACE Program The Medicare PACE Program has submitted PDEs for Beneficiary B for Covered Part D drugs that total $6,000			
Standard Benefit Category	Total Covered Drug Cost	LICS	CPP	Portion of CPP eligible for Reinsurance	NPP	Standard Benefit Category	Total Covered Drug Cost	CPP	NPP
Deductible	The first $250	$245 (.98*250)	$5 (.02 * 250)	$0	$0	Deductible	The first $250	$0	$250
Initial Cost sharing	The next $2,000 > $250 and ≤ $2,250	$460 (.23*2000)	$1,540 (.02 * 2000) + (.75 * 2000)	$0	$0	Initial Cost sharing	The next $2,000 > $250 and ≤ $2,250	$1500	$500
Coverage Gap	The next $2,850 > $2,250 and ≤ $5,100	$2,793 (.98*2850)	$57 (.02*2850)	$0	$0	Coverage Gap	The next $2,850 > $2,250 and ≤ $5,100	$0	$2,850
Defined Standard Catastrophic Coverage	The next $104 > $5,100 and ≤ $5,204†	$86.32 (.83 * 104)	$17.68 (.15 * 104) + (.02 * 104)	$0	$0	Defined Standard Catastrophic Coverage	The remaining $900 > $5,100	$135	$765
PACE Catastrophic Coverage (Reinsurance)	The remaining $796 > $5,204† and ≤ $6,000	$39.80 (.05*796)	$756.20 (.15 * 796) + (.80 * 796)	$796	$0				
Total	$6,000	$3,624.12	$2,375.88	$796	$0			$1,635	$4,365
		CMS will build a beneficiary/plan level summary record totaling the dollars arrayed in LICS, CPP and the portion of CPP eligible for Reinsurance. • Plan level LICS total is the basis for reconciling Low-Income Cost-Sharing Subsidy (see Section 10). • Plan level total Reinsurance represents Allowable Reinsurance Costs used to reconcile the Reinsurance Subsidy (see Section 12). • Plan level total CPP represents the Allowable Risk Corridor Costs used in Risk Corridor calculations (see Section 13).				CMS will build a beneficiary/plan level summary record totaling the dollars arrayed in LICS, CPP and the portion of CPP eligible for Reinsurance. • LICS - none • Plan level total Reinsurance - none • Plan level total CPP represents the Allowable Risk Corridor Costs used in Risk Corridor calculations (see Section 13).			

† In 2006, the threshold is reached at $3,600 in true out-of-pocket costs and will correspond to $5,204 in total covered drug spending for PACE organizations.

Section 15. Special rules for payment demonstration plans

Section 15.1 Overview

In 2006 to 2010, Part D plans may participate in payment demonstrations to study the effects of providing supplemental insurance in the coverage gap. Plans may choose among three variant payment structures that are described in detail at http://www.cms.hhs.gov/pdps/PmntNtcNRskAdjMdl.asp:

1. The flexible capitation option;
2. The fixed capitation option; and
3. The MA rebate option

Since payment demonstration plans will have non-standard benefit structures and some variations in payment methodology, they have several different rules for submitting PDE data for payment calculations. In this section, we describe requirements particular to these plans. Note that unless otherwise specified, payment demonstration plans are subject to all other instructions for submitting PDE data.

In this section, we define rules for cost allocation that only apply to the flexible capitated option and the fixed capitated option, and we provide illustrative examples. Then we provide examples for special TrOOP accounting that only apply to the MA rebate option. In all the examples, we illustrate the simplest case where the beneficiary does not qualify for low income cost-sharing subsidy and the beneficiary has no other health insurance.[6]

Section 15.2 Rules for populating PDE records (flexible and fixed capitation options)

The PDE reporting rules for payment demonstration plans implementing either the flexible or the fixed capitated options are very similar to the rules for reporting enhanced alternative cost sharing (see Section 7). We require these rules because risk sharing for both options differs from risk sharing for other plans as they share risk based on all amounts they would have paid under the standard benefit, including the 80% reinsurance subsidy. These rules allocate all plan paid amounts, including those amounts that would otherwise be included in the reinsurance subsidy, as if the claim had been adjudicated according to the standard benefit. Plan paid dollars allocated to the standard benefit are included in risk corridor calculations. Plan paid dollars that exceed the standard benefit are considered supplemental benefits and are excluded from risk corridor calculations.

The fixed capitated option differs from the flexible capitated option in one important way. Fixed capitation plans will always administer catastrophic coverage at $5,100 of total covered drug spending, so the attachment point claim is always reported at $5,100. From that point forward, the plan will administer and report the benefit according to the standard catastrophic coverage rules.

The rules impact reporting in the following three fields: Patient Pay Amount, Covered D Plan Paid Amount (CPP) and Non-covered Plan Paid Amount (NPP). Note that there is no change in the business rules to populate three other related fields: Catastrophic Coverage Code, Gross Drug Cost Above Out-Of-Pocket Threshold (GDCA) and Gross Drug Cost Below Out-Of-Pocket Threshold (GDCB).

---

[6] Payment demonstration plans calculate the low-income cost-sharing subsidy (LICS) in the same way that all other plans do (see Section 10).

Patient Pay Amount, Covered Plan Paid Amount (CPP), Non-covered Plan Paid Amount (NPP)

When reporting PDE records for covered drugs, payment demonstration plans will apply the following rules to calculate amounts submitted in Patient Pay Amount, Covered D Plan Paid Amount and Non-Covered Plan Paid Amount.

Definitions and terminology:
Total covered drug cost – the sum of Ingredient Cost, Dispensing Fee, and Sales Tax for a given PDE
Year-to-date (YTD) total covered drug cost – the sum of all total covered drug costs for a beneficiary to-date within a coverage year
Initial coverage period – the phase of the benefit above the deductible and at or below the initial coverage limit in the defined standard benefit
Payment demonstration coverage period – the phase of the benefit above the initial coverage limit in the defined standard benefit up to the point at which the beneficiary has reached $3,600 in true out-of-pocket (TrOOP) spending. If the plan does not completely fill in the coverage gap as defined by the standard benefit, the payment demonstration coverage period extends from the defined standard initial coverage limit up to the initial coverage limit in the demonstration plan's benefit package.

Rules to calculate CPP and NPP

1. Pay pharmacy according to plan's cost sharing formula and note the patient and plan paid amounts at POS.
2. Report patient cost share at point of sale (POS) in Patient Pay Amount field.
3. Calculate the amount to report in Covered D Plan Paid Amount (CPP). CPP Amount is determined by the standard benefit, and will not necessarily be the same as the plan paid amount at POS (as calculated in step 1). To calculate CPP Amount, multiply total covered drug cost by the applicable percentage in rules 1-4 below.

   Note that the purpose of the rules is to allocate plan paid dollars between two payment fields: Covered Plan Paid Amount (CPP) and Non-covered Plan Paid Amount (NPP). The CPP field captures allowable risk corridor costs. Costs in the NPP field are excluded from allowable risk corridor costs.

   When YTD total covered drug costs ≤$5,100, allocation rules are the same for both options.

   When YTD total covered drug costs > $5,100, the rules differ slightly for the two capitation options. Their different cost allocation rules reflect the fact that beneficiaries cross into catastrophic coverage (or reach the OOP threshold) at a higher YTD total drug costs in the flexible option compared to the fixed option. By way of illustration, the rules consider YTD total covered drug cost above $5,100 into two categories: costs > $5,100 but still ≤ the OOP threshold, and costs > the OOP threshold. Fixed capitated plans will never have costs in the former category, but both flexible and fixed plans will have costs in the latter category. Both rules have the same effect which is to allocate all plan-paid covered drug costs above $5,100 to CPP.

Rule #	YTD Total Covered Drug Cost	Percentage to calculate standard benefit	
		Flexible Capitated Option	Fixed Capitated Option
1	≤ $250*	0%	
2	> $250 and ≤ $2,250	75%	
3	> $2,250 and ≤ $5,100	0%	
4	> $5,100 and ≤ Out-of-Pocket Threshold	Lesser of 95% or (Total Covered Drug Cost - $2/$5)	N/A†
5	> Out-of-Pocket Threshold	Lesser of 95% or (Total Covered Drug Cost - $2/$5)	Lesser of 95% or (Total Covered Drug Cost - $2/$5)

***Not applicable to plans that retain the full $250 deductible*
†By definition, the Out-of-Pocket threshold will always coincide with $5,100 in YTD total covered drug costs in the fixed capitated option.

4. Determine the amount to report in Non-covered Plan Paid Amount (NPP). Subtract Patient Pay Amount (Step 2) and Covered D Plan Paid Amount (Step 3) from total covered drug cost.[7]

Section 15.3 Examples: flexible capitation option

Plan A – Plan A illustrates the flexible capitated option. Plan A retains the $250 deductible. After the deductible is satisfied, it offers 25% cost sharing throughout the benefit until the beneficiary reaches catastrophic coverage. Because Plan A eliminates the coverage gap, a beneficiary does not reach the out-of-pocket threshold until total covered drug costs equal $13,650.

Example 1 – The beneficiary's YTD total covered drug costs = $2,000. The beneficiary purchases a covered drug for $100. Apply Rule #2.

YTD Total Covered Drug Cost = $2,000 – Rule #2				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount (a) * .25	Plan Paid at POS (a) * .75	Covered D Plan Paid Amount (CPP) (a) * .75	NPP (a) - (b + d) or (c-d)
$100	$25	$75	$75	$0

[7] If a beneficiary has other health insurance (reported in PLRO or Other TrOOP Amount) and/or Low-Income Cost-Sharing Subsidy (reported in LICS), we also subtract those amounts from total covered drug cost to determine NPP.

Explanation: According to the standard benefit the beneficiary is in the Initial Coverage Period where the beneficiary pays 25% cost sharing and the plan pays 75%. Plan A's benefit structure is the same. There is no difference between the plan's benefit structure and the standard benefit structure.

Example 2 – The beneficiary's total covered drug costs = $3,000. The beneficiary purchases a covered Part D drug for $100. Apply Rule #3.

YTD Total Covered Drug Cost = $3,000 – Rule #3				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount (a) * .25	Plan Paid at POS (a) * .75	Covered D Plan Paid Amount (CPP) (a) * 0	NPP (a) - (b + d) or (c-d)
$100	$25	$75	$0	$75

Explanation: According to the standard benefit, the beneficiary is in the coverage gap where the beneficiary pays 100% cost sharing and the plan pays 0%. In Plan A's benefit structure, the beneficiary is in the payment demonstration coverage period. In Plan A the beneficiary pays 25% cost share and the plan pays 75%. The difference between the plan liability in the Plan's benefit structure (75%) and the standard benefit plan structure (0%) is a supplemental benefit. This amount is reported in the NPP field.

Example 3 – The beneficiary's YTD total covered drug costs = $6,000. The beneficiary purchases a covered Part D drug for $100. Apply Rule #4.

YTD Total Covered Drug Cost = $6,000 – Rule #4				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount (a) * .25	Plan Paid at POS (a) * .75	Covered D Plan Paid Amount (CPP) (a) * .95	NPP (a) - (b + d) or (c-d)
$100	$25	$75	$95	-$20

Explanation: According to the standard benefit the beneficiary is in the catastrophic phase of the benefit where the beneficiary cost sharing is the greater of $2/$5 or 5%. In Plan A's benefit structure, the beneficiary is in the payment demonstration coverage period where the beneficiary pays 25% cost share and the plan pays 75%. As with prior examples, the amount reported in the CPP field is the amount the plan would pay under the standard benefit, $95. This constraint results in a negative NPP amount to account for the difference between what the plan actually paid at POS and what the plan would have paid under the standard benefit. Note also that Plan A would be reporting a Catastrophic Coverage Code = blank for this event, indicating that the beneficiary has not reached catastrophic coverage under Plan A's benefit structure. All drug costs would be reported as below the out-of-pocket threshold in the GDCB field.

Example 4 – The beneficiary's YTD total covered drug costs = $13,651. The beneficiary purchases a covered drug for $100. Apply Rule #5.

YTD Total Covered Drug Cost = $13,651 - Rule #5				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount (a) * .05	Plan Paid at POS (a) * .95	Covered D Plan Paid Amount (CPP) (a) * .95	NPP (a) - (b + d) or (c-d)
$100	$5	$95	$95	$0

Explanation: The beneficiary has reached $3,600 in true out-of-pocket costs, thus is in the catastrophic phase of the benefit where cost sharing is the greater of $2/$5 or 5%. Plan A must provide catastrophic coverage under the standard benefit provisions from here forward, so there is no difference between the Plan's benefit structure and the standard benefit plan structure. Also note that Plan A would be reporting a Catastrophic Coverage Code = C for this event, indicating that this is catastrophic coverage under Plan A's benefit structure, and all drug costs would be reported as above the out-of-pocket threshold in the GDCA field.

Section 15.4 Examples: fixed capitation option

Plan B - Plan B illustrates the fixed capitated option; it eliminates both the $250 deductible and cost sharing in the coverage gap. This plan offers tiered cost sharing in the following structure: $5/$20/$40 (these amounts are for illustration only and are not necessarily representative of an actuarially equivalent benefit structure. Also note that a flexible Capitated plan can offer a tiered cost-sharing arrangement). In the fixed capitated option, the beneficiary reaches catastrophic coverage at $5,100 of YTD total drug spending rather than $3,600 of TrOOP.

Example 1 – The beneficiary's YTD total covered drug costs = $50. The beneficiary purchases a covered Part D drug for $40. The copay for this drug is $5. Apply Rule #1.

YTD Total Covered Drug Cost = $50 - Rule #1				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount	Plan Paid at POS	Covered D Plan Paid Amount (CPP)	NPP (a) - (b + d) or (c-d)
$40	$5	$35	$0	$35

Explanation: According to the standard benefit, the beneficiary is in the deductible phase where the beneficiary pays 100% cost sharing and the plan pays 0%. In Plan B's benefit structure, the beneficiary cost sharing is reduced to a flat $5 copay. The difference between the plan liability in the plan's actual benefit structure ($35) and the plan's payment under standard benefit plan structure ($0) is a supplemental benefit. This amount is reported in the NPP field.

Example 2 – The beneficiary's YTD total covered drug costs = $1,400. The beneficiary purchases a covered Part D drug for $100. The copay for this drug is $20. Apply Rule #2.

YTD Total Covered Drug Cost = $1,400 - Rule #2				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount	Plan Paid at POS	Covered D Plan Paid Amount (CPP)	NPP (a) - (b + d) or (c-d)
$100	$20	$80	$75	$5

Explanation: According to the standard benefit, the beneficiary is in the initial coverage period where the beneficiary pays 25% cost share and the plan pays 75%. In Plan B's benefit structure, the beneficiary has a flat $20 copay, which is 20% of the total drug cost. The plan liability is $80 under Plan B's benefit structure as compared with $75 under the standard defined benefit. The difference between the plan liability in the plan's benefit structure and the standard benefit plan structure is a supplemental benefit. This amount is reported in the NPP field.

Example 3 – The beneficiary's YTD total covered drug costs = $1,500. The beneficiary purchases a covered Part D drug for $100. The copay for this drug is $40. Apply Rule #2.

YTD Total Covered Drug Cost = $1,500 - Rule #2				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount	Plan Paid at POS	Covered D Plan Paid Amount (CPP)	NPP (a) - (b + d) or (c-d)
$100	$40	$60	$75	-$15

Explanation: According to the standard benefit, the beneficiary is in the initial coverage period where the beneficiary pays 25% cost share and the plan pays 75%. In Plan B's benefit structure, the beneficiary has a flat $40 copay, which is 40% of the total drug cost. The plan liability is $60 under Plan B's benefit structure as compared with $75 under the standard defined benefit. The difference between the plan liability in the Plan's benefit structure and the standard benefit plan structure is a supplemental benefit. In this case, the amount is negative because the plan paid less than under the defined standard. This amount is reported in the NPP field.

Example 4 – The beneficiary's YTD total covered drug costs = $3,000. The beneficiary purchases a covered Part D drug for $100. The copay for this drug is $40. Apply Rule #3.

YTD Total Covered Drug Cost = $3,000 - Rule #3				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount	Plan Paid at POS	Covered D Plan Paid Amount (CPP)	NPP (a) - (b + d) or (c-d)
$100	$40	$60	$0	$60

Explanation: According to the standard benefit, the beneficiary is in the coverage gap where the beneficiary pays 100% cost sharing and the plan pays 0%. In Plan B's benefit structure, the beneficiary is in the payment demonstration coverage period. In Plan B the beneficiary has a flat $40 copay, which is 40% of the total drug cost. The plan liability is $60 under Plan B's benefit structure as compared with $0 under the standard defined benefit. The difference between the plan liability in the plan's benefit structure and the standard benefit plan structure is a supplemental benefit. This amount is reported in the NPP field.

Example 5 – The beneficiary's YTD total covered drug costs = $6,000. The beneficiary purchases a covered Part D drug for $100. Apply Rule #5.

YTD Total Covered Drug Cost = $6,000 - Rule #5				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount	Plan Paid at POS	Covered D Plan Paid Amount (CPP)	NPP (a) - (b + d) or (c-d)
$100	$5	$95	$95	$0

Explanation: According to the standard benefit, the beneficiary is in the catastrophic phase of the benefit where the beneficiary cost sharing is the greater of $2/$5 or 5%. Since Plan B is a fixed capitation plan, the OOP threshold is reached and catastrophic coverage commences when total covered drug cost reaches $5,100 regardless of accumulated TrOOP. Plan B should report a Catastrophic Coverage Code = C for this event, indicating that the beneficiary has reached catastrophic coverage under Plan B's benefit structure. All drug costs would be reported as above the out of pocket threshold in the GDCA field.

Section 15.5 Examples: MA rebate option

Payment demonstration plans that implement the MA rebate option are considered to be the same as the standard benefit with one qualifier. These plans reduce or eliminate the coverage gap, with all plan spending in that phase of the benefit funded by A/B rebates which count towards TrOOP. In the coverage gap, all plan spending shall be attributed to Other TrOOP amount and therefore counted toward cumulative TrOOP (see example 2). These plans may offer tiered cost sharing in the initial coverage period provided the cost sharing is actuarially equivalent to the defined standard. On average, the cumulative TrOOP will reach $3,600 at the same time that total covered drug spend reaches $5,100. Above $3,600 TrOOP, these plans must offer the standard catastrophic coverage.

Reporting in the initial coverage period and in the catastrophic phase of the benefit will be the same as for any plan that offers basic Part D coverage, that is, all plan spending for covered drugs is considered covered plan paid amounts.

Plan C –Plan C retains the deductible and it eliminates the coverage gap, funding the additional coverage with A/B rebate dollars. The plan offers tiered cost sharing that is actuarially equivalent to the defined standard, but carries this cost sharing throughout the benefit up until catastrophic coverage. The plan offers the following cost sharing structure: $5/$20/$40 (these amounts are for illustration only and are not necessarily representative of an actuarially equivalent benefit structure).

Example 1 – The beneficiary's YTD total covered drug costs = $1,650. The beneficiary purchases a covered Part D drug for $100. The copay for this drug is $40.

YTD Total Covered Drug Cost = $1,650				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount	Plan Paid at POS	Covered D Plan Paid Amount (CPP)	Other TrOOP (a) - (b + d) or (c-d)
$100	$40	$60	$60	$0

Explanation: According to the standard benefit, the beneficiary is in the initial coverage period, which for a MA Rebate Option plan must be actuarially equivalent to the standard defined benefit. In this phase of the benefit, all plan spending is reported as Covered Plan Paid Amount.

Example 2 – The beneficiary's YTD total covered drug costs = $3,000. The beneficiary purchases a covered Part D drug for $100. The copay for this drug is $5.

YTD Total Covered Drug Cost = $3,000				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount	Plan Paid at POS	Covered D Plan Paid Amount (CPP)	Other TrOOP (a) - (b + d) or (c-d)
$100	$5	$95	$0	$95

Explanation: According to the standard benefit, the beneficiary is in the coverage gap where the beneficiary pays 100% cost sharing and the plan pays 0%. In Plan C's benefit structure, the beneficiary is in the payment demonstration coverage period. In Plan C, the beneficiary has a flat $5 copay for this drug, which is 5% of the total drug cost. The plan liability is $95 under Plan C's benefit structure as compared with $0 under the standard defined benefit. The plan liability of $95 is reported in the Other TrOOP field.

Example 3 – The beneficiary's YTD total covered drug costs = $5,200. The beneficiary purchases a covered Part D drug for $150. The copay for this drug is $40 normally, but is the greater of 5% or $2/$5 in the catastrophic phase (in this case, 5% is greater).

YTD Total Covered Drug Cost = $5,200				
(a)	(b)	(c)	(d)	(e)
Total Covered Drug Cost	Patient Pay Amount	Plan Paid at POS	Covered D Plan Paid Amount (CPP)	Other TrOOP (a) - (b + d) or (c-d)
$150.00	$7.50	$142.50	$142.50	$0.00

Explanation: The beneficiary is in the catastrophic phase of the benefit, and Plan C must administer and report the benefit in a manner consistent with the rules governing catastrophic coverage.

Section 15.6 Payment reconciliation: flexible and fixed capitation options

Payment reconciliation for the flexible capitated option and the fixed capitated option differ from other plan types in two ways. There is no reinsurance reconciliation and the target amount is computed differently.

Target amount

The capitated reinsurance payment is added to the target amount since risk sharing is applied to reinsurance. Thus, the calculation for the target amount outlined in Section 13 changes to:

Direct subsidy
+ Beneficiary premiums for payment purposes
+ A/B rebate
+ Capitated reinsurance payment
= Target amount before administrative cost adjustment
* (1 - Administrative cost ratio)
= Target amount

Adjusted allowable risk corridor costs

Reinsurance calculations outlined in Section 12 do not apply. Therefore, the reinsurance subsidy amount subtracted in the calculation for adjusted allowable risk corridor costs is always zero (see Section 13).

Section 16. Special Instructions for Employer/Union-Only Group Waiver Plans

This Section applies to employer/unions that directly contract with Medicare to become prescription drug plans (PDPs) and to MA-PDs, PDPs and section 1876 cost plans that offer employer/union-only group plans. These plans are authorized under §1857(i) and §1860D-22(b) of the Act which provides that CMS may waive or modify requirements that "hinder the design of, the offering of, or the enrollment in" such employer sponsored plans. CMS refers to employer or union-sponsored plans in these arrangements as employer/union-only group waiver plans (EGWPs) and to the subset of directly contracted plans as Direct EGWPs. These instructions apply to both types of EGWPs and are applicable to these plans pursuant to CMS's waiver authority and to the executed Part D contractual agreements between CMS and these entities.

Section 16.1 Background

Employers and unions that offer retiree medical coverage that includes prescription drug benefits have several options under the MMA beginning in the 2006 coverage year. As referenced above, under CMS statutory waiver authority, these options include becoming Part D plans through direct contracting with CMS or obtaining customized coverage for their retirees through special arrangements with Part D plan sponsors.

All EGWPs must report PDE data according to the requirements in this Section. These plans remain subject to the requirements of 42 CFR §423.104(d) and (e) to provide standard coverage or a benefit that has the same gross value, and these plans may also offer an enhanced package with a value above the standard benefit. Due to unique payment provisions and waivers for EGWPs, we are providing clarification of the rules for data submission by these plans. Note that all PDE submission rules apply unless plans are instructed otherwise.

Note: Employers and unions also have the option to elect to receive a 28 percent federal subsidy to apply towards their non-Part D retiree drug coverage. We refer to these plans as Retiree Drug Subsidy (RDS) plans. RDS plans will not submit data to CMS at the PDE level and should follow separate guidance from CMS for their cost submission requirements.

Section 16.2 Plan types

Only for purposes of PDE reporting instructions, all EGWPs will be considered enhanced alternative plans as defined and described in Section 7. They will use the same instructions provided in Section 7.3 to report supplemental drugs for exclusion from payment. They will report enhanced alternative cost sharing benefits in accordance with the instructions in Section 7.4 for mapping to the defined standard benefit. The mapping enables CMS to distinguish standard from enhanced cost sharing benefits for payment purposes.

Section 16.3 Tracking TrOOP and Gross Covered Drug Costs

EGWPs are responsible for tracking their enrollees' true out-of-pocket costs (TrOOP) and gross covered drug costs (GDCA and GDCB). Like all Part D plans, EGWPs must track enrollee balances in these two categories because they are required to transfer these amounts to a new

plan if a beneficiary changes enrollment during the year. The beneficiary's accumulated TrOOP costs determines when they would reach catastrophic coverage in the new plan, and the beneficiary's accumulated gross covered drug costs determine what phase of the new plan's PBP they are placed into. The balances must be tracked on a calendar year basis even if the EGWP operates on a non-calendar year basis, because the Part D benefit is paid and administered on a calendar year basis.

Section 16.4 Reinsurance

EGWPs are only eligible for the federal reinsurance subsidy if they operate on a calendar year basis. Those that administer benefits on a calendar year basis are subject to all reporting and payment provisions in Section 12 except that they will not receive prospective reinsurance payments during the year. Instead, CMS will make retrospective payment in reconciliation after the end of the year, based on allowable costs reported on PDEs. EGWPs that operate on a non-calendar year basis are not eligible for reinsurance. However, they are still required to administer all catastrophic coverage provisions prescribed by the MMA, in regulation, and in these Instructions. Specifically, once the beneficiary reaches the OOP threshold by accumulating $3,600 in TrOOP costs (see Section 8), beneficiary cost sharing is limited to the statutory amount or an alternative amount that was approved by CMS in the plan's bid. Also, above the OOP threshold, non-calendar year EGWPs must report gross covered drug costs above the threshold (GDCA) and must populate the Catastrophic Coverage Code field with "A" or "C" as appropriate.

Section 16.5 Risk sharing

EGWPs are not subject to risk sharing. Therefore, the payment and reconciliation calculations in Section 13 do not apply to these plans. However, EGWPs must still report covered plan-paid amounts (CPP) to CMS as described in Section 7, to distinguish covered and non-covered benefits.

Section 17. Medicare as Secondary Payer (MSP)

17.1 Background

This Section is a follow-up to our Coordination of Benefits (COB) guidance issued July 1, 2005 (http://www.cms.hhs.gov/pdps/cob.asp). In Sections E and J of the COB guidance, we provided an introduction to the role of Medicare as Secondary Payer (MSP) in coordinating benefits under the MMA. This document extends that early guidance by describing certain MSP scenarios in greater detail and delineating rules for calculating and reporting PDE data in MSP situations.

The Part D benefit is structured with Medicare as a primary payer and in most cases of other health insurance coverage, Medicare will be primary. However, there will be times when other insurers are primary. Clarification regarding a limited number of MSP situations is provided below; however, all MSP laws shall be properly applied whether or not they are mentioned in this document. Part D plans should reference other CMS guidance for detailed rules about establishing payer precedence and interacting with the Coordination of Benefits Contractor (COBC) to establish, verify or manage an MSP situation.

The MMA extended MSP laws applicable to MA organizations to Part D sponsors (§1860D-2(a)(4)). Accordingly, Part D sponsors will have the same responsibilities under MSP laws as do MA plans, including collection of mistaken primary payment from insurers, group health plans, employer sponsors, enrollees, and other entities; and the interaction of MSP rules with State laws. Part D plans must properly apply MSP laws and regulations to their payments (e.g., working aged, worker's compensation, other).

17.2 Verifying and establishing MSP

The COBC is the central repository for verifying and establishing an MSP situation. It has sole responsibility for establishing an MSP record for a beneficiary in the Medicare Beneficiary Database (MBD), although Part D plans and beneficiaries have various responsibilities to exchange COB information with each other, with other payers, and with the COBC (http://www.cms.hhs.gov/pdps/cob.asp).

The COBC uses a variety of investigational tools, such as MSP questionnaires, telephone contacts, and data exchanges to determine if there is an MSP situation. Once the COBC updates the Medicare Beneficiary Database (MBD) with an MSP record indicating that Medicare is the secondary payer for a beneficiary, Part D plans are responsible for adjudicating enrollees' claims and submitting prescription drug event (PDE) records in accordance with the following MSP rules. Also, the plans are then responsible for identifying and recovering any MSP-related mistaken payments and submitting associated adjustments to CMS.

According to law, Medicare is the secondary payer in the following situations:

1. Employer group health plans (EGHP) MSP
    a. Working Aged GHP – The beneficiary is actively working and is covered under the employer's GHP or the beneficiary's spouse is actively working and the

beneficiary is covered under the spouse's employer GHP (≥20 employees; or another employer in GHP≥ 20 employees.) (42 U.S.C. §1395(y)(b))

b. Disability with GHP – The beneficiary is actively working for a large employer and is covered under the employer's GHP, or a beneficiary's family member is actively working for a large employer and the beneficiary is covered under the family member's employer GHP (LGHP, ≥100 employees)
c. End Stage Renal Disease (ESRD) GHP – GHP (any size) is primary for the first 30 months when an individual also becomes eligible for Medicare Part A due to ESRD status. After thirty months of Part A eligibility, Medicare becomes primary.

2. Non-GHP MSP
    a. Worker's Compensation (WC) – Beneficiary covered under WC due to job-related illness or injury
    b. Black Lung (BL) – The beneficiary has black lung disease and is covered under the Federal Black Lung Program
    c. No-Fault/Liability – The beneficiary is covered by no-fault or liability insurance due to an accident

However, Part D plans should not immediately pay only as secondary. The action required of the Part D plan is dependent on the type of other primary payer as follows:

1. For the types of Employer Group Health Plans (EGHP) listed above, the Part D plan will always deny primary claims that fall within the EGHP's applicable coverage dates and default to MSP. The types as listed above include: working aged GHP, disability GHP, and ESRD GHP for first 30 months of Medicare Part A eligibility.

2. For Worker's Compensation (WC), Black Lung (BL), and No-Fault or Liability coverage the plan will always make conditional primary payment unless the plan is aware that the enrollee has WC/BL/No-Fault/Liability coverage and has previously established that a certain drug is being used exclusively to treat a related injury. For example, when a beneficiary refills a prescription previously paid for by WC, the Part D plan may deny primary payment and default to MSP.

    In all other instances, the Part D plan is required to make conditional primary payment then recover any mistaken payments where it should have only paid secondary to WC/BL/No-Fault/Liability coverage. For example, if a plan does not know whether a given drug for which it is billed is related to the covered injury, the plan must pay for the drug (if it is covered) and later retrieve any amounts that the other insurance was supposed to cover.

17.3 Mistaken payment recovery

Once a Part D plan has determined that a non-EGHP settlement has occurred for a beneficiary for whom the plan has reported PDE records, the plan must determine and recover any payments that should have been covered by the other party. Once the other party has adjudicated related

claims, the Part D plan must submit adjustment and/or deletion PDEs for those claims to CMS. The plan must also re-determine beneficiary liability for those claims.

CMS instructs plans to submit adjustments only after the primary payer has reimbursed the plan for mistaken payments. However, plans should report these data as soon as possible and exert every effort so that adjusted PDEs may be included in the next reconciliation.

CMS will issue additional guidance to plans on rules for mistaken payment recovery, for example reporting settlements that are received after a given coverage year has been closed out for reconciliation.

17.4 Populating the PDE record as MSP

Once an MSP situation has been established, Part D plans will use the following rules to calculate and report MSP payments on PDE records.

17.4.1 Pricing Exception Code

CMS renamed the field Out-of-Network Code to Pricing Exception Code. It now has two values:
O = Out-of-network claim, non-MSP
M = Medicare as Secondary Payer (MSP) claim (includes OON claims where Medicare is secondary payer)

Plans will populate this field with 'M' to indicate that the PDE has been paid in accordance with MSP rules. If both codes 'O' and 'M' apply for a given PDE, report 'M' as the overriding code because it has the greater effect in payment calculations. Only report value = 'O' when an event is out-of-network and there is no MSP for the event.

17.4.2 Pricing and calculation rules

In the logic for pricing and adjudicating an MSP claim under Part D, the provider/pharmacy receives at least the Part D plan's negotiated price for the drug. Payments are applied to this price in the following order: primary insurer's payment, beneficiary cost sharing liability under the Part D PBP, and finally the Part D plan picks up any remaining balance. In other words, the primary payment reduces plan-paid amounts first, then beneficiary liabilities. If the primary payment is greater than or equal to the negotiated price, no other payments are made. In particular, plans shall use the following steps to price an MSP claim and populate a PDE record:

1. Price or re-price the claim according to the Part D plan's negotiated price for the drug. In the GDCB or GDCA field, report the negotiated price if the drug is covered or $0 if the drug is non-covered.

2. Report the primary payment amount in the PLRO field. Note that if PLRO ≥ gross drug cost (negotiated price), all other payment amounts on the PDE record are $0.

3. Determine the beneficiary and Part D plan liabilities under the PBP.

4. Subtract the primary payment from the negotiated price.

5. Determine Patient Pay Amount. The beneficiary will actually be responsible for either the amount from Step 3 or the remainder in Step 4, whichever is less. Report the lesser amount in Patient Pay Amount; if the lesser amount is negative, report $0 in Patient Pay Amount.

6. Calculate Part D Plan Paid amount at POS. The Part D plan pays the pharmacy any amount remaining after the primary payment and the beneficiary's cost sharing under the PBP have been applied, up to the Part D plan's negotiated price.

7. Report this payment, Part D Plan Paid, in CPP, NPP and/or LICS as follows:

a) If the PBP only provides basic coverage or if the drug is a supplemental drug, the Plan-Paid amount at POS is reported in CPP (for covered drugs) or NPP (for non-covered drugs).

b) The calculations to determine LICS Amount do not change under MSP (see Section 10).

c) If the PBP provides enhanced alternative cost-sharing, use the following rules to calculate and report CPP Amount and NPP Amount:

i. Use the mapping rules in Section 7 to calculate what CPP would be under non-MSP rules; we refer to this value as CPP_c.
ii. Subtract the primary payment from CPP_c to determine CPP_r, the value to report in CPP Amount on the PDE record. Note that if primary payment $\geq CPP_c$, $CPP_r = \$0$; CPP_r shall not be a negative amount.
iii. (Part D Plan Paid - CPP_c) = NPP_r, the value to report in NPP Amount on the PDE record.

Notes:

- If PLRO $\geq CPP_c$, then NPP_r Amount = Part D Plan-Paid
  and CPP_r Amount = $0

- If PLRO $< CPP_c$, then CPP_r Amount = (CPP_c – PLRO)
  and NPP_r Amount = (Part D Plan Paid – CPP_r)

LICS Amounts reduce NPP Amounts when there is enhanced alternative cost sharing. Specifically:

- If PLRO $\geq CPP_c$, then NPP_r Amount = (Part D Plan-Paid – LICS Amount)
  and CPP_r Amount = $0

- If PLRO $< CPP_c$, then CPP_r Amount = (CPP_c – PLRO)
  and NPP_r Amount = (Part D Plan-Paid - LICS Amount – CPP_r Amount).

8. Report a value = M in the Pricing Exception Code field.

17.4.3 Non-standard data format

If a Part D plan receives notice of a primary payment via a beneficiary-submitted claim, Explanation of Benefits, pharmacy receipt or other non-standard method, the plan will follow the instructions in Section 4 to submit a non-standard format PDE record.

17.4.4 PDE Examples

The following examples illustrate how a plan will use these steps to price a claim and populate a PDE record when a primary payment has already been made. In each example, a Part D plan receives a COB segment or non-standard format claim indicating payment by a primary payer.

Examples 1 – 4 Defined standard benefit

In examples 1-4, the beneficiary is enrolled in a defined standard PBP and the drug is a covered Part D drug. In examples 1-3, the beneficiary is in the initial coverage period; in example 4, the beneficiary is in the coverage gap and is eligible for LICS at Level 2 (see Section 10). The examples are summarized in the following table and are then described in detail in the text below it.

MSP: Defined Standard Benefit				
	Ex #1	**Ex #2**	**Ex #3**	**Ex #4**
Primary Payer Payment	$75	$65	$90	$40
Part D Plan Negotiated Price (based on NDC on COB segment)	$100	$100	$100	$100
Part D Plan Liability under the PBP	$75	$75	$75	$0
Beneficiary Liability under the PBP	$25	$25	$25	~~$100~~ $5
Part D Plan pays pharmacy	$0	$10	$0	$55
PDE field: CPP Amount	$0	$10	$0	$0
PDE field: Patient Pay Amount	$25	$25	$10	$5
PDE field: PLRO	$75	$65	$90	$40
PDE field: GDCB	$100	$100	$100	$100
PDE field: LICS Amount	$0	$0	$0	$55

Example 1
The primary payment was $75 and the beneficiary is in the initial coverage period.

1. The plan prices the claim at its negotiated price of $100, and reports this amount in the GDCB field.
2. The plan reports the primary payment of $75 in PLRO. (Steps 3 and 6-7 describe how this payment reduces the plan liability by $75).
3. It determines the beneficiary's liability of $25 and plan liability of $75 under the PBP.
4. The difference between the negotiated price and the primary payment is $100 - $75 = $25.
5. The beneficiary is responsible for whichever is less, the cost sharing under the PBP (from Step 3) or the difference between the negotiated price and the amount paid by the primary payer

(from Step 4). In this example, the amounts are the same, $25. The plan reports $25 in the Patient Pay Amount field.
6. The Part D plan pays the pharmacy any amount remaining after the primary payment and the beneficiary's cost sharing under the PBP have been applied, up to the Part D plan's negotiated price. Since the primary paid $75 and the beneficiary liability is $25, the full negotiated price has been covered and Plan-Paid at POS is zero.
7. This is a basic plan and a covered drug, so CPP Amount = $0.
8. The plan reports Pricing Exception field = 'M'.

Example 2
The primary payment was $65 and the beneficiary is in the initial coverage period.

1. The plan prices the claim at its negotiated price of $100, and reports this amount in the GDCB field.
2. The plan reports the primary payment of $65 in PLRO. (Steps 3 and 6-7 describe how this payment reduces the plan liability by $65).
3. It determines the beneficiary's liability of $25 and plan liability of $75 under the PBP.
4. The difference between the negotiated price and the primary payment is $100 - $65 = $35.
5. The beneficiary is responsible for whichever is less, the cost sharing under the PBP (from Step 3, $25) or the difference between the negotiated price and the amount paid by the primary payer (from Step 4, $35). The plan reports $25 in the Patient Pay Amount field.
6. The Part D plan is only responsible for any amount remaining after the primary payment and the beneficiary's cost sharing under the PBP have been applied, up to the Part D plan's negotiated price. The sum of the primary payment ($65) and beneficiary liability ($25) = $90. The plan pays the pharmacy the remaining $10 of the negotiated price ($100 - $90 = $10).
7. This is a covered drug under a basic plan, so the Plan-Paid amount at POS is reported as CPP Amount = $10 on the PDE.
8. The plan reports Pricing Exception field = 'M'.

Example 3
The primary payment was $90 and the beneficiary is in the initial coverage period.

1. The plan prices the claim at its negotiated price of $100, and reports this amount in the GDCB field.
2. The plan reports the primary payment of $90 in PLRO. (Steps 3 and 5-7 describe how this payment reduces the plan liability by $75 and the beneficiary liability by $15, for a total liability reduction of $90).
3. It determines the beneficiary's liability of $25 and plan liability of $75 under the PBP.
4. The difference between the negotiated price and the primary payment is $100 - $90 = $10.
5. The beneficiary is responsible for whichever is less, the cost sharing under the PBP (from Step 3, $25) or the difference between the negotiated price and the amount paid by the primary payer (from Step 4, $10). The plan reports $10 in the Patient Pay Amount field.
6. The Part D plan is only responsible for any amount remaining after the primary payment and the beneficiary's cost sharing under the PBP have been applied, up to the Part D plan's negotiated price. The sum of the primary payment ($90) and beneficiary liability ($25) = $115,

exceeding the negotiated price. Since the full negotiated price has been covered; there is no remaining amount to be paid by the plan.
7. The plan reports CPP Amount = $0.
8. The plan reports Pricing Exception field = 'M'.

Example 4
The primary payment was $40 on a brand name covered drug. The beneficiary is in the coverage gap and is eligible for LICS at Level 2.

1. The plan prices the claim at its negotiated price of $100, and reports this amount in the GDCB field.
2. The plan reports the primary payment of $40 in PLRO. (Steps 3 and 6-7 describe how the plan's liability including LICS is reduced by $40, from $100 to $55).
3. It determines the beneficiary's liability of $5 (see Section 10) and plan liability of $0 under the PBP.
4. The difference between the negotiated price and the primary payment is $100 - $40 = $60.
5. The beneficiary is responsible for whichever is less, the cost sharing under the PBP (from Step 2, $5) or the difference between the negotiated price and the amount paid by the primary payer (from Step 3, $60). The plan reports $5 in the Patient Pay Amount field.
6. At POS, the Part D plan pays any amount remaining after the primary payment and the beneficiary's cost sharing under the PBP have been applied, up to the Part D plan's negotiated price. The sum of the primary payment ($40) and beneficiary liability ($5) = $45. Even though the beneficiary is in the coverage gap, he/she is eligible for LICS so the plan pays the pharmacy the remaining $55 of the negotiated price ($100 - $45 = $55).
7. It reports this payment in LICS Amount.
8. The plan reports Pricing Exception field = 'M'.

Example 5 Primary payment > negotiated price

In example 5, we illustrate calculating and reporting rules in an MSP situation where the primary payment exceeds the negotiated price of the drug. The plan is an alternative plan (either basic or enhanced). We also use this example to show calculations in a case where a beneficiary has no cost sharing for a particular drug under their PBP. The example is summarized in the following table and then described in detail in the text below it.

MSP: Primary Payment > Negotiated Drug Price	
	Ex #5
Primary Payer Payment	$15
Part D Plan Negotiated Price (based on NDC on COB segment)	$10
Part D Plan Liability under the PBP	$10
Beneficiary Liability under the PBP	$0
Part D Plan-Paid at POS	$0
PDE field: Patient Pay Amount	$0
PDE field: CPP Amount	$0
PDE field: NPP Amount	$0
PDE field: PLRO	$15
PDE field: GDCB	$10
PDE field: LICS Amount	$0

Example 5
A beneficiary is in the pre-catastrophic phase of his/her benefit and fills a prescription for a generic covered drug with zero beneficiary cost sharing. The primary payment was $15 which is greater than the negotiated price of the drug.

1. The plan prices the claim at its negotiated price of $10 and reports this amount in the GDCB field.
2. The plan reports the primary payment of $15 in PLRO. Note that all other payment fields will equal $0 since PLRO > gross drug cost (negotiated price).
3. It determines that there is no beneficiary liability for a generic drug under the PBP, so plan liability is $10.
4. The difference between the negotiated price and the primary payment is $10 - $15 = -$5.
5. The beneficiary is responsible for whichever is less, the cost sharing under the PBP (from Step 3, $0) or the difference between the negotiated price and the amount paid by the primary payer (from Step 4, -$5). However, the beneficiary cannot have a negative cost-share so the plan reports $0 in the Patient Pay Amount field.
6. The Part D plan is only responsible for any amount remaining after the primary payment and the beneficiary's cost sharing under the PBP have been applied, up to the Part D plan's negotiated price. The sum of the primary payment ($15) and beneficiary liability ($0) = $15, exceeding the negotiated price. Since the full negotiated price has been covered; there is no remaining amount to be paid by the plan.
7. Therefore, CPP Amount = $0.
8. The plan reports Pricing Exception field = 'M'.

Examples 6 – 9 Enhanced alternative benefits

In examples 6-9, the beneficiary is in an enhanced alternative (EA) plan (see Section 7). We illustrate the MSP rules and rules for reporting EA benefits to populate a PDE record for covered and non-covered drugs. Note that third party payments are applied to covered benefits

before non-covered benefits; specifically, they reduce CPP amounts before NPP amounts. Also, NPP can be negative as described in Section 7, but CPP cannot be reduced below zero.

The enhanced PBP has no coverage gap and the enhanced initial coverage period has a tiered cost sharing structure of $5/$20/$40/25%. The beneficiary purchases a Tier 2 drug. The examples are summarized in the following table and are then described in detail in the text below it.

MSP: Enhanced alternative benefits				
	Ex #6	**Ex #7**	**Ex #8**	**Ex #9**
Primary Payer Payment	$60	$40	$50	$10
Part D Plan Negotiated Price (based on NDC on COB segment)	$100	$100	$100	$100
Part D Plan Liability under the PBP (non-LI)	$80	$80	$80	$80
Beneficiary Liability under the PBP	$20	$20	$20	~~$20~~ $2
Part D Plan-Paid at POS	$20	$40	$30	$88
CPP_c	$75	N/A	$15	$15
CPP_r	$15	N/A	$0	$5
NPP_r	$5	N/A	$30	$65
PDE field: Patient Pay Amount	$20	$20	$20	$2
PDE field: CPP Amount	$15	$0	$0	$5
PDE field: NPP Amount	$5	$40	$30	$65
PDE field: PLRO	$60	$40	$50	$10
PDE field: GDCB	$100	$0	$100	$100
PDE field: LICS Amount	$0	$0	$0	$18

Example 6
Year-to-date (YTD) total covered drug costs = $300 and the drug is a covered Part D drug.

1. The plan prices the claim at its negotiated price of $100, and reports this amount in the GDCB field.
2. The plan reports the primary payment of $60 in PLRO. (Steps 3 and 6-7 describe how CPP is reduced by this amount).
3. Under the PBP, the beneficiary is in the initial coverage period and is liable for a co-pay of $20. The plan liability is $80.
4. The difference between the negotiated price and the primary payment is $40 (100 - $60).
5. The beneficiary is responsible for whichever is less, the cost sharing under the PBP (from Step 3, $20) or the difference between the negotiated price and the amount paid by the primary payer (from Step 4, $60). The plan reports $20 in the Patient Pay Amount field.
6. The Part D plan is only responsible for any amount remaining after the primary payment and the beneficiary's cost sharing under the PBP have been applied, up to the Part D plan's negotiated price. The sum of the primary payment ($60) and beneficiary liability ($20) = $80. So at POS, the plan-paid amount is $20.

7. Since this is an enhanced alternative plan and a covered drug, the plan calculates CPP_c = $75 by mapping to the defined standard benefit (Section 7, Rule #2).

- PLRO < CPP_c, so CPP_r Amount = (CPP_c -PLRO) = ($75-$60) = $15.
- NPP Amount = (Patient Pay Amount + LICS Amount – CPP_r) = ($20-$15) = $5.

8. The plan reports Pricing Exception field = 'M'.

Example 7
YTD total covered drug costs = $4,600 and the drug is a supplemental drug.

1. The plan prices the claim at its negotiated price of $100. Because the drug is non-covered, the plan reports $0 in the GDCB field.
2. The plan reports the primary payment of $40 in the PLRO field.
3. Under the PBP, the beneficiary is still in the initial coverage period so is liable for a $20 co-pay. The plan liability is $80.
4. The difference between the negotiated price and the primary payment is $60 (100 - $40).
5. The beneficiary is responsible for whichever is less, the cost sharing under the PBP (from Step 3, $20) or the difference between the negotiated price and the amount paid by the primary payer (from Step 4, $60). The plan reports $20 in the Patient Pay Amount field.
6. The Part D plan is only responsible for any amount remaining after the primary payment and the beneficiary's cost sharing under the PBP have been applied, up to the Part D plan's negotiated price. The sum of the primary payment ($40) and beneficiary liability ($20) = $60. So at POS, the plan-paid amount is $40.
7. Since this is a supplemental drug, this $40 payment is reported in NPP Amount.
8. The plan reports Pricing Exception field = 'M'.

Example 8
YTD total covered drug costs = $6,000, beneficiary is in the enhanced initial coverage period, and the drug is a covered drug.

1. The plan prices the claim at its negotiated price of $100, and reports this amount in the GDCB field.
2. The plan reports the primary payment of $50 in the PLRO field.
3. Under the PBP, the beneficiary is still in the initial coverage period so is liable for a $20 co-pay. The plan liability is $80.
4. The difference between the negotiated price and the primary payment is $50 (100 - $50).
5. The beneficiary is responsible for whichever is less, the cost sharing under the PBP (from Step 3, $20) or the difference between the negotiated price and the amount paid by the primary payer (from Step 4, $50). The plan reports $20 in the Patient Pay Amount field.
6. The Part D plan is only responsible for any amount remaining after the primary payment and the beneficiary's cost sharing under the PBP have been applied, up to the Part D plan's negotiated price. The sum of the primary payment ($50) and beneficiary liability ($20) = $70, so Plan-Paid at POS = $30.
7. Since this is an enhanced alternative plan and a covered drug, the plan calculates CPP_c = $15 by mapping to the defined standard benefit (Section 7, Rule #4).

- PLRO > CPP_c, so NPP Amount = Plan-Paid at POS = $30.
- CPP Amount = $0.

(Note: Due to the primary payment, CPP and NPP have been reduced by $15 and $35 respectively ($50 total) from what they would otherwise have been under Section 7 rules. CPP was reduced first).
8. The plan reports Pricing Exception field = 'M'.

Example 9
The conditions are the same as in Example 8 except the beneficiary is eligible for LICS at Level II (see Section 10) and the primary payment is $10.

1. The plan prices the claim at its negotiated price of $100, and reports this amount in the GDCB field.
2. The plan reports the primary payment of $10 in the PLRO field. (Steps 3, 6, and 7 show how CPP and NPP were reduced by this amount).
3. Under the PBP, the beneficiary is liable for a $20 co-pay, reduced to $2 because of LICS. The plan liability is $80 (not taking LICS into account).
4. The difference between the negotiated price and the primary payment is $90 (100 - $10).
5. The beneficiary is responsible for whichever is less, the cost sharing under the PBP (from Step 3, $2) or the difference between the negotiated price and the amount paid by the primary payer (from Step 4, $90). The plan reports $2 in the Patient Pay Amount field.
6. The Part D plan is only responsible for any amount remaining after the primary payment and the beneficiary's cost sharing under the PBP have been applied, up to the Part D plan's negotiated price. The sum of the primary payment ($10) and beneficiary liability ($2) = $12, so Plan-Paid at POS = $88.
7a) LICS calculations do not change under MSP, so LICS Amount is the difference between the non-LI cost sharing and the LI cost sharing under the PBP (see Section 10). LICS Amount = ($20 - $2) = $18.
7b) Since this is an enhanced alternative plan and a covered drug, the plan calculates CPP_c = $15 by mapping to the defined standard benefit (Section 7, Rule #4).

- PLRO < CPP_c, so NPP Amount = (Plan-Paid at POS – LICS) = ($88 - $18) = $65. CPP_r Amount = $5.

(Note: Due to the primary payment, CPP was reduced by $10and NPP remained the same).
8. The plan reports Pricing Exception field = 'M'.

17.5 MSP and progression through the Part D benefit

In an MSP situation, payments by both the primary party and Medicare contribute in certain ways to a beneficiary's progression through their Part D benefit. If the drug is a Part D covered drug, the price that the Part D plan allows for the drug (the negotiated price) will count towards total covered drug costs for purposes of moving a beneficiary through their Part D benefit.

Patient Pay Amounts and other applicable payments for Part D covered drugs (e.g., LICS) will count towards TrOOP costs. Payments by a primary payer never count towards TrOOP. However, they must be reported on the PDE record as reductions to beneficiary and/or Part D plan liability, in the PLRO field. These data assure that TrOOP costs and plan-paid amounts for risk sharing are accurate.

When a beneficiary has Part D coverage, CMS recommends that primary insurers always file a secondary claim with the Part D plan. Much of the time, beneficiaries will have benefits under their Part D plan that can only be claimed by filing a PDE record with CMS. However, even if a beneficiary does not have coverage for a given drug under their Part D plan, it is beneficial for other insurers to report all utilization to the Part D plan to ensure coordination under any Part D medication therapy monitoring program or utilization management program. The Part D plan may deny the claim, but the plan will have more comprehensive utilization information about their enrollee for use in such programs.

17.6 Reinsurance under MSP

We anticipate having few beneficiaries in the catastrophic coverage phase with Medicare as a secondary insurance. However, in those instances CMS will not calculate reinsurance on amounts paid by a primary insurer. Instead, CMS will use adjusted GDCA which will be calculated as:

Adjusted GDCA = GDCA – PLRO

The reinsurance calculation will be:

0.80 * (Adjusted GDCA – reinsurance DIR)

Note: If Adjusted GDCA includes both a Part D plan-paid amount (CPP) and a Patient Pay Amount, reinsurance will cover 80 percent of the sum of these amounts, net of direct and indirect remuneration (DIR). If the Part D plan has no liability and there is only a Patient Pay Amount, the Patient Pay Amount is the only component of Adjusted GDCA and reinsurance will cover 80 percent of the Patient Pay Amount net of DIR.

17.7 Sample Q&As

1. If a beneficiary has Workers' Compensation (WC) coverage, is WC the primary payer or is Part D?

If the Part D Plan knows that the drug used to treat the condition is related to the WC injury and claim, WC would be primary. However, Part D plans should not deny all incoming primary claims simply because a beneficiary has WC coverage. Part D plans will make primary payment in all situations where they do not know whether or not the drug on the claim is related to the WC injury, and should only deny a primary claim when the Part D plan has confidence that the drug is related to the WC injury. If WC was primary, the plan must recover any mistaken payment and submit an adjustment or deletion record to CMS reflecting the change in claim adjudication.

2. If WC or another payer is primary, would the amounts paid by the primary count towards a beneficiary's Part D TrOOP costs and/or total drug costs?

Payments by a primary payer never count towards TrOOP. However, they must be reported on the PDE record as reductions to beneficiary and/or Part D plan liability, in the PLRO field.

If the drug is a Part D covered drug, the price that the Part D plan allows for the drug (the negotiated price) will count towards total covered drug costs for purposes of moving a beneficiary through their Part D benefit. If the drug is covered under a Part D supplemental benefit, the price that the Part D plan allows will count towards supplemental (non-covered) drug costs.

3. Does CMS want PDE records submitted for prescriptions covered under WC or another liability case such as automobile insurance?

In general, yes. Technically, if the drug is not covered at all under the beneficiary's Part D plan, the plan will deny any claim and a PDE does not need to be submitted. Similarly, where a Part D plan denies a claim because it knows that the drug on the claim is related to the WC injury, it would not submit a PDE record to CMS. However, much of the time beneficiaries will have benefits under their Part D plan that need to be claimed by filing an PDE record with CMS. If a beneficiary files a claim with Part D after WC or other liable party pays, or if a claim is automatically filed under the COB system, the drug costs may count towards TrOOP or other progression by a beneficiary through their Part D benefit (see #2) and should therefore be reported.

In addition, even if a beneficiary does not have coverage for a given drug under their Part D plan, it is beneficial to report all utilization to the Part D plan to ensure coordination under any Part D medication therapy monitoring program or utilization management program. The Part D plan would deny the claim and would not submit a PDE record, but it would have more comprehensive utilization information about their enrollee for use in such programs.

4. If a beneficiary has coverage under AIDS Drug Assistance Program (ADAP), would the ADAP be primary or secondary to Part D?

ADAPs do not fall into any of the categories of primary payers under the MSP laws (GHP, no-fault, liability, or worker's compensation), so they will always be secondary to Part D; there is no MSP with regard to ADAPs. In general, when a plan discovers information about any other health insurance possessed by a beneficiary, it should first report that information to the COBC according to the rules found in the forthcoming Electronic Correspondence Referral System (ECRS) Welcome Packet. The COBC will then follow federal, state, National Association of Insurance Commissioners (NAIC), and other guidelines to determine payer of precedence. If a payer is primary to Part D, the COBC will post an MSP record in MBD as notice to the Part D plan.

Glossary of Acronyms

Because we refer to many organizations and terms by acronym in this document, we list these acronyms and their corresponding terms in alphabetical order as follows:

ADAP	AIDS Drug Assistance Program
BL	Black Lung
CFR	Code of Federal Regulations
CMS	Centers for Medicare & Medicaid Services
COB	Coordination of benefits
COBC	Coordination of Benefits Contractor
CPP	Covered D Plan Paid Amount
DAW	Dispense as written
DCB	Drug Claims Database
DDPS	Drug Data Processing System
DEA	Drug Enforcement Administration
DIR	Direct and indirect remuneration
DOB	Date of Birth
DOS	Date of Service
EA	Enhanced alternative
EACS	Enhanced alternative cost sharing
ECRS	Electronic Correspondence Referral System
EGHP	Employer group health plan
EGWP	Employer/Union-Only Group Waiver Plan
EIN	Employer Identification Number
ESRD	End stage renal disease
FBDE	Full benefit dual eligible
GDCA	Gross Drug Cost Above the Out-Of-Pocket Threshold
GDCB	Gross Drug Cost Below the Out-Of-Pocket Threshold
GHP	Group health plan
HICN	Health Insurance Claim Number
HIPAA	Health Insurance Portability and Accountability Act of 1996
I/T/U	Indian Health Service/Tribe/Tribal organization/Urban Indian program
LGHP	Large group health plan
LI	Low income
LICS	Low income cost-sharing subsidy
LIS	Low income subsidy
MA	Medicare Advantage
MA-PD	Medicare Advantage Prescription Drug plan
MBD	Medicare Beneficiary Database
MMA	Medicare Prescription Drug Benefit, Improvement and Modernization Act of 2003
MSP	Medicare as Secondary Payer
NAIC	National Association of Insurance Commissioners
NCPDP	National Council for Prescription Drug Programs
NDC	National Drug Code
NPI	National Provider Identifier
NPP	Non-covered Plan Paid Amount

OHI	Other Health Insurance
OON	Out-of-Network
OOP	Out-of-Pocket
OTC	Over-the-counter
PACE	Program of All Inclusive Care for the Elderly
PAP	Pharmaceutical Assistance Program
PBM	Pharmacy benefit manager
PBP	Plan Benefit Package
PDE	Prescription Drug Event
PDFS	Prescription Drug Front-End System
PDP	Prescription drug plan
PFFS	Private fee-for-service
PLRO	Patient Liability Reduction due to Other Payer Amount
PO	PACE organization
POS	Point of sale
RDS	Retiree drug subsidy
RRB	Railroad Retirement Board
SPAP	State Pharmaceutical Assistance Program
TIN	Tax Identification Number
TrOOP	True out-of-pocket
UPIN	Unique Provider Identification Number
WC	Worker's Compensation
YTD	Year to date