U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES

COLLECTION OF PRESCRIPTION DRUG EVENT DATA FROM CONTRACTED PART D PROVIDERS FOR PAYMENT

OFFICE OF MANAGEMENT AND BUDGET
CLEARANCE PACKAGE SUPPORTING STATEMENT

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CONTENTS

BACKGROUND

In December 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173), referred to as the Medicare Modernization Act (MMA). The Medicare Prescription Drug Benefit program (Part D) was established by section 101 of the MMA and is codified in section 1860D-1 through 1860 D-41 of the Social Security Act.

Effective January 1, 2006, the Part D program establishes an optional prescription drug benefit for individuals who are entitled to Medicare Part A and/or enrolled in Part B. The new Part D benefit constitutes perhaps the most significant change to the Medicare program since its inception in 1965. The addition of outpatient drugs to the Medicare program reflects Congress' recognition of the fundamental change in recent years in how medical care is delivered in the United States (U.S.). It recognizes the vital role of prescription drugs in our health care delivery system, and the need to modernize Medicare to assure their availability to Medicare beneficiaries.

In general, coverage under the new prescription drug benefit is provided predominately through private at-risk prescription drug plans that offer drug-only coverage (PDPs), Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans) or through Cost Plans that offer prescription drug benefits.

Part D plans may offer plans with either: (1) basic prescription drug coverage; or (2) enhanced alternative coverage, which includes certain supplemental benefits such that the total value of the coverage exceeds the value of basic prescription drug coverage. PDPs may offer enhanced alternative coverage for a supplemental premium. MA-PD plans may offer enhanced alternative coverage either for a supplemental premium, or they may buy down the supplemental premium with savings from their bids for medical benefits (also known as Medicare Advantage rebate dollars). PDP plans must offer at least one plan with basic prescription drug coverage in each service area in which they operate. In order to operate in a service area, MA-PD organizations must offer at least one plan with basic prescription drug coverage or enhanced alternative coverage for no supplemental premium. Medicare cost plans and Program for All-Inclusive Care for the Elderly (PACE) organizations may, at their election, offer Part D coverage similar to an MA-PD plan. For cost plans that elect to offer Part D coverage, such coverage will be a supplemental benefit even when the coverage offered is basic prescription drug coverage. CMS has established 26 MA Regions and 34 PDP Regions, not including territories, in which PDPs or regional MA-PDs may be offered. PDP and MA-PD plans may offer national (i.e., offering a plan in every region) or regional (i.e., offering a plan in one or more region) plans. MA-PD plan applicants may also offer local plans (down to the county level).

The MMA requires that each region have at least two Part D plans from which to choose, and at least one of which must be a PDP. In areas where the required minimum number of plan choices is not available, the MMA requires CMS to contract with Fallback Entities. Fallback Entities must satisfy the same requirements as PDPs, but will receive

reimbursement for drug costs from CMS on a cost rather than a risk basis. Fallback Entities have not been necessary to date given strong interest by private entities in offering Part D plans in all regions.

Part D plans have flexibility in terms of benefit design. This flexibility includes, but is not limited to, authority to establish a formulary that limits coverage to specific drugs within each therapeutic class of drugs, and the ability to have a cost-sharing structure other than the statutorily defined structure (subject to certain actuarial tests).

History of Program Implementation and Industry Consultation

Initially, CMS envisioned that the disclosure and provision of information needed to carry out the payment provisions of the MMA would encompass the quantity, type and costs of pharmaceutical prescriptions filled that could be linked to individual enrollee data in our systems; that is, linked to the Medicare beneficiary health insurance claim number (HICN). We believed that frequent data feeds, other than annually (for example: weekly, monthly or quarterly), would allow us to identify and resolve data issues and to be more supportive of various payment processes. Our fundamental goal was to determine the least burdensome data submission requirements necessary to acquire the data needed for accurate payment and appropriate program oversight. Those views led us to believe that we would need at least the following data items for 100 percent of prescription drug claims or events from plans offering Part D coverage for the processes discussed below:

- Beneficiary HIC#
- Eleven-digit NDC code
- Quantity dispensed
- Prescription drug cost before co-payment (ingredient cost, dispensing fee, sales tax)
- Beneficiary co-payment amount
- Date prescription filled

We further anticipated that we would need similar data on prescription drug claims or events for appropriate risk-adjustment, reconciliation of reinsurance subsidies, and calculation of risk sharing payments or savings, and program auditing. We believed that those subsequent needs would require additional data submission formatting for the following processes:

- A risk adjustment process that would require 100 percent of drug claims in order to develop and calibrate the weights for the model for this new benefit.
- The reinsurance subsidy payment process that would require 100 percent of claims for each enrollee for whom the plan claimed allowable reinsurance costs.
- The risk sharing process that would require 100 percent of claims for all enrollees for the calculation of total allowable risk corridor costs.
- The low income cost sharing subsidy process that would require 100% of claims for each enrollee for whom the plan paid low income cost sharing subsidy costs.

- The program audit process that would require at least a statistically valid random sample of all Part D drug claims.

Thus, we requested public comments on the content, format, and frequency for those proposed disclosures, processes and provisions of information in our Notice of Proposed Rulemaking (NPRM) on August 3, 2004. The NPRM may be reviewed in Federal Register, Vol. 69, No. 148, CMS-4068-P. (46686-46687). In this publication in the "Collection of Information" section, CMS also requested industry input and discussion, as required under §3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA). As required under this PRA section, we solicited comments on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

CMS addressed the NPRM and PRA comments on January 28, 2005 in the Final Rule, which may be reviewed in Federal Register, Vol. 70, No. 18, CMS-4068-F. (4307-4308) and (4443, 4447-4448 for the PRA).

On April 27, 2006, CMS issued instructions on Requirements for Submitting Prescription Drug Event Data (PDE) (See Attachment A) which specified the manner, form and frequency of data transmission to CMS. The instructions specified that PDE records must be submitted to CMS electronically at least once a month.

Submission Requirements

The MMA requires Medicare payment to MA organizations, PDP plans, Fallbacks and other plans offering coverage of outpatient prescription drugs under the new Medicare Part D benefit. The Act provided four summary mechanisms for paying plans:

- direct subsidies
- subsidized coverage for qualifying low-income individuals
- federal reinsurance subsidies
- risk corridor payments

In order to make payment in accordance with these provisions, CMS has determined to collect a limited set of data elements for 100 percent of prescription drug claims or events from plans offering Part D coverage. In determining these requirements, we have incorporated feedback from industry and other stakeholders obtained by formal and informal means including the rulemaking process, Open Door Forums and other consultation. We used four criteria in selecting the required data elements:

- ability to pay plans timely and accurately using the four legislated payment mechanisms (direct subsidy, reinsurance, risk corridors, and low-income subsidy);

- minimal administrative burden on CMS, plans, and other entities including MA-PDs, PDPs, fallback plans, pharmacy benefit managers, pharmacies, and others;
- legislative authority; and
- validity and reliability of the data elements requested, to ensure that the information will be useful.

The requirements for submitting PDE data provide that much of the data, especially financial fields, will be used primarily for payment. However, other data elements will be used for validation of the claims as well as for other legislated functions such as quality monitoring, program integrity, and oversight.

Our instructions for submitting PDE data require that plans must submit a PDE record for each dispensing event. The PDE record is a summary record that documents the final adjudication of the dispensing event. Since the pharmacy industry has an effective drug claims submission standard, which is electronically automated, we will use the National Council of Prescription Drug Programs (NCPDP) version 5.1 as the data format for PDE submissions. Thus, our 40 required PDE elements include 15 data elements from the NCPDP billing transaction, 5 data elements from the NCPDP billing response transaction and 18 CMS defined data elements. Although a number of the statutory requirements of the Act were not available in the NCPDP data elements, we utilized the NCPDP format to construct the CMS defined data elements to ensure minimal burden on plans. See Attachment B for the Prescription Drug Event Record Layout.

Collection of Prescription Drug Event Data

As a condition of payment, all Part D plans must submit data and information necessary for CMS to carry out payment provisions. 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 other legislated functions such as quality monitoring, program integrity, and oversight.

Every time a beneficiary fills a Part D prescription, plans must submit a summary record called the prescription drug event (PDE) record to CMS. The PDE data is an extract of information from claims made by beneficiaries purchasing prescription drugs that are covered under Part D. 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 Part D drug costs above and below the out-of-pocket threshold; distinguish supplemental benefits from benefits provided under basic prescription drug coverage; and will record payments made by Part D plans, 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 costs, 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. PDE data also reflect how a plan has administered its Part D benefit package. CMS uses the data to reconcile low-income cost-sharing subsidy

and reinsurance payments and to implement risk sharing between the plan and the Federal government.

In most situations, the MA-PD/PDP or a designated third party processor on its behalf processes the claim that has been submitted electronically by the network provider (e.g., pharmacy or physician office) and determines the applicable cost sharing to be made by the beneficiary. Typically, the network providers provide billing transactions to MA-PD/PDP in real-time and the claim processor can file the information to CMS promptly. In a limited number of situations, a beneficiary or other entity may submit a non-standard format claim such as a paper claim to a plan or its third party processor. The plan/processor then creates a PDE record from the claim to submit electronically to CMS in a non-standard format (for example, there are special rules and exceptions for populating certain non-financial data elements).

The Prescription Drug Event (PDE) record contains prescription drug cost and payment data that enable CMS to make payment to plans and otherwise administer the Part D benefit. Specifically, the PDE record includes covered drug costs above and below the Out-of-Pocket (OOP) threshold; distinguishes enhanced alternative costs from the costs of drugs provided under the Basic Benefit; and records payments made by Part D plans, other payers, beneficiaries, or individuals on behalf of a beneficiary. Plans must also identify costs that contribute toward a beneficiary's True Out-of-Pocket (TrOOP) limit.

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 (POS) by plan adjudication of the claim, and drives eventual plan payment to the pharmacy. The PDE record contains information that is vital for payment, quality oversight, and program integrity.

For each dispensing event, the plan must submit a PDE record. Most organizations 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.

The following is an illustration of the prescription drug event dataflow.

Prescription Drug Event Dataflow

The pharmacy, physician, or other provider submits a claim to the Part D Plan.

If necessary, the pharmacy generates a secondary claim to any other payers via the TrOOP facilitator.

The Part D Plan submits data to CMS via the PDE record.

The Part D Plan successfully submits PDE records at least once a month to PDFS/DDPS.

The PDE records are sent to PDFS where front-end edits are applied.

The PDFS response report indicates file acceptance or rejection. If any PDE records fail front-end edits, PDFS will report the failure on the PDFS Response Report.

After passing the PDFS checks, the file is submitted to DDPS where detail editing is performed.

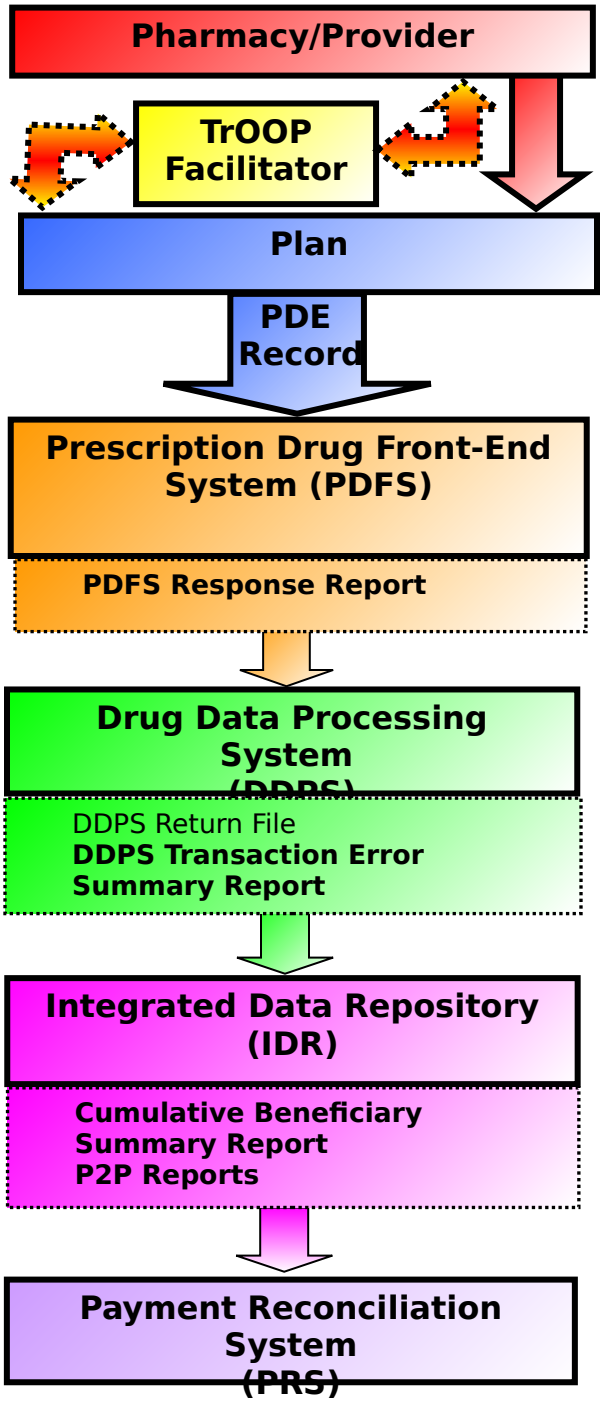
After processing the file, DDPS sends the DDPS Return File. It shows the disposition of all DET records and identifies errors.

The DDPS Transaction Error Summary displays the count and rate for each error code found in the submitted data.

The IDR sums LICS and calculates unadjusted reinsurance and risk corridor costs.

Management reports are generated in the IDR and provide a summary of net accumulated totals for all dollar fields.

PRS creates a beneficiary/plan record for each beneficiary enrolled in a plan during the payment year and calculates reconciliation payments at the beneficiary and plan level.



Prescription Drug Event (PDE)

PDE Record Fields

The record contains 40 fields. Included in these fields are 40 data elements that plans must populate for CMS to reconcile payment and provide program oversight. Plans must sort DET records within each batch by the Health Insurance Claim Number (HICN). This section reviews data elements within the DET record, with emphasis on data used for payment reconciliation.

Beneficiary Identifiers: The following data elements identify the beneficiary:

- HICN
- Cardholder ID
- Patient Date of Birth (DOB)
- Patient Gender

The HICN is the only data element used to identify a beneficiary that is not available in NCPDP standard format. The HICN is a Medicare beneficiary's identification number. Both SSA and the Railroad Retirement Board (RRB) issue Medicare HICNs.

Prescription Drug Event Identifiers: Thirteen data elements, which are standard throughout the industry, describe both the drug and the method in which the drug was dispensed.

- Date of Service
- Prescription Service Reference Number
- Product Service ID
- Service Provider ID Qualifier
- Service Provider ID
- Fill Number
- Dispensing Status
- Compound Code
- Dispense as Written (DAW) Product Selection Code
- Quantity Dispensed
- Days Supply
- Prescriber ID Qualifier
- Prescriber ID

Three non-financial data elements are unique to Part D:

- Paid Date.
- Catastrophic Coverage Code
- Drug Coverage Status Code

Dollar Fields: The PDE Record layout includes 13 fields that must be populated with dollar amounts. These 13 fields can be categorized as detail cost fields, summary cost fields, patient liability payment fields, and plan payment fields. Each of these fields impacts Part D payment. In cost fields, plans must report the dollar amount paid to the pharmacy.

- Ingredient Cost Paid
- Dispensing Fee Paid
- Total Amount Attributed to Sales Tax
- Gross Drug Cost Below Out-of-Pocket Threshold (GDCB)
- Gross Drug Cost Above Out-of-Pocket Threshold (GDCA)
- Patient Pay Amount
- Other TrOOP Amount
- Low Income Cost Sharing Subsidy Amount (LICS)
- Patient Liability Reduction Due to Other Payer Amount (PLRO)
- Covered Plan Paid Amount (CCP)
- Non Covered Plan Paid Amount (NPP)
- Estimated Rebate at POS (Point-of-Sale)
- Vaccine Administration Fee

The data elements on the PDE record are:

Field #	Field Name	Description
1	Contract Number	This field contains the unique number CMS assigns to each contract that a Part D plan has with CMS.
2	Plan Benefit Package (PBP) ID	This field contains 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	This field is an optional, free-form field. It may be used by plans to identify unique events 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)	This field contains 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. References to HICN mean HICN or RRB# as appropriate. 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	CMS collects 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)	Patient date of birth (DOB) is optional and is used in conjunction with HICN and gender to verify beneficiary identity. It is used as a cross-reference to ensure the event has identified the correct beneficiary.
7	Patient Gender Code	Together with HICN and DOB (when reported), gender confirms the identity of the beneficiary.
8	Date of Service (DOS)	Date of Service (DOS) is the date on which the prescription was filled.
9	Paid Date	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 uses Paid Date to reconcile drug costs reported on PDE records to withdrawals for drug costs from the fallback plan's draw-down account.
10	Prescription Service Reference Number	This field contains 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.
11	Product Service ID	This field identifies the dispensed drug using a National Drug Code (NDC). NDC is 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.
12	Service Provider ID Qualifier	This field indicates the type of provider identifier used.
13	Service Provider ID	This field identifies the pharmacy where the prescription was filled. This data helps CMS identify a unique prescription drug event. Prior to National Provider Identifier (NPI) implementation in May 2008, the National Council of Prescription Drug Plans (NCPDP) number was primarily reported. Since May 2008 the NPI is primarily reported in this field. CMS prefers the use of the NPI in this field. If the NPI is unavailable, the field should contain the NCPDP number, which all NCPDP billers are assigned. If neither the NPI number nor the NCPDP number is available for a provider who submitted in Non-Standard Format (e.g., home infusion, physicians when providing vaccines), then the UPIN, State License Number, Federal Tax Identification Number (TIN) or

		Employer Identification Number (EIN) or the default value of "PAPERCLAIM" will be the required identifier.
14	Fill Number	This field indicates the number fill of the current dispensed supply.
15	Dispensing Status	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.
16	Compound Code	This field indicates 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	Dispense As Written (DAW)/Product Selection Code	This field indicates the prescriber's instruction regarding substitution of generic equivalents or order to dispense the specific product written.
18	Quantity Dispensed	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	This field indicates the number of days' supply of medication dispensed by the pharmacy and consists of the amount the pharmacy enters for the prescription.
20	Prescriber ID Qualifier	This field indicates the type of identifier that is used in the Prescriber ID field.
21	Prescriber ID	This field contains the prescriber's unique identification number. Following National Provider Identifier (NPI) implementation in May 2008 CMS prefers the use of the national provider identifier (NPI). If the NPI is not available, 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.
22	Drug Coverage Status Code	This field indicates whether or not the drug is covered under the Medicare Part D benefit and/or a specific PBP.
23	Adjustment/ Deletion Code	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. 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 key fields (key fields are Service Provider ID, Service Provider ID Qualifier, Prescription/Service Reference Number, Date of Service, Fill Number and Dispensing Status).
24	Non-Standard Format Code	This data element is 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.
25	Pricing Exception Code	This field indicates that the PDE reports an out-of-network or Medicare as Secondary Payer (MSP) service that is subject to unique pricing rules.
26	Catastrophic Coverage Code	This field indicates that a beneficiary has reached the out-of-pocket (OOP) threshold. At this point, catastrophic coverage provisions begin, namely reinsurance and reduced beneficiary cost sharing.
27	Ingredient Cost Paid	This field contains the amount paid for the drug itself. Dispensing fees or other costs shall not be included in this amount except as allowed on non-standard format claims.
28	Dispensing Fee Paid	This field contains amounts paid for dispensing the medication. Include only those activities related to the transfer of possession of 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, the preamble to the rule and in chapter 5 of the Prescription Drug Benefit Manual. 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	This field contains the sum of all amounts paid to cover sales tax.
30	Gross Drug Cost Below Out-Of-Pocket Threshold (GDCB)	This field represents the gross drug cost (Ingredient Cost Paid + Dispensing Fee Paid + Total Amount Attributed to Sales Tax + Vaccine Administration Fee) paid below the OOP threshold for a given PDE for a covered Part D drug. For claims before a beneficiary has reached the out-of-pocket threshold, this field will list a positive dollar amount. For claims above the out-of-pocket threshold, this field will have a zero dollar value. For a claim on which the out-of-pocket threshold 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	This field represents the gross drug cost (Ingredient Cost Paid + Dispensing Fee Paid + Total Amount Attributed to Sales Tax+ Vaccine Administration Fee) paid above the OOP

	(GDCA)	threshold for a given PDE for a covered Part D drug. For claims before a beneficiary has reached the out-of-pocket threshold, this field will list a zero dollar amount. For claims above the out-of-pocket threshold, this field will have a positive dollar value. For a claim on which the out-of-pocket threshold 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	This field lists the dollar amount the beneficiary paid that is not reimbursed by a third party (e.g., co-payments, coinsurance, deductible or other patient pay amounts). This amount contributes to a beneficiary's TrOOP only when it is payment for a covered Part D drug. 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 CMS expects 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 field, payments that do not contribute to TrOOP shall be reported in the PLRO field, and payment by the government under the low-income cost-sharing subsidy shall be reported in LICS Amount.
33	Other TrOOP Amount	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)	The Act provides for Medicare payments to plans to subsidize the cost-sharing liability of qualifying low-income beneficiaries at the point of sale. In accordance with statutory language, CMS refers 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	This field takes into account coordination of benefits that

	Reduction Due to Other Payer Amount (PLRO)	result 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. 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. 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).
36	Covered Plan Paid Amount (CPP)	This field contains the net amount the plan paid for basic benefits (covered Part D drugs). 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)	This field shall contain the net amount paid by the plan for non-Part D covered benefits. Thus, this value includes all plan payment for supplemental benefits (supplemental drugs and supplemental cost sharing) as well as over-the-counter drugs paid under plan administrative costs for basic prescription drug coverage in accordance with CMS policy. 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.
38	Estimated Rebate at Point-of-Sale (POS)	This field contains the estimated amount of rebate that the plan sponsor has elected to apply to the negotiated price as a reduction in the drug price made available to the beneficiary at the point of sale. This estimate should reflect the rebate amount that the plan sponsor reasonably expects to receive from a pharmaceutical manufacturer or other entity.
39	Vaccine Administration Fee	This field contains the fee reported by a pharmacy, physician, or provider to cover the cost of administering a vaccine, excluding the ingredient cost and dispensing fee.
40	Prescription Origin Code	This field contains the code indicating the origin of the prescription (i.e., not specified, written, telephone, electronic, facsimile).

B. JUSTIFICATION

1. Need and Legal Basis

a) Need

Our fundamental goal is to have the least burdensome data submission requirements necessary to acquire the data needed for accurate payment and appropriate program oversight. We believe that claims data provide the most reliable approach to ensuring that payment calculations are accurate. In the absence of claims level data, we would not be able to determine that reinsurance and risk corridor payments are accurate, that fallback plans have been paid accurately, or that low income subsidies are appropriate. The prescription drug industry commonly uses the NCPDP claim format for data transmissions. This format includes over 450 data elements. We require only 40 data elements, and 20 of those elements are NCPDP elements. We believe that our limited data element requirement will greatly reduce the burden of data collection and management, while maintaining the accuracy of payment related calculations. Also, by focusing on a small number of critical data elements the ability of plans to collect and submit accurate and complete data for the purpose of payment calculations will be optimized. Our view is that in order to fulfill the statutory requirements of the Act, we will need the following data categories:

- Entity identification (for example, submitter ID, contract number and PBP ID)
- Beneficiary identification (for example, HIC#, date of birth, gender).
- Event identification information (for example, claim control number, and adjustment/deletion code).
- Drug and Quantity identification information (for example, date of service, fill number and Compound Code).
- Cost information (for example, paid date, ingredient cost, dispensing fee and sales tax).
- Payment Breakout information (for example, catastrophic coverage code, beneficiary amount paid and low income cost sharing subsidy amount).
- Prescriber information (for example, prescriber ID, prescriber ID qualifier and DAW/product selection code).

In addition to data for interim payments (i.e., Direct subsidies), we will need these data on 100 percent of prescription drug claims for appropriate risk adjustment, reconciliation of reinsurance and low income subsidies, calculation of risk sharing payments or savings, and program auditing. Data will also be required for assessing and improving quality of care.

b) Legal Basis

The sections of the Act that provide the statutory authority for data submission in the prescription drug benefit program are the following:

- Payments, 1860D-11(g) (5), 1860D–14, 1860D-15, 1860D-22
- Data Submission, 1860D–15 (c)(1)(C), 1860D–15 (c) (2) (C), 1860D–15 (d)(2), 1860D–15 (f).

The regulations set forth in this requirement for submitting Prescription Drug Event Data are codified in 42 CFR Part 423–Voluntary Medicare Prescription Drug Benefit. There are a number of places in which statutory provisions in Part D reference specific sections in Part C of Medicare (the MA program). The MA regulations appear at 42 CFR Part 422-The Medicare Advantage Program. The major subjects applicable to the proposed Prescription Drug data submission in Parts 423 Subparts are as follows:

Subpart G
Subpart G of part 423 (§423.301) implements section 1860D-15 of the Act and the deductible and cost sharing provisions are addressed in section 1860D–14(a) of the Act. This section sets forth rules for the calculation and payment of our direct and reinsurance subsidies for Part D plans; the application of risk corridors and risk sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments. References to §422 of our regulations are provided in the new MA rules found in Part 422.

Requirements for Disclosure of Information (§423.322): Payments to a Part D sponsor are conditioned upon provision of information to CMS that is necessary to carry out this subpart, as provided under sections 1860D-15(c)(1)(C), 1860D-15(c) (2) (C), 1860D-15(d)(2) and 1860D–15(f) of the Act and in §423.322 and §423.329 (b) (3) (i) – (ii) of our regulations.

Subpart P
Subpart P of part 423 (§423.771, §423.772, §423.780, §423.782, and §423.800) implements section 1860D-14. This section sets forth rules for Premiums and Cost-Sharing Subsidies for Low-Income beneficiaries. References to §422 of our regulations are provided in the new MA rules found in Part 422 (§422.1, §422.2, §422.4(c), and §422.304(b)).

Subpart Q
Subpart Q of part 423 (§423.875) implements section 1860D-11 (g) of the Act, and sets forth, but not limited to, the amount payable for a fallback prescription drug plan in accordance with §423.871 (e).

Subpart R
Subpart R of part 423 (§423.888) provides payment methods, including provision of necessary information, and implements section 1860D-22 (a) of the Act, as

amended by section 101 of the MMA. This section implements the statutory requirement that a subsidy payment be made to sponsors of qualified retiree prescription drug plans.

42 CFR Part 422
Part 422 (§422.310) sets forth rules for submitting data that can be linked at the individual level to Part A and Part B data.

2. Information Users

The transmission of the statutorily required data will be in an electronic format. The information users will be Pharmacy Benefit Managers (PBM), third party administrators and pharmacies and the PDPs, MA-PDs, Fallbacks and other plans that offer coverage of outpatient prescription drugs under the Medicare Part D benefit to Medicare beneficiaries. The statutorily required data is used primarily for payment, and is used for claim validation as well as for other legislated functions such as quality monitoring, program integrity and oversight.

3. Use of Information Technology

Prescription Drug Data Processing Systems Overview

The Drug Data Processing System (DDPS) is the information system that collects, validates and stores PDE data received from PDPs, MA-PDs, Fallback and other plans offering coverage of outpatient prescription drugs under the Medicare Part D benefit. PDE records enter the DDPS through the Prescription Drug Front-end Processing System (PDFS). The PDFS receives the PDE records at least monthly, once the plans', organizations', or sponsoring entities' PBMs or other third party administrators have received drug claims from pharmacies and completed their "in-cycle" events. Plans or their third party submitters must submit PDE records electronically. The PDFS 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. The DDPS also receives corrected and adjusted PDE records.

The PDFS consists of two levels of edits front-end (face validity and file format) and detail (validity and verification) edits. CMS provides a processing system that allows all critical data fields to be edited before rejecting or returning a file for more information to allow, at a minimum, a one-time resubmission for corrected data.

The system also provides simplified reporting. Plan sponsor organizations will receive one complete report with all transactions and status listed. The report identifies which PDEs were accepted and which were not, along with explanations. Data tracking is improved by reporting complete results

immediately. Plan sponsor organizations also receive periodic summary reports that outline the number of drug events submitted, rejected and accepted.

Drug event data can be submitted via the Medicare Data Communications Network (MDCN) utilizing Internet Protocol (IP) and File Transfer protocol (FTP) or Systems Network Architecture (SNA) and Connect Direct or through the CMS GENTRAN mail boxing system. Production PDE data are submitted into the Prescription Drug Front End System (PDFS) and the Drug Data Processing System (DDPS). When data are submitted, each system runs various edit checks of the data and issues response reports to submitters describing data that was accepted, rejected and any errors that were or may be present in the data so that plans can manage, correct and resubmit their data as necessary.

The DDPS edits records at the detail level, checking event-level information on the beneficiary, drug, costs and other items. The DDPS performs many edits. CMS maintains a complete, up-to-date listing of edits at http://www.csscoperations.com/new/pdic/edits/edits.html.

Once DDPS performs all necessary edits, the accepted PDE records are forwarded to the Integrated Data Repository (IDR). The IDR stores PDE records and accumulates summary data for payment reconciliation. PRS creates a beneficiary/plan record for each beneficiary enrolled in a plan during the payment year and calculates reconciliation payments at the beneficiary and plan level. Specific reports issued from the IDR inform plans of their year-to-date financial values in preparation for reconciliation. CMS calls these management reports.

An outside contractor, Palmetto GBA, manages the data submission process for CMS and maintains a Customer Service and Support Center (CSSC) that provides customer service and support to data submitters.

All data (100%) is collected electronically.

(Refer to page 8 for an illustration of the dataflow.)

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

The collection of information will have a minimal impact on small businesses or other small organizational entities since the applicants must possess an insurance license and be able to accept risk. Generally, state statutory licensure requirements effectively prevent small organizations from accepting the level of risk needed to provide the pharmacy benefits required in the Medicare Prescription Drug Benefit program.

6. Less Frequent Collection

Less frequent collection would delay payment. In order for reimbursement to proceed in a timely and accurate manner while minimizing the burden, CMS requires prescription drug plans to submit data monthly.

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

A 60-day Federal Register notice was published on June 5, 2009. No comments were received.

Outside Consultation

Initially, CMS envisioned that the disclosure and provision of information needed to carry out the payment provisions of the MMA would encompass the quantity, type and costs of pharmaceutical prescriptions filled that could be linked to individual enrollee data in our systems; that is, linked to the Medicare beneficiary identification number (HIC#). We believed that frequent data feeds, other than annually (for example: weekly, monthly or quarterly), would allow us to identify and resolve data issues and to be more supportive of various payment processes. Our fundamental goal was to determine the least burdensome data submission requirements necessary to acquire the data needed for accurate payment and appropriate program oversight. Those views led us to believe that we would need at least the following data items for 100 percent of prescription drug claims or events from plans offering Part D coverage for the processes discussed below:

- Beneficiary HIC#
- Eleven-digit NDC code
- Quantity dispensed
- Prescription drug cost before co-payment (ingredient cost, dispensing fee, sales tax)
- Beneficiary co-payment amount
- Date prescription filled

We further anticipated that we would need similar data on prescription drug claims or events for appropriate risk-adjustment, reconciliation of reinsurance subsidies, and calculation of risk sharing payments or savings, and program auditing. We believed that those subsequent needs would require additional data submission formatting for the following processes:

- A risk adjustment process that would require 100 percent of drug claims in order to develop and calibrate the weights for the model for this new benefit.
- The reinsurance subsidy payment process that would require 100 percent of claims for each enrollee for whom the plan claimed allowable reinsurance costs.
- The risk sharing process that would require 100 percent of claims for all enrollees for the calculation of total allowable risk corridor costs.
- The low income cost sharing subsidy process that would require 100% of claims for each enrollee for whom the plan paid low income cost sharing subsidy costs.
- The program audit process that would require at least a statistically valid random sample of all Part D drug claims.

Thus, we requested public comments on the content, format, and frequency for those proposed disclosures, processes and provisions of information in our Notice of Proposed Rulemaking (NPRM) on August 3, 2004. The NPRM may be reviewed in Federal Register, Vol. 69, No. 148, CMS-4068-P. (46686-46687). In this publication in the "Collection of Information" section, CMS also requested industry input and discussion, as required under §3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA). As required under this PRA section, we solicited comments on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

CMS addressed the NPRM and PRA comments on January 28, 2005 in the Final Rule, which may be reviewed in Federal Register, Vol. 70, No. 18, CMS-4068-F. (4307-4308) and (4443, 4447-4448 for the PRA).

On April 27, 2006, CMS issued instructions on Requirements for Submitting Prescription Drug Event Data (PDE) (see Attachment A) which specified the manner, form and frequency of data transmission to CMS. The instructions specified that PDE records must be submitted to CMS electronically at least once a month.

Ongoing Communication

The table below is a summary of our specific communications and consultations with the industry. The table breaks out events by Type, Date and Status.

Type of Communication	Dates	Status
Monthly MA Conference Calls with Plans and Industry Associations (AAHP, HIAA, & BCBSA)	Began December 2003	Active (now held quarterly)
Publication, Notice of Proposed Rulemaking (NPRM); Federal Register Vol. 69, CMS-4068-P	August 3, 2004	Complete
Open Door Forum, "Prescription Drug Transaction Data"	January 4, 2005	Complete
Publication, Notice of Final Rule; Federal Register Vol. 70, CMS-4068-F	January 28, 2005	Complete
Weekly Part D User Group Teleconferences	Began February 9, 2005	Active (now held biweekly)
Publication, Instructions: Requirements for Submitting Prescription Drug Event Data	April 12, 2005	Complete
Updated Instructions for Submitting Prescription Drug Event Data	April 27, 2006	Complete
Regional Risk Adjustment Training for PDP, MAPD and Fallback Plans	July 18, 2005 July 26, 2005 August 1, 2005 August 9, 2005 February 16, 2006 July 19, 2006 June 18, 2007 June 25, 2007 August 7, 2007 August 11, 2008 August 26, 2008	Complete
Regional PDE Training for PDP, MAPD and Fallback Plans	July 19, 2005 July 20, 2005 July 27, 2005 July 28, 2005 August 2, 2005 August 3, 2005 August 10, 2005 August 11, 2205 July 20, 2006 July 21, 2006 June 20, 2007 June 21, 2007 June 22, 2007	Complete

	June 27, 2007 August 9, 2007 August 13, 2008 August 14, 2008 August 28, 2008 August 29, 2008	
National Training for PACE plans, "Risk Adjustment and Prescription Drug Data Collection and Submission"	August 17, 2005	Complete
NCPDP Workgroup	August 2006 November 2006 November 2007 August 2008 May 2009	Active

9. Payments/Gifts to Respondents

Filing a prescription drug benefit claim does not result in gifts to respondents; many conditions must be met before payment can be made to a plan sponsor. Submitting information using the prescribed CMS format is one of the requirements for participation in the Medicare Part D drug benefit program.

10. Confidentiality

The information provided by the plan or sponsor organizations regarding prescription drug events are protected and held confidential in accordance with 20 CFR 401.3. The information provided electronically and on the forms will become part of the contracted organization's computer history, microfilm, and hard copy records retention system as originally established at 70 FR 58436 (October 6, 2005) titled "Medicare Drug Data Processing System (DDPS),'' System No. 09–70–0553,and updated on May 2008 (as in 73 FR 30943) to broaden access for purposes related to CMS's responsibilities for program administration and research~~published in the *Federal Register*, Part VI, "Privacy Act of 1974 System of Records" on September 20, 1976 (HI CAR 0175.04).~~

All electronic claims or drug events sent from pharmacies to PBMs or other third party administrators and from them to plans constitute HIPAA-covered transactions. Any plan or sponsor organizations that utilize an electronic format for their drug data collection will need to convert to ANSI X12.

11. Sensitive Questions

Other than the labeled information noted above in section 10 above, there are no questions of a sensitive nature.

12. Burden Estimate (Hours & Wages)

The burden placed on Part D plans (contracts) associated with submitted PDE data is predicated upon the following factors: a) the amount of data that must be submitted; b) the number of plans submitting data; and c) the time required to complete the data processing and transmission transactions.

a) PDE Data Submission: The amount of data that must be submitted is a function of the number of prescription drug events per beneficiary and the number of data elements per event (40). Based on three years of enrollment data (2007, 2008, and 2009), CMS estimates that an annual average of 25,460,444 Medicare beneficiaries enroll in Part D prescription drug coverage. The average number of PDEs per year is 947,881,770 (based on 2006, 2007, and 2008). To compute the average number of PDEs per beneficiary, we divide the average number of PDEs per year by the average number of beneficiaries enrolled per year. This computation leads to an average of 39.6 PDEs per beneficiary per year.

b) Number of Part D Contracts (Respondents): The average number of Part D contracts per year is 747 (based on 2007, 2008, and 2009 data).

c) Time Required to Process Data: The third factor that contributes to the burden estimate for submitting PDE data depends upon the time and effort necessary to complete data transaction activities. Since our regulations require Part D plans/sponsors to submit drug event data to CMS that can be linked at the individual level to Part A and Part B data in a form and manner similar to the process provided under §422.310 (Part C), the data transaction timeframes will be based on risk adjustment (Part C) and prescription drug industry experiences. Moreover, our PDE data submission format (as well as the drug industry's) will only support electronic formats. The drug industry's estimated average processing time for electronic data submission is 1 hour for 500,000 records. The risk adjustment estimated average annual electronic processing time cost per hour is $15.00. Thus, the estimated average processing time for electronic PDE data transactions is 1 hour for 500,000 transactions, and the estimated cost for that effort is $38.07.

All three factors are reflected in Table 1 and illustrate the relationship between these results and the burden estimate.

TABLE 1			
			NOTES
A	NUMBER OF RESPONDENTS	747	747 is the annual average number of Part D contracts from 2007, 2008 and 2009
B	NUMBER OF MEDICARE BENEFICIARIES ENROLLED IN PART D PER YEAR	25,460,444	Average number of Medicare beneficiaries enrolled in Part D
C	AVERAGE NUMBER OF PART D BENEFICIARIES PER PLAN	34,084	(B) divided by (A)
D	AVERAGE NUMBER OF PDES PER YEAR	947,881,770	The average is based on annual average PDEs from 2006 to 2008
E	FREQUENCY OF RESPONSE	39.6 PDEs/year/beneficiary	average PDEs per beneficiary per year
F	NUMBER OF TRANSACTIONS PER HOUR	500,000	drug industry's estimated average processing volume per hour
G	TOTAL ANNUAL TRANSACTION HOURS	1896	(D) divided by (F)
H	AVERAGE ELECTRONIC COST PER HOUR	$15.00	Based on $15.00 per hour, the risk adjustment estimated average annual electronic processing cost per hour
I	COST OF ANNUAL TRANSACTION HOURS	$28,436	(H) multiplied by (G)
J	AVERAGE COST PER PART D BENEFICIARY	$0.0011	
I	ANNUAL COST TO RESPONDENTS	$38.07	(J) multiplied by (C)

13. <u>Capital Costs</u>

There are no significant start-up costs that are directly associated with this effort. Any administrative and/or capital costs incurred will be recouped through the bidding process and secured through the reinsurance and/or risk corridors processes. The average number of Part D contracts per year is 747 (based on 2007, 2008, and 2009 data). These entities have sufficient capital assets in place to address reporting drug data. MA-PD plans also have sufficient capital assets in place to address drug data reporting.

14. Cost to Federal Government

CMS has estimated that the total cost of the PDE data submission activities utilizing the PDFS and DDPS will be approximately $7.8 million.

	PDFS	**DDPS**
Labor	$1.7 Million	$3.6 Million
Infrastructure (or other Direct Costs)	$1.6 Million	$3.9 Million
Totals	$3.3 Million	$7.5 Million

15. Changes to Burden

This is a revision of a currently approved data collection/submission request. The burden estimate has been reduced approximately 40% from the original burden estimate. This change reflects actual numbers from the first 3.5 years of the Part D program.

16. Publication/Tabulation Dates

The purpose of this data submission request is to support the payment of outpatient prescription drugs for beneficiaries who are members of Part D plans and who receive services under the Medicare Part D benefits program. There are no publication and tabulation dates.

17. Expiration Date

This collection is not a data collection instrument (i.e., survey or form). Display of an expiration date is not applicable.

18. Certification Statement

CMS has no exceptions to Item 19, "Certification for Paperwork Reduction Act Submissions" of OMB Form 83-I.

PART B - Collection of Information Employing Statistical Methods

Requirements for this data collection do not employ statistical methods.