INSTRUCTIONS: REQUIREMENTS FOR SUBMITTING PRESCRIPTION DRUG EVENT DATA

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Introduction

i. Background

In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act, 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 and payment demonstration plans should especially note Sections 14 and 15 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.

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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.

Finally, we provide special rules pertaining to PACE organizations and payment demonstration plans in Sections 14 and 15. 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, 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 (e.g., home infusion, physicians when providing vaccines) will not have NCPDP numbers. For these providers, the federal Tax Identification Number (TIN) or Employer Identification Number (EIN) 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. Out-of-Network (OON) Code (Format cross reference **- DET 26)**
This field reports an out-of-network service.

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 six fields to identify a single unique prescription drug event. A change in any of the following six fields indicates a different event:

- HICN
- Service Provider
- 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 six 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:

<u>Optional fields –</u> Prescriber ID Qualifier and Prescriber ID. **All other fields must be reported.**

<u>Instructions for Ingredient Cost Paid, Dispensing Fee Paid, and Total Amount Attributed to Sales Tax –</u> 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 the physician's tax identification number in lieu of the pharmacy's NCPDP (formerly NABP) number in the Service Provider ID field. Plans will report the corresponding value of '10' in the Service Provider ID Qualifier field.
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, usually because it is on the plan's formulary or because a beneficiary successfully appeals non-coverage. **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 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")

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

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 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 an eight-field match: the six key fields, 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, 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 4). 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)):

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)

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[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).

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

Data to identify enhanced alternative benefits
To make correct payments, CMS will utilize data reported in two fields to identify enhanced alternative benefits:

> 1. Drug Coverage Status = E identifies enhanced alternative drugs. DDPS will exclude records with Drug Coverage Status value = E from reinsurance, risk corridor, TrOOP, and LICS calculations.
>
> 2. Non-covered Plan Paid Amount (NPP) – The NPP data element will be used to report OTC drugs, non-Part D supplemental drugs, and enhanced alternative cost sharing (EACS). EACS is additional cost-sharing fill-in for covered Part D drugs under an enhanced alternative plan, beyond the standard benefit amount. The dollar amount reported in NPP will be excluded from risk corridor calculations. Note that the dollar amount reported in NPP is mutually exclusive of dollar amounts reported in CPP, Patient Pay Amount, Other TrOOP Amount, LICS, and PLRO Amount.

DDPS will use the following processing rules to exclude enhanced alternative benefits from payment:

- TrOOP - Patient Pay Amounts for enhanced alternative drugs (Drug Coverage Status = E) are not included in TrOOP. Note that only dollars in Patient Pay Amount, Other TrOOP Amount, and LICS fields in PDE records for covered Part D drugs are included in TrOOP. (PDE records with Drug Coverage Status = C are considered covered Part D drugs).
- LICS will not be paid on enhanced alternative drugs (Drug Coverage Status = E).
- Reinsurance subsidy – Claims for enhanced alternative drugs will be excluded from reinsurance payment (Drug Coverage Status = E)
- Risk corridor calculations – Claims for enhanced alternative drugs will be excluded from risk corridor calculations (Drug Coverage Status = E). Also, for covered Part D drugs (Drug Coverage Status = C), the dollar amount reported in NPP will be excluded from risk corridor calculations.

7.3 Reporting enhanced alternative cost sharing for covered drugs

Enhanced alternative (EA) plans must use the business rules provided in this section to divide plan-paid amounts into amounts that would be paid under the standard benefit from amounts that exceed the standard benefit. Plans shall report amounts that would be paid under the standard benefit in the CPP field, and these amounts are considered allowable risk corridor costs (see Section 13). Plans report amounts paid in excess of the standard benefit in the NPP field, and these amounts are excluded from allowable risk corridor costs.

First, 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 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).

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

When reporting PDE records for covered drugs, plans will apply the following rules to calculate amounts to submit in Patient Pay Amount, CPP Amount and NPP Amount.

1. Pay pharmacy according to plan's cost-sharing formula and note the patient and plan-paid amounts at the point of sale (POS).
2. Report patient cost sharing at POS in the Patient Pay Amount field.
3. The 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 below; YTD total covered drug cost determines which rule to use:

Rule #	YTD Total Covered Drug Cost	Percentage to calculate standard benefit
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)
5	> Out-of-Pocket Threshold	Lesser of 95% or (Total Covered Drug Cost - $2/$5)

4. Determine the enhanced alternative cost-sharing amount (EACS) by subtracting Patient Pay Amount (Step 2) and CPP Amount (Step 3) from total covered drug cost,[3] then report the EACS amount in the NPP field. Alternatively, determine EACS by subtracting the CPP Amount from the plan-paid amount at POS, recording the difference in the NPP field.

   In formula:
   EACS = (Total Covered Drug Cost - Patient Pay Amount - LICS - Other TrOOP - PLRO – CPP)
   or EACS = (plan-paid amount at POS – CPP Amount)

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

[3] 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 enhanced alternative cost sharing.

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

<u>Plan C</u> – 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: CMS does not anticipate that plans will offer enhanced alternative cost sharing above the out-of-pocket threshold. 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 out-of-network services or generic/brand 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.

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

TrOOP-eligible	**Not TrOOP-eligible**
Qualified SPAPs	Governmental programs (VA, Black Lung, TRICARE, other)
Qualified charities	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†	Group health plans

†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[4] 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 cost-sharing phase, or the coverage gap.

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

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

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			
	Patient Pay Amount	Other TrOOP Amount	LICS	NPP	CPP	PLRO	TrOOP Impact
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.[5] 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 1A-1B, 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

[5] 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 1A. 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 of June 15, June 30 and July 15 show that the beneficiary paid 100% coinsurance. The PDE with service date of July 30 shows that the beneficiary has paid back the receivable and re-entered catastrophic coverage. By the time the plan adjudicated the Aug 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. The plan submits a PDE deletion record for the 4/15 PDE. The plan establishes a receivables account.

[e] Corrections

[f] Beneficiary re-enters coverage gap

g Beneficiary re-enters catastrophic coverage

Table 1B. 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 do not impose any data reporting requirements on plans. Plans will need to report on low-income cost-sharing amounts. Cost-sharing reductions will be applied at the point of sale and paid by the plan. In accordance with statutory language, we refer to these amounts as Low-Income Cost-Sharing Subsidies or LICS amounts. CMS will pay plans prospectively for the LICS amounts, and reconcile to actual amounts paid after the payment year.

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 2006, CMS will make monthly prospective payments to plans to help cover LICS costs as they are incurred and will conduct final reconciliation at the end of the coverage year.

In order to pay the plan accurately, CMS has defined a Low Income Cost-Sharing Subsidy (LICS) Amount field.[6] Plans will populate the LICS field with the amount they pay the pharmacy at the point of sale for an eligible beneficiary's cost sharing. To populate this field appropriately, plans must adjudicate a PDE as if the beneficiary were not eligible for a low-income subsidy and determine the corresponding unsubsidized beneficiary cost-sharing amount. Then plans must calculate the Patient Pay Amount that takes into account the amount of low-income cost-sharing subsidy for which the beneficiary is eligible. The difference between the unsubsidized cost-sharing amount and this Patient Pay Amount will be placed in the LICS field, representing the amount of subsidy advanced by the plan.

10.3 PDE Examples

The following examples demonstrate how plans will populate the PDE fields Patient Pay Amount and Low Income Cost-Sharing Subsidy Amount (LICS) and how plans will identify TrOOP-eligible dollars at the PDE level. Examples 1-4 show cost sharing specific to each phase of the basic benefit with actuarially equivalent cost sharing for five types of beneficiaries: a beneficiary who does not qualify for low income cost-sharing (non-LI) and beneficiaries eligible for each of four different cost-sharing subsidies (see Figure 2): Level I (L-I), Level II (L-II), Level III (L-III), and institutionalized beneficiaries in Level I and Level II. In our examples, the non-LI beneficiary has no other health insurance. The examples are based on a plan that offers an actuarially equivalent standard benefit package. The plan offers tiered cost-sharing (5% / 25% / 30%). The Tier 1 cost-sharing is 5% for generic drugs. The Tier 2 cost-sharing is 25% for preferred brand drugs. The Tier 3 cost-

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

sharing is 30% for non-preferred brand drugs.

Example 5 demonstrates how plans will populate various fields including Other TrOOP Amount when a qualified party makes a payment on a beneficiary's behalf that counts towards TrOOP. Examples 6 and 7 show sample data for a low-income subsidy eligible beneficiary in an enhanced alternative plan (see Section 7). Example 6 demonstrates how enhanced alternative plans will report enhanced alternative cost sharing on PDE records. Example 7 demonstrates how enhanced alternative plans will report enhanced alternative drugs (supplemental drugs) on PDE records.

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

Figure 2. Provisions and Eligibility Rules for the Low-Income Cost-Sharing Subsidy

Low Income Level	Eligibility Rules	Deductible	Initial Coverage Period	Coverage Gap	Catastrophic
I	< 100%	$0	$1-generic $3-brand	$1-generic $3-brand	$0
II	< 135%	$0	May not exceed $2-generic $5-brand	May not exceed $2-generic $5-brand	$0
III	< 150%	$50	15%	15%	May not exceed $2-generic $5-brand
Institutionalized	all L-I and all L-II	$0	$0	$0	$0

Lesser Of logic: If non-low income cost sharing is less than low income cost sharing, the low income beneficiary pays the non-low income cost sharing and LICS does not apply.

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 for $50.

	(a)	(b)	(c)	(d)	(e)	(f)
Beneficiary Type	Cost sharing	Total Covered Drug Cost (c)+(d)+(e)	Patient Pay Amount	LICS	Covered D Plan Paid Amount (CPP)	TrOOP Amount (c) + (d)
Non-LI	100%	$50	$50	n/a	$ 0	$50
LI-I	$3	$50	$ 3	$47	$ 0	$50
LI-II	$5	$50	$ 5	$45	$ 0	$50
LI-III	100% (up to $50)	$50	$50†	$ 0	$ 0	$50
Institutionalized	$0	$50	$0	$50	$ 0	$50

†LI-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)	(f)
Beneficiary Type	Cost sharing	Total Covered Drug Cost (c)+(d)+(e)	Patient Pay Amount	LICS	Covered D Plan Paid Amount (CPP)	TrOOP Amount (c) + (d)
Non-LI	5%	$5.00	$.25	n/a	$ 4.75	$.25
LI-I	$1.00	$5.00	~~$1.00*~~ $.25	$ 0.00	$ 4.75	$.25
LI-II	$2.00	$5.00	~~$2.00~~* $.25	$ 0.00	$ 4.75	$.25
LI-III	15%	$5.00	~~$.75~~* $.25	$ 0.00	$ 4.75	$.25
Institutionalized	$0.00	$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 for $250.

	(a)	(b)	(c)	(d)	(e)	(f)
Beneficiary Type	Cost sharing	Total Covered Drug Cost (c)+(d)+(e)	Patient Pay Amount	LICS	Covered D Plan Paid Amount (CPP)	TrOOP Amount (c) + (d)
Non-LI	100%	$250	$250	n/a	$ 0	$250
LI-I	$3	$250	$3	$ 247	$ 0	$250
LI-II	$5	$250	$5	$ 245	$ 0	$250
LI-III	15%	$250.00	$37.50	$ 212.50	$ 0.00	$250.00
Institutionalized	$0	$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)	(f)
Beneficiary Type	Cost sharing	Total Covered Drug Cost (c)+(d)+(e)	Patient Pay Amount	LICS	Covered D Plan Paid Amount (CPP)	TrOOP Amount (c) + (d)
Non-LI	Greater of $2/$5 or 5%	$150.00	$7.50	n/a	$ 142.50	$7.50
LI-I	$0.00	$150.00	$0.00	$ 7.50	$ 142.50	$7.50
LI-II	$0.00	$150.00	$0.00	$ 7.50	$ 142.50	$7.50
LI-III	$5.00	$150.00	$5.00	$ 2.50	$ 142.50	$7.50
Institutionalized	$0.00	$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)	(g)
Beneficiary Type	Cost sharing	Total Covered Drug Cost (c)+(d)+(e)+(f)	Patient Pay Amount	LICS	Other TrOOP Amount	Covered D Plan Paid Amount (CPP)	TrOOP Amount (c)+(d)+(e)
Non-LI	100%	$250	$250	n/a	$0	$0	$250
LI-I	$3	$250	~~$3~~ $0	$247	$3	$0	$250
LI-II	$5	$250	~~$5~~ $0	$245	$5	$0	$250
LI-III	15%	$250.00	~~$37.50~~ $0.00	$212.50	$37.50	$0.00	$250.00
Institutionalized	$0	$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
LI-I	$100	$ 3	$12	$10	$ 75	$15
LI-II	$100	$ 5	$10	$10	$ 75	$15
LI-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 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 beneficiary purchases a supplemental drug for $100.

	(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
LI-I	$0	$15	$ 0	$85	$ 0	$ 0
LI-II	$0	$15	$ 0	$85	$ 0	$ 0
LI-III	$0	$15	$ 0	$85	$ 0	$ 0
Institutionalized	$0	$15	$ 0	$85	$ 0	$ 0

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). 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

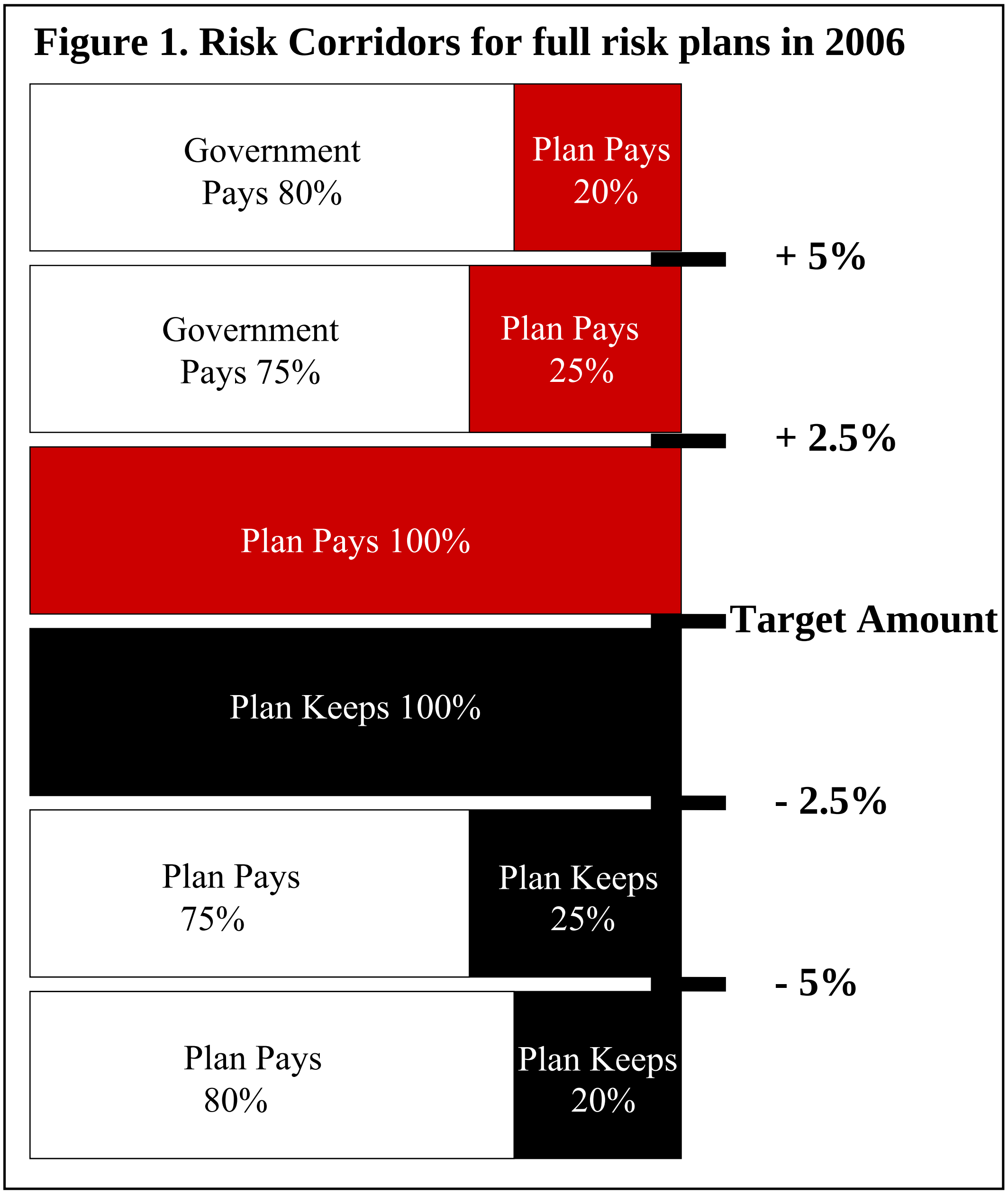
Note that CMS will have data to calculate the components that make up the target amount that will be used in reconciliation at the end of the year. For example, risk-adjusted direct subsidies that take into account any A/B rebates will be paid to plans monthly per beneficiary, and CMS will also know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



<u>Calculate adjusted allowable risk corridor costs</u>
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.

<u>Determine where costs fall with respect to the thresholds and calculate payment adjustment</u>
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)

Note that in 2006, 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 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.

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, 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.

<table>
<tr><th colspan="2"></th><th colspan="4">Dual Eligible PACE Program
The Dual Eligible PACE Program has submitted PDEs for Beneficiary A for Covered Part D drugs that total $6,000</th><th colspan="4">Medicare PACE Program
The Medicare PACE Program has submitted PDEs for Beneficiary B for Covered Part D drugs that total $6,000</th></tr>
<tr><th>Standard Benefit Category</th><th>Total Covered Drug Cost</th><th>LICS</th><th>CPP</th><th>Portion of CPP eligible for Reinsurance</th><th>NPP</th><th>Standard Benefit Category</th><th>Total Covered Drug Cost</th><th>CPP</th><th>NPP</th></tr>
<tr><td>Deductible</td><td>The first $250</td><td>$245

(.98*250)</td><td>$5

(.02 * 245)</td><td>$0</td><td>$0</td><td>Deductible</td><td>The first $250</td><td>$0</td><td>$250</td></tr>
<tr><td>Initial Cost sharing</td><td>The next $2,000

> $250 and ≤ $2,250</td><td>$460

(.23*2000)</td><td>$1,540

(.02 * 2000) + (.75 * 2000)</td><td>$0</td><td>$0</td><td>Initial Cost sharing</td><td>The next $2,000

> $250 and ≤ $2,250</td><td>$1500</td><td>$500</td></tr>
<tr><td>Coverage Gap</td><td>The next $2,850

> $2,250 and ≤ $5,100</td><td>$2,793

(.98*2850)</td><td>$57

(.02*2850)</td><td>$0</td><td>$0</td><td>Coverage Gap</td><td>The next $2,850

> $2,250 and ≤ $5,100</td><td>$0</td><td>$2,850</td></tr>
<tr><td>Defined Standard Catastrophic Coverage</td><td>The next $104 > $5,100 and ≤ $5,204†</td><td>$86.32

(.83 * 104)</td><td>$17.68

(.15 * 104) + (.02 * 104)</td><td>$0</td><td>$0</td><td rowspan="2">Defined Standard Catastrophic Coverage</td><td rowspan="2">The remaining $900

> $5,100</td><td rowspan="2">$135</td><td rowspan="2">$765</td></tr>
<tr><td>PACE Catastrophic Coverage (Reinsurance)</td><td>The remaining $796 > $5,204† and ≤ $6,000</td><td>$39.80

(.05*796)</td><td>$756.20

(.15 * 796) + (.80 * 796)</td><td>$796</td><td>$0</td></tr>
<tr><td>Total</td><td>$6,000</td><td>$3,624.12</td><td>$2,375.88</td><td>$796</td><td>$0</td><td></td><td></td><td>$1,635</td><td>$4,365</td></tr>
<tr><td colspan="2"></td><td colspan="4">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).</td><td colspan="4">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).</td></tr>
</table>

† 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.[7]

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).

[7] 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.

Note the following definitions:
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.[8]

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

[8] 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.

<u>Target amount</u>

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
<u>+ Capitated reinsurance payment</u>
= Target amount before administrative cost adjustment
<u>* (1 - Administrative cost ratio)</u>
= Target amount

<u>Adjusted allowable risk corridor costs</u>
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).

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:

CFR	Code of Federal Regulations
CMS	Centers for Medicare & Medicaid Services
COB	Coordination of benefits
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
EACS	Enhanced alternative cost sharing
EIN	Employer Identification Number
GDCA	Gross Drug Cost Above the Out-Of-Pocket Threshold
GDCB	Gross Drug Cost Below the Out-Of-Pocket Threshold
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
LICS	Low-income cost-sharing subsidy
MA	Medicare Advantage
MA-PD	Medicare Advantage Prescription Drug plan
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MSP	Medicare as Secondary Payer
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
POS	Point of sale
RRB	Railroad Retirement Board
SPAP	State Pharmaceutical Assistance Program

TIN	Tax Identification Number
TrOOP	True out-of-pocket
UPIN	Unique Provider Identification Number