

CMS Guide to Requests for

Medicare Part D

Prescription Drug Event (PDE) Data

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Important Links:

- -- Final Rule <u>http://edocket.access.gpo.gov/2008/pdf/08-1298.pdf</u>
 -- ResDAC <u>http://www.resdac.umn.edu/</u>
 -- Data Use Agreement <u>http://www.cms.hhs.gov/cmsforms/downloads/cms-r-0235.pdf</u>

I. Overview

A. Purpose

The purpose of this guide is to provide a comprehensive document for the Part D data requestor community that includes information about the:

- Part D data rule governing the release of Part D data
- CMS Part D Prescription Drug Event (PDE) data release process
- PDE data and their limitations for research and other purposes,
- Process for submitting a PDE data request (including the Data Use Agreement (DUA) form)
- CMS processes for reviewing and approving PDE data requests

This guide may be updated over the coming months as we gain experience with PDE data requests.

B. Background on Rulemaking

The final regulation allowing Medicare Part D Prescription Drug Event data (PDE data) to be used for program oversight and monitoring, research, analysis, care coordination and disease management, public reporting, public health functions and other purposes was effective on June 27, 2008. It is available on the CMS website at:

http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/08_PartDData.asp

CMS will provide PDE data to other Federal agencies, States, and other requestors through a process that builds upon the safeguards that exist today for other Medicare data, such as:

- Providing only the minimum data necessary for the project;
- Requiring that the results of the project (if applicable) be in the public domain; and
- If an external entity, requiring that the requestor have the requisite experience and be working for, or on behalf of, a reputable institution.

CMS is taking additional steps to safeguard beneficiary privacy and plans' commercially sensitive data. For example,

- CMS will not release beneficiary, prescriber, or pharmacy identifiers to other government agencies or external requestors unless these are absolutely necessary for the project (for example, to link to another database). Where identifiers are disclosed, CMS will ensure that strict privacy protections are in place, including transmission in an encrypted manner. After data linkage, CMS will require that identifiers are again encrypted to minimize the opportunities for inadvertent disclosure.
- To protect commercially sensitive plan data, the final rule addresses only 37 elements of PDE data and does not extend to Part D plan-specific bid data, rebates, risk-sharing, reinsurance, or payment information collected outside of a Part D claim.

• When released to external requestors, Part D plan identifiers will be encrypted and event cost data elements (ingredient cost, dispensing fee, and sales tax) will be aggregated.

C. Data Request Process

Requestors will submit their data request packages to the Research Data Assistance Center or ResDAC, the CMS contractor assisting with requests for CMS data. ResDAC will review the data requests for completeness and forward the completed packages to CMS. CMS will acknowledge receipt of the completed package and provide to the requestor a CMS contact. CMS will then evaluate each PDE data request package to determine if it is acceptable in accordance with our minimum data necessary policy and other data sharing procedures.

Once the request is approved, CMS requires other government agencies and external requestors to sign a Data Use Agreement (DUA) that outlines certain restrictions placed on the data, including a requirement that once a project is completed, the data must be destroyed. The DUA and instructions are found in Appendix B.

For questions about how to request PDE data, requestors should contact ResDAC. ResDAC will answer questions, provide technical assistance, and provide training for Part D data requestors. Requestors are encouraged to participate in ResDAC training and technical assistance prior to submitting data requests. Information regarding ResDAC, including hyperlinks to its website, is found in section II of this document.

D. PDE Data Elements and Availability

Requestors should familiarize themselves with the chart in Appendix A and Section III detailing what data elements are available and those that may be encrypted and/or unavailable depending on the particular requestor entity and the demonstrated need for an element. For additional questions please contact ResDAC (Section II). Requestors should check the ResDAC website regularly for updated Part D data information.

II. Data Request Process and ResDAC

A. Data Request Process

The Research Data Assistance Center (ResDAC) will assist requestors in preparing their requests for Part D PDE data. Requestors will submit their data request packages to ResDAC. ResDAC will review the data requests for completeness and forward the completed packages to CMS. CMS will acknowledge receipt of the completed package and provide to the requestor a CMS contact. CMS will then evaluate each PDE data request package to determine if it is acceptable in accordance with our minimum data necessary policy and other data sharing procedures.

CMS will review requests for PDE claims data to ensure that disclosure is limited to those data required for the project. Accordingly, requestors need to do the following:

- Justify why a particular PDE element or group of PDE elements are necessary for the project, identify basis to support the justification, and explain the risk to the project or limitations of the study if certain PDE elements are not available for use.
- Identify the minimum sample size needed for the project, to ensure that there is an appropriate sampling framework in place. In the case of small sample sizes or linked data where certain elements are not masked on the Part A and B side, requestors may be asked for further justification of why an element(s) is required and to ensure that unintentional disclosures are not made with respect to the published results of the study, if applicable.
- Attest that they will protect identifiers (beneficiary, plan, prescriber, and pharmacy) from disclosure in any public presentation or publication.

It is important to keep in mind that CMS will:

- Not release PDE elements reflecting pricing data unless they are necessary for the requestor's project;
- Aggregate PDE drug cost elements (i.e., ingredient cost, dispensing fee, and sales tax) for releases to other, non-HHS executive branch governmental agencies, States, and external entities;¹
- Encrypt Plan identifiers for external entities; and
- As a general matter, encrypt PDE beneficiary identifiers, pharmacy identifiers, and prescriber identifiers for external entities where they are not needed (i.e., to link to another data set).

Once the request is approved, CMS requires other government agencies and external requestors to sign a Data Use Agreement (DUA) that outlines certain restrictions placed on the data,

¹ CMS will aggregate ingredient cost and dispensing fee for Congressional Support entities unless requested separately. Also, upon request, CMS will exclude sales tax from the aggregation at the individual claim level if necessary for the project.

including a requirement that once a project is completed, the data must be destroyed. The DUA and instructions are found in Appendix B.

B. <u>RESDAC</u>

The Research Data Assistance Center (ResDAC) is a CMS contractor that provides free assistance to academic, government, and other external entities and researchers interested in requesting Medicare and/or Medicaid data. ResDAC is staffed by a consortium of epidemiologists, public health specialists, health service researchers, biostatisticians, and health informatics specialists from the <u>University of Minnesota</u>. ResDAC's website is found at: <u>http://www.resdac.umn.edu/</u>. ResDAC's website will contain updated information about Part D data, so requestors should check it frequently.

ResDAC can assist requestors in understanding and obtaining the Medicare and Medicaid data files. The staffs of the ResDAC Help Desk are experienced with:

- History of the Medicare and Medicaid systems as they relate to research
- Creation of CMS's administrative data files and claims processing
- Strengths, weaknesses, and applications of Medicare and Medicaid data
- Methods of cohort identification and file specification
- Conversion of raw data into usable datasets
- Medicare and Medicaid program policies and coverage issues
- Process of requesting data from CMS
- Use of the Decision Support Access Facility (DSAF) and the Data Extraction System (DESY) using the CMS Data Center

ResDAC also provides education and training opportunities through many channels, including workshops and a national <u>outreach program</u>.

- <u>Workshops</u> are presented locally at the University of Minnesota, where ResDAC is located, and nationally at other locations. These workshops will help requestors become aware of the strengths and limitations of CMS databases, and how claims-based studies might explore important health care issues.
- National <u>outreach program</u> of meetings, exhibits and presentations facilitated by experts in the fields of epidemiology, public health, health services, biostatistics, and health informatics.

How to Reach ResDAC

- Via Web Submit a request by logging into <u>Request Response and Transmission System</u> (<u>RRTS</u>)
- Via E-Mail Send e-mail at <u>resdac@umn.edu</u>
- Via Phone Call at 1-888-9RESDAC (1-888-973-7322)
- Via Fax Fax at 612-378-4866

III. Prescription Drug Event (PDE) Data Element Availability

A. PDE Data Element Availability

CMS and its contractors have access to all PDE elements. The chart below shows the data elements that are *available* for release to other federal and state agencies and external entities in the final rule under CMS's *minimum necessary data* policy, subject, in certain cases, to encryption of certain identifiers and aggregation of cost data to protect beneficiary confidentiality and commercially sensitive data of Part D sponsors. Thus, a requestor would not automatically receive *all* of the available elements, but would only receive those *necessary* for their project. (*Note: As stated in the preamble to the final rule, this chart applies only when data is collected under section 1860D-12 of the Act, and does not apply to any uses or disclosures already permitted under section 1860D-15 of the Act, including to carry out audits and evaluations necessary to ensure accurate and correct payment and to otherwise oversee Medicare reimbursement under Part D. These uses are already contemplated under both the statute and the regulations at §423.322(b) and are not the subjects of this final rule.)*

Data Elements	Other (i.e., non- CMS) DHHS entities* <i>See Note 1</i>	Non-HHS Executive Branch Agencies and States	External Entities
Identifiers			

Identifiers

Encryption permits analysis on a beneficiary, plan, prescriber, or pharmacy level without disclosure of the actual identifying information. CMS will link our data to other data files, to the extent feasible, to minimize the extent to which other parties need identifiers for data linkage purposes. CMS has the sole authority to determine whether a particular data element is needed for a request.

Beneficiary ID (HIC Number, Cardholder ID, Patient date of birth) See Note 2	Encrypted, but available if needed.	Encrypted, but available if needed.	Encrypted, but available if needed to link to another dataset.
Plan ID (PBP identifier, Contract identifier) See Note 3	Encrypted, but available if needed. Additionally, non- encrypted data will be available for purposes of performance measures.	Encrypted, but available if needed.	Encrypted.
Prescriber ID (Prescriber Identifier)	Encrypted, but available if needed.	Encrypted, but available if needed.	Encrypted, but available if needed to

Data Elements	Other (i.e., non- CMS) DHHS entities* See Note 1	Non-HHS Executive Branch Agencies and States	External Entities
See Notes 4	Additionally, non- encrypted data will be available for purposes of performance measures.		link to another dataset.
Pharmacy ID (Service provider identifier) See Note 5	Encrypted, but available if needed.	Encrypted, but available if needed.	Encrypted, but available if needed to link to another dataset.
Qualifying Identifiers (Service & Prescriber Identifier Qualifiers – codes that denote whether NPI, NCPDP, UPIN, state license number, DEA, or non-standard code is used)	Available	Available	Available
Internal plan/pharmacy prescription identification numbers (<i>Claim Control Number - a code</i> <i>intended for the plan to identify</i> <i>unique events & Prescription</i> <i>Service Reference Number - a</i> <i>code assigned by the pharmacy at</i> <i>the time the prescription is filled</i>)	Available	Unavailable	Unavailable
Drug Utilization Information			
Date of Service	Available	Available	Available
Drug information (Product/Service Identifier, Drug Coverage Status Code, Quantity Dispensed, Days Supply, Compound Code, Fill Number, Dispensing Status.)	Available	Available	Available
Other utilization information (Dispense as Written/Product Selection Code, Drug Coverage Status Code)	Available	Available	Available

Data Elements	Other (i.e., non- CMS) DHHS entities* See Note 1	Non-HHS Executive Branch Agencies and States	External Entities
Drug Cost Information			
Total Drug Costs (Ingredient Cost, Dispensing Fee, Total Amount Attributable to Sales Tax) See Note 6	Available, Disaggregated	Available, Aggregated	Available, Aggregated
Coverage Information			
Date Paid	Available	Available	Available
Plan Paid Amounts (Covered D Plan Paid Amount, Non-covered Plan Paid Amounts)	Available	Available	Available
Beneficiary cost sharing (<i>Patient Pay Amount</i> ,)	Available	Available	Available
Other Payer Amounts (Other True Out of Pocket Amount, Patient Liability due to Other Payer Amount	Available	Available	Available
Low-Income Subsidy Amount	Available	Available	Available
Other Financial Information (Gross Drug Cost below Out-of- pocket Threshold, Gross Drug Cost Above Out-of-pocket Threshold)	Available	Available	Available
Other Descriptive Data			
Patient gender	Available	Available	Available
Catastrophic Coverage Indicator (Catastrophic Coverage Code)	Available	Available	Available

Data Elements	Other (i.e., non- CMS) DHHS entities* <i>See Note 1</i>	Non-HHS Executive Branch Agencies and States	External Entities
In-network versus OON or MSP claim (Pricing Exception code)	Available	Available	Available
Electronic versus Paper Claim (Non-Standard format Code)	Available	Available	Available
Original versus Adjusted PDE (Adjustment/Deletion code)	Available	Final Action claims would be provided, so this element should not be needed.	Final Action claims would be provided, so this element should not be needed

Generally, the notes apply to all columns across the row.

Note 1 – MIPPA provides Congressional support agencies (defined as GAO, MedPAC, CBO and CRS) with access to Part D PDE data without regard to the Secretary's minimum data necessary policy. CMS will revise the Part D data rule accordingly and will provide GAO, MedPAC, CBO, and CRS (when acting on behalf of a committee) with Part D PDE data. CRS is considered a Congressional support agency, but only when acting on behalf of a committee pursuant to its authority in 2 U.S.C. § 166(d)(1). Otherwise, CRS is considered to be an external entity. Note also that OIG has authority independent of both sections 1860D-12 and 1860D-15 of the Social Security Act to collect data.

Note 2 - CMS will encrypt all beneficiary identifiers unless they are needed. An example of where they might be needed is linkage to another dataset. When CMS sends real identifiers in order to permit the requestor to link files, CMS will encrypt identifiers during transmission, provide a link key to un-encrypt the files, allow the linkage, and then require the requestor to re-encrypt identifiers. Public disclosure of research results will not include beneficiary identifying information.

Note 3 –In general, CMS will link the Part D claims to plan level benefits and formulary data if needed by the requestor, and then encrypt the plan ID. However, CMS will not link certain information if it will lead to a de facto identification of the plan. CMS may develop plan specific performance measures which are publicly reported.

Note 4 - CMS will link to physician characteristics from CMS files if needed by the requestor. Generally, when CMS sends real identifiers in order to permit the requestor to link files, CMS will encrypt identifiers during transmission, provide a link key to un-encrypt the files, allow the linkage, and then require the requestor to re-encrypt identifiers.

Note 5– To the extent available, CMS will provide pharmacy characteristics from CMS files. However, CMS will not release pharmacy ID, together with drug cost information, in order to guard against the disclosure of negotiated price information.

Note 6 – Generally, CMS will aggregate ingredient cost, dispensing fee, and sales tax at the individual claim level. Upon request, CMS will exclude sales tax from the aggregation at the individual claim level if necessary for the project.

B. Linking

We understand that for many projects and studies, requestors will need to link PDE data to other Medicare data sets (including the use of Finder Files), and potentially data not directly associated with Medicare. Generally, CMS will provide a link key enabling requestors to match PDE data to other Medicare data sets in a manner that (as noted earlier) protects individual beneficiary and/or commercially sensitive information. Toward that end, when Medicare data is linked, CMS will require that existing identifiers are again encrypted to minimize the opportunities for inadvertent disclosure. Requestors that need to link data should discuss their proposed linkage needs with ResDAC.

IV. Prescription Drug Event (PDE) Data Limitations

Prescription Drug Event (PDE) data are not the same as individual drug claim transactions; rather, they represent summary extracts using CMS-defined standard fields. Requestors using PDE data should keep in mind that a PDE is not the actual claim paid at the pharmacy, but a record of that claim manipulated by the Part D sponsor prior to its submission to CMS for payment reconciliation. Thus, PDE data may have limitations for certain projects.

CMS only has PDE data for Medicare Part D enrollees who are filing a claim for Part D payment of their drug. In 2009, nearly 60% of Medicare beneficiaries are enrolled in a Part D plan and some Part D enrollees have other drug coverage that would not be reflected within the PDE data. Therefore, PDE data does not necessarily reflect all drug claims submitted by a Medicare beneficiary. Drug claims filed with other sources of health insurance coverage, such as a former employer or union, the VA, TRICARE, or FEHBP are not available from CMS. Analysis of Part D claims experience cannot be readily extrapolated to the Medicare population as a whole, since Part D enrollees are not a representative sample of Medicare beneficiaries—they are more likely to be disabled, institutionalized, minorities, to die during the year, and in poor health.

Additional information regarding data limitations is available in "Overview of PDEs presentation" presented at the October 30, 2008 PDE symposium on the CMS website at: http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/08_PartDData.asp

Below are other limitations requestors should consider:

- The coverage information provided in the PDE (plan paid amounts, beneficiary cost sharing, other payer amounts and LIS amounts) may not reflect what was actually paid to the pharmacy at the point-of-sale due to some of the following reasons:
 - 1. <u>Retroactive Low-income Subsidy (LIS) adjustments</u> A pharmacy may have submitted a claim that the plan sponsor processed as a non-LIS claim in which the pharmacy collected the full cost share from the beneficiary. Later the beneficiary is found retroactively LIS eligible. In these situations, the plan sponsor does not reverse the actual claim to the pharmacy, but rather reimburses the beneficiary directly for its overcharged payment. The PDE is created (or corrected) to indicate the low-income cost sharing subsidy amount paid on behalf of the beneficiary. As a result, the patient pay amount (i.e., the beneficiary cost sharing) under the claim at the pharmacy is different than what is reflected on the PDE.
 - 2. <u>Reimbursement by Other Payers</u> A pharmacy may have submitted a Part D claim to a State Pharmaceutical Assistance Program (SPAP) and received payment from an SPAP based upon the SPAP's negotiated rate with the pharmacy. The SPAP discovers that the beneficiary is enrolled in a Part D plan and reconciles directly with the plan sponsor. The plan sponsor then generates a PDE indicating the reimbursement to the SPAP for the Part D member. In this

case, the pharmacy claim would continue to reflect what was paid to them by the SPAP (which could be more or less), but the PDE reflects a plan paid amount that was reimbursed to the SPAP.

- 3. <u>The 2006 State to Plan Demonstration Project</u> -- Under this demonstration, participating Medicaid agencies and SPAPs paid primary for claims and were later reimbursed by CMS under a special waiver and demonstration authority. CMS reconciled the claims with the Part D plans. The "State to Plan" PDEs created by the plan sponsors do not reflect the amount paid by the plan sponsor to the pharmacy, since in these cases, the pharmacy claims would reflect the state payment, not the Part D plan sponsor payment.
- Requestors should be cautioned that they cannot rely on PDE data to:
 - 1. Determine that a drug is covered on a plan formulary --Covered drugs reflected on the PDE may be a result of an exception process, transition, or COB claim.
 - Ascertain that an individual is LIS eligible In 2006, as a result of start-up issues, a number of plan sponsors defaulted some beneficiaries to an LIS cost sharing levels (\$1 and \$3) who were later found not to be eligible for LIS. Based on these start-up issues, CMS lifted some edits in the first year of the program. Thus, the low-income cost sharing subsidy field on the PDE reflects what was paid for reimbursement purposes only and is not a true indicator of LIS eligibility status.
 - 3. Study the drug history for an individual since not all drugs are covered and paid for by a Part D plan. -- Some drugs may be covered under Medicare Part B, Medicaid, a pharmaceutical patient assistance program outside of the Part D benefit, other coverage, or paid for out-of-pocket by a beneficiary.
- As a result of the Plan-to-Plan Reconciliation Process that CMS established to limit pharmacy reversals as a result of enrollee plan changes, PDEs associated with a particular plan (whose identity will be masked for external parties) may not represent the true plan of record within CMS's enrollment system. Rather, a PDE may have been submitted by one plan sponsor, but the costs associated with the PDE may have been reimbursed and attributed in CMS' payment system to another sponsor that held the actual enrollment of the beneficiary.
- It is quite possible extraction errors may exist within the data sample (for example, changes in decimal places or transposition errors from the claim to the PDE).

Appendices

#	Data Element	Field Description	Field Value
1	Contract Number	This field contains the unique number CMS assigns to each contract that a Part D plan has with CMS.	Contract number assigned by CMS.
2	Plan Benefit Package (PBP) Identifier	This field contains the unique number CMS assigns to identify a specific PBP within a contract.	PBP number assigned by CMS.
3	Claim Control Number	This field is an optional field, free-form field. It is intended for use by plans to identify unique events or for other plan purposes.	Optional field.
4	Health Insurance Claim Number (HICN)	This field contains the unique number identifying the primary beneficiary under the Social Security Administration and Railroad Retirement Board (RRB) programs.	Medicare HICN or RRB number.
5	Cardholder Identifier	This field contains the plan-assigned number used to identify the beneficiary.	Plan identification of the enrollee (assigned by the plan).
6	Patient Date of Birth (DOB)	This field contains the beneficiary date of birth.	CCYYMMDD
7	Patient Gender	This field identifies the gender of the beneficiary.	1=M 2=F
8	Date of Service	This field contains the date on which the prescription was filled.	CCYYMMDD
9	Paid Date	This field contains 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. This field is a mandatory field for fallback plans and optional for all other plan types.	CCYYMMDD
10	Service Provider Identifier Qualifier	This field indicates the type of provider identifier used in field 11 (Service Provider Identifier).	01 = NPI 06 = UPIN 07 = NCPDP Number 08 = State License 11 = Federal Tax Identifier 99 = Other Values of '06', '08', '11' and '99' only acceptable if non-Standard format='B', 'X' or 'P'
11	Service Provider Identifier	This field identifies the pharmacy where the prescription was filled. CMS will transition to the use of the National Provider Identifier (NPI) when it is implemented. In the interim, this field typically contains the NCPDP number which all NCPDP billers are assigned. Some Part D service providers who submit in Non-Standard Format (e.g., home infusion, physicians when providing vaccines, etc.) will not have NCPDP numbers. For these providers, the Unique Provider Identification Number (UPIN), State License Number, Federal Tax Identification Number, Employer Identification Number, or the default value of 'PAPERCLAIM' will be the identifier.	For Standard Data Format, valid values are: 01 = NPI 07 = NCPDP Provider Identifier For non-Standard data format, any value in Service Provider Identifier Qualifier is valid. When Plans report Service Provider Identifier Qualifier '99' this field will contain 'PAPERCLAIM'.
12	Prescriber Identifier Qualifier	This field indicates the type of identifier that is used in field 13 (Prescriber Identifier field).	01 = NPI 06 = UPIN 08 = State License Number 12 = Drug Enforcement Administration (DEA) number

Appendix A – Prescription Drug Event (PDE) Data Dictionary

#	Data Element	Field Description	Field Value
13	Prescriber Identifier	This field contains the prescriber's unique identification number. CMS will transition to the use of the 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 UPIN is used.	Prescriber's unique identification number.
14	Prescription/Service Reference Number	This field contains the prescription reference number assigned by the pharmacy at the time the prescription is filled.	Prescription reference number. Field length is 9 to accommodate proposed future NCPDP standard.
15	Product/Service Identifier	This field identifies the dispensed drug using a National Drug Code (NDC). The 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 is used.	NDC code in the following format: MMMMMDDDDPP followed by 8 spaces. CMS rejects the following codes: 99999999999, 99999999992, 999999999993, 99999999994, 999999999995 and 99999999996.
16	Compound Code	This field indicates whether or not the dispensed drug was compounded or mixed.	0 = Not specified1 = Not a compound2 = Compound
17	Dispense as Written/Product Selection Code	This field indicates the prescriber's instruction regarding substitution of generic equivalents or order to dispense the specific product written.	 0 = No Product Selection Indicated 1 = Substitution Not Allowed by Prescriber 2 = Substitution Allowed - Patient Requested Product Dispensed 3 = Substitution Allowed - Pharmacist Selected Product Dispensed 4 = Substitution Allowed - Generic Drug Not in Stock 5 = Substitution Allowed - Brand Drug Dispensed as Generic 6 = Override 7 = Substitution Not Allowed - Brand Drug Mandated by Law 8 = Substitution Allowed - Generic Drug Not Available in Marketplace 9 = Other
18	Quantity Dispensed	This field indicates how many dosage units of the medication were dispensed in the current drug event.	Number of units, grams, milliliters, other. If compounded item, total of all ingredients will be supplied as Quantity Dispensed.
19	Days Supply	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.	0 - 999
20	Fill Number	This field indicates the number fill of the current dispensed supply.	0 - 99; if unavailable, 0 will be populated.

#	Data Element	Field Description	Field Value
21	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.	Blank = Not specified or full quantity P = Partial Fill C = Completion of Partial Fill
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.	C = Covered E = Supplemental drugs (reported by Enhanced Alternative plans only) O = Over-the-counter drugs
23	Adjustment/Deletion Code	This field distinguishes original from adjusted or deleted PDE records so CMS can adjust claims and make accurate payment for revised PDE records.	A = Adjustment D = Deletion Blank = Original PDE
24	Non-Standard Format Code	This data element is used by CMS to identify PDE records that are compiled from non-standard sources. NCPDP is the standard format in which plans receive data from pharmacies.	X = X12 837 B = Beneficiary submitted claim P = Paper claim from provider Blank = NCPDP electronic format
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.	M = Medicare as Secondary Payer O = Out-of-Network pharmacy Blank = In-Network pharmacy and Medicare Primary
26	Catastrophic Coverage Code	This field indicates that a beneficiary has reached the out- of-pocket threshold or attachment point. At this point, catastrophic coverage provisions begin, namely reinsurance and reduced beneficiary cost sharing.	A = Attachment point met on this event C = Above Attachment point Blank = Attachment point not met
27	Ingredient Cost Paid	This field contains the amount paid to the pharmacy for the drug itself. Dispensing fees or other costs are not to be included in this amount except as allowed on non-standard format claims.	Amount paid to pharmacy for drug.
28	Dispensing Fee Paid	This field contains amounts paid to the pharmacy for dispensing the medication. This field should only contain the 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 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 PBP level.	Amounts paid to pharmacy for dispensing medication.
29	Total Amount Attributed to Sales Tax	This field contains the sum of all amounts paid to the pharmacy to cover sales tax.	Amounts paid to pharmacy to cover sales tax.

#	Data Element	Field Description	Field Value
30	Gross Drug Cost Below Out-of-Pocket Threshold (GDCB)	This field represents the gross drug cost paid to the pharmacy below the Out-of-Pocket threshold for a given PDE for a covered drug. For claims received prior to a beneficiary reaching the attachment point, this field will contain a positive dollar amount. For claims above the attachment point, this field will contain a zero 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 field 31 (GDCA).	When the Catastrophic Coverage Code = 'Blank', this field equals the sum of Ingredient Cost Paid + Dispensing Fee Paid + Total Amount Attributed to Sales Tax.When the Catastrophic Coverage Code = 'A', this field equals the portion of Ingredient Cost Paid + Dispensing Fee Paid + Total Amount Attributed to Sales Tax falling at or below the Out-of-Pocket threshold. The remaining portion is reported in GDCA.
31	Gross Drug Cost Above Out-of-Pocket Threshold (GDCA)	This field represents the gross drug cost paid to the pharmacy above the Out-of-Pocket threshold for a given PDE for a covered drug. For claims received prior to a beneficiary reaching the attachment point, this field will contain a zero dollar amount. For claims above the attachment point, this field will contain 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 field 30 (GDCB).	 When the Catastrophic Coverage Code = 'C', this field equals the sum of Ingredient Cost Paid + Dispensing Fee Paid + Total Amount Attributed to Sales Tax above the Out-of-Pocket threshold. When the Catastrophic Coverage Code = 'A', this field equals the portion of Ingredient Cost Paid + Dispensing Fee Paid + Total Amount Attributed to Sales Tax falling above the Out-of-Pocket threshold. The remaining portion is reported in GDCB.
32	Patient Pay Amount	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. Payments made by the beneficiary or family and friends shall also be reported in this field. Other third party payments made on behalf of a beneficiary that contribute to TrOOP shall be reported in field 33 (Other TrOOP Amount) or field 34 (Low-Income Cost-Sharing Amount) and payments that do not contribute shall be reported in field 35 (Patient Liability Reduction due to Other Payer Amount).	Amount beneficiary paid that is not reimbursed by a third party.
33	Other True Out-of- Pocket (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 a qualified State Pharmacy Assistance Program, charities, or other TrOOP-eligible parties.	Amount of qualified third party payments that contribute to a beneficiary's TrOOP.
34	Low-Income Cost- Sharing Subsidy Amount (LICS)	This field contains 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 Point of Sale.	Amount the plan reduced patient liability due to a beneficiary's LICS status.

#	Data Element	Field Description	Field Value
35	Patient Liability Reduction due to Other Payer Amount (PLPRO)	This field takes into account coordination of benefits that result in reduced patient liability, excluding any TrOOP-eligible payers.	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. Examples of non-TrOOP-eligible payers are group health plans, Worker's Compensation and governmental programs (e.g. VA, TRICARE).
36	Covered D Plan Paid Amount (CPP)	This field contains the net amount the plan paid for standard benefits (covered Part D drugs).	Net amount the plan has paid for a Part D covered drug (where Drug Coverage Code = 'C'). If Drug Coverage Code = 'E' or 'O', the CPP field is zero.
37	Non-covered Plan Paid Amount (NPP)	This field contains the net amount paid by the plan for benefits beyond the standard benefit.	Net amount the plan has paid for all over-the-counter drugs, enhanced alternative drugs, and enhanced alternative cost- sharing amounts.