CMS Guide to Requests for

Medicare Part D

Prescription Drug Event (PDE) Data

Version 2.0
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Table of Contents

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

I. Executive Summary

Purpose

The purpose of this guide is to create a comprehensive document to be used by the Part D data requestor community that includes: information regarding the Part D data rule which governs the CMS Part D Prescription Drug Event (PDE) data release process, information about PDE data and their limitations for research and other purposes, the process for submitting a PDE data request (including the Data Use Agreement form), and CMS processes for reviewing and approving PDE data requests. When establishing these procedures, CMS balanced access to the PDE data to safeguard public health and promote broader public knowledge about the operations of the Part D program, with new protections for beneficiary privacy and commercially-sensitive plan information. This guide may evolve over the next several months as we gain experience with PDE data requests and as the PDE data become available.

Background on Rulemaking

On May 28, CMS published 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. The regulation 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;
- 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 date. For example,

- To the extent feasible, CMS will link PDE data to other databases to minimize the need to send identifiers for data linkage purposes. 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, this 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.

MIPPA

Subsequent to the CMS rulemaking described above, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) was enacted. MIPPA section 181 allows the Secretary to use the Part D PDE data for improving public health through research on the utilization, safety, effectiveness, quality, and efficiency of health care services, and conducting Congressional oversight, monitoring, and analysis of the program. It also requires the Secretary to make this information available to Congressional support agencies in accordance with their obligations to support Congress in their authorizing statutes.

As a result of MIPPA, CMS will make conforming changes to the Part D data regulation. In this version of the Guide, we have updated the chart on data element availability, which was published as an appendix to the final rule, in order to conform to MIPPA. Congressional support agencies will continue to send their data requests through ResDAC, which is CMS' single point of contact for Part D data requests.

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 PDE 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 (see Appendix C).

CMS will review each request pending availability of 2006 Part D data which is anticipated to be ready in December 2008. CMS anticipates that 2007 PDE data will be available toward the end of this calendar year or early in the next calendar year. The 2005 Medicaid drug claims data are expected to be available toward the end of this calendar year as well. The 2007 Medicare A and B claims data are expected to be available later this summer (August 2008). These dates may change as data are loaded, tested, and files are built. Requestors should check the ResDAC website regularly for updated availability dates.

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.

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.

Linked Data

We understand that for certain projects and studies, many requestors will need to link PDE data to other Medicare data sets. We realize we have only addressed data linkage peripherally within this version of the guide, therefore requestors can expect further details on linking data sets in future issuances of this guide and communications via our contractor, ResDAC.

II. ResDAC

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 University of Minnesota. ResDAC's website is found at: http://www.resdac.umn.edu/. ResDAC's website will contain updated information about Part D data availability, so requestors should check it frequently.

ResDAC can assist requestors in understanding and obtaining the Medicare and Medicaid data files. The staff 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 outreach program.

- Workshops 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 outreach program 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 Request Response and Transmission System (RRTS)
- Via E-Mail - Send e-mail at resdac@umn.edu
- Via Phone - Call at 1-888-9RESDAC (1-888-973-7322)
- Via Fax - Fax us at 612-378-4866

III. Prescription Drug Event (PDE) Data Element Availability (as amended by MIPPA)

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* *See Note 1*	Non-HHS Executive Branch Agencies and States	External Entities
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 link to another

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.		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 (*Claim Control Number - a code intended for the plan to identify unique events & Prescription Service Reference Number – a code assigned by the pharmacy at the time the prescription is filled)*	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 *(Patient Pay Amount,*)	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* *See Note 1*	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.

IV. Prescription Drug Event (PDE) Data Limitations

To date, CMS has used PDE data for payment purposes only. With the publication of the final rule, CMS will use the PDE data for additional purposes and may find additional data limitations as our experience with the data grows. The limitations described below may be revised based upon our additional experience.

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 the PDE data should keep in mind that a PDE is not the actual claim paid at the pharmacy, but a record of that claim that has been manipulated by the Part D sponsor prior to its submission to CMS for payment reconciliation. Thus, PDE data may not be useful for certain research projects and reports.

PDE data does not reflect all drug claims submitted by a Medicare beneficiary. CMS only has PDE data for Medicare Part D enrollees who are filing a claim for Part D payment of their drug. Nearly half of all Medicare beneficiaries do not have Part D, and some Part D enrollees have other drug coverage that would not be reflected within the PDE data. Furthermore, payments made by secondary or other payers are not part of the PDE data.

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. Retroactive Low-income Subsidy (LIS) adjustments – 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. Reimbursement by Other Payers – 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. The 2006 State to Plan Demonstration Project -- 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.

    2. 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).

V. Questions and Answers on Obtaining Prescription Drug Event (PDE) Data

What is ResDAC's role in rolling out the Part D drug data regulation?
The Research Data Assistance Center (ResDAC) is the primary source of information about CMS data release policies and procedures to the data request community. ResDAC has a toll-free help desk and comprehensive website to disseminate the latest changes to CMS databases and data release policies. ResDAC offers assistance at all the major health service research conferences and conducts data use workshops 4-6 times a year. See section II for more information on CMS' contractor, ResDAC.

How do I get more information about and/or request PDE data?
CMS will continue to update these guidelines and develop workshops to inform potential requestors about how they can access PDE data. Additional information is available from our research data assistance center at: http://www.resdac.umn.edu/

What are Prescription Drug Event (PDE) data?
Every time a beneficiary fills a prescription under Medicare Part D, a prescription drug plan sponsor must submit a summary record called the prescription drug event (PDE) data to CMS. The PDE data are not the same as individual drug claim transactions, but are summary extracts using CMS-defined standard fields.

Are both stand alone prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA-PDs) required to submit PDE data?
Yes.

What data are contained in PDE records?
The PDE record contains prescription drug cost and payment data that enables CMS to make payments to plans and otherwise administer the Part D benefit. Fields available to requestors are described in the data availability chart located in section III**.**

Can I get rebate data on the PDE record?
No. This final rule applies only to the PDE data, and not to rebates, risk-sharing or reinsurance data reported outside the PDE record. Also, in 2006 and 2007, no rebate data was reported on the PDE record. In 2008, rebates at the point of sale were added as an element included on the PDE record. However, we have made clear in the final rule that this element is *not* a part of the final rule.

For what purposes can I get Part D PDE data?
The Part D data final rule allows the public to receive identifiable PDE data for research purposes. We are using the definition of research in the HIPAA Privacy Rule which defines research as *"a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge"*. We do not release identifiable data to external entities when their research is not designed to develop or contribute to generalizable knowledge. States and federal government agencies may also request PDE data for additional purposes. The data will be made available to beneficiaries for their personal health records. We will not release identifiable data for commercial purposes.

Are PDE data available for all 44 million Medicare beneficiaries?
No. The Medicare prescription drug benefit is a voluntary insurance program and PDE records are only available for Medicare beneficiaries who are enrolled in a Part D plan. In 2008, about 25 million Medicare beneficiaries are enrolled in Part D plans. We do not have PDE data for beneficiaries who receive their drug coverage from other sources such as employers or unions with the Medicare Retiree Drug Subsidy, Veterans Administration, TRICARE, or FEHBP.

Can the data be linked with Medicare physician and hospital claims under Parts A and B of the program?
Yes. In 2008, there are about 17 million beneficiaries who are in Original Medicare with a stand-alone Part D prescription drug plan. These Medicare Part A, B, and D data are available for research purposes. PDE data is also available for the approximately 8 million beneficiaries enrolled in a Medicare Advantage plan (i.e., we do not have Part A and B claims for those beneficiaries). (Data source: CMS news release, Medicare Prescription Drug Benefits Projected Costs Continue to Drop, Jan. 31, 2008, with link to data files, http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/01_Overview.asp.) Further information regarding how data will be linked will be addressed in future versions of this guide.

What year of data is available now?
Prescription Drug Event data for calendar year 2006 will be available for public release after files are prepared, which we estimate may take 5 months. Medicare enrollment numbers for 2006 are lower than those cited above for 2008 (i.e., total Part D enrollment in 2006 was 22 million). (Data source: HHS news release, Over 38 Million People With Medicare Now Receiving Prescription Drug Coverage, June 14, 2006, with included tables. See: http://www.hhs.gov/news/press/2006pres/20060614.html.)

Updated information on when 2006 data will be available will be posted to CMS and ResDAC websites. In the meantime, CMS will process requests for data so that they can be filled as soon as the data are ready.

Are limited data sets going to be available? How do I get one?
Yes. We intend to develop limited data sets, which exclude direct identifiers, which will be available to the public, including those who wish to use them for a commercial purpose. We will develop these datasets after consulting with the public about the content of the files. At the open door forum on June 11, 2008 we solicited information from the public about what information would be useful to include in such files. Further information regarding the availability of limited data sets, including cost, will be available in future versions of this guide.

When will the Chronic Condition Warehouse (CCW) be able to provide Part D drug event data to requestors?
It will take about 5 months from the effective date of the regulation for CMS to test and load the 2006 PDE data into CCW. NOTE: The Part A and B claims, eligibility and

assessment data have already been loaded and linked at the individual beneficiary level. The CCW database will release the minimum data necessary in an encrypted format. The CCW will also support requestors who need to link the PDE data to other datasets.

ResDAC will be the requestor's definitive source about how to obtain PDE data.

Is CMS going to sponsor training for PDE data requestors?
Yes. CMS will sponsor training for Part D requestors via our contractor, ResDAC.

How much does the PDE data cost?
CMS establishes data file costs in order to recover the actual amount expended in the data distribution process. This includes the cost of processing the request and producing the actual data file. Once fees are set, ResDAC will provide this information to data requestors.

Can I get PDE data to link to my current Part A and B claims data?
CMS is still developing guidelines for linked data requests. More information will be available in the next iteration of this guide.

Can I get PDE data to link to my clinical trial data?
We will address this question in future versions of this guide.

Is CMS going to sponsor a PDE data users group?
No. CMS will not sponsor a PDE data users group.

Why do the PDE data only reflect benefit year 2006? Why don't they include 2007 and when will 2007 data be available?
Calendar Year 2006 is the only full year of PDE data that is complete. Calendar Year 2007 information includes payment and prescription drug event data reported by the Part D sponsors that have not been finalized and reconciled with CMS.

CMS will be releasing 2006 PDE data by approximately December 2008. On an ongoing basis, PDE data will be available approximately 6 to 8 months after the end of the calendar year to which the claims are related. CMS is not able to release the PDE data in a more timely fashion since Part D claims are paid by Part D plan sponsors, who have up to 6 months to submit PDEs to CMS for purposes of payment reconciliation.

What is your most current year of data availability to the public for Medicare Part A and B data?
CMS is currently providing 2006 Medicare Parts A and B data. We anticipate that 2007 Medicare Parts A/B data will be available later this summer (2008).

How specific do we need to be to justify the PDE elements?
See Appendices to this guide. Requestors will be required to complete a Data Use Agreement (Appendix B), PDE data worksheet (Appendix D) along with the requestor's

executive summary (Appendix E) in order to justify the PDE elements they are requesting.

As a Federal grantee, will it be possible to link individuals to their complete formulary and benefit design, for the purposes of studying adverse selection?
CMS will link the PDE data 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 specific plan.

Will the claims data include plan identifiers?
Plan identifiers are available, but will be encrypted. Certain government agencies may obtain plan identifiers if needed.

Will it be possible to obtain out-of-pocket costs paid by the beneficiary and amounts paid by insurer to study the demand for prescription drugs? What about quantity and day supply information?
Yes. Total drug cost - Ingredient cost, dispensing fee and sales tax (aggregated) will be available. Patient pay amount, plan amount, quantity dispensed and day supply will also be available. See the data availability chart in section IV of this guide.

Appendices

Appendix A – Prescription Drug Event (PDE) Data Dictionary

#	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'.

#	Data Element	Field Description	Field Value
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
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, 99999999993, 99999999994, 99999999995 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.

#	Data Element	Field Description	Field Value
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.
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 results 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.

Appendix B - Data Use Agreement

INSTRUCTIONS FOR COMPLETING THE DATA USE AGREEMENT (DUA) FORM CMS-R-0235

(AGREEMENT FOR USE OF CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) DATA CONTAINING INDIVIDUAL IDENTIFIERS)

This agreement must be executed prior to the disclosure of data from CMS' Systems of Records to ensure that the disclosure will comply with the requirements of the Privacy Act, the Privacy Rule and CMS data release policies. It must be completed prior to the release of, or access to, specified data files containing protected health information and individual identifiers.

Directions for the completion of the agreement follow:

Before completing the DUA, please note the language contained in this agreement cannot be altered in any form.

- First paragraph, enter the Requestor's Organization Name.
- Section #1, enter the Requestor's Organization Name.
- Section #4 enter the Study and/or Project Name and CMS contract number if applicable for which the file(s) will be used.
- Section #5 should delineate the files and years the Requestor is requesting. Specific file names should be completed. If these are unknown, you may contact a CMS representative to obtain the correct names The System of Record (SOR) should be completed by the CMS contact or Project Officer. The SOR is the source system the data came from.
- Section #6, complete by entering the Study/Project's anticipated date of completion.
- Section #12 will be completed by the User.
- Section #16 is to be completed by Requestor.
- Section #17, enter the Custodian Name, Company/Organization, Address, Phone Number (including area code), and E-Mail Address (if applicable). The Custodian of files is defined as that person who will have actual possession of and responsibility for the data files. **This section should be completed even if the Custodian and Requestor are the same.** This section will be completed by Custodian.
- Section #18 will be completed by a CMS representative.
- Section #19 should be completed if your study is funded by one or more other Federal Agencies. The Federal Agency name (other than CMS) should be entered in the blank. The Federal Project Officer should complete and sign the remaining portions of this section. If this does not apply, leave blank.
- Sections #20a AND 20b will be completed by a CMS representative.
- Addendum, CMS-R-0235A, should be completed when additional custodians outside the requesting organization will be accessing CMS identifiable data.

Once the DUA is received and reviewed for privacy and policy issues, a completed and signed copy will be sent to the Requestor and CMS Project Officer, if applicable, for their files.

DATA USE AGREEMENT

DUA # _____

(AGREEMENT FOR USE OF CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) DATA CONTAINING INDIVIDUAL IDENTIFIERS)

CMS agrees to provide the User with data that reside in a CMS Privacy Act System of Records as identified in this Agreement. In exchange, the User agrees to pay any applicable fees; the User agrees to use the data only for purposes that support the User's study, research or project referenced in this Agreement, which has been determined by CMS to provide assistance to CMS in monitoring, managing and improving the Medicare and Medicaid programs or the services provided to beneficiaries; and the User agrees to ensure the integrity, security, and confidentiality of the data by complying with the terms of this Agreement and applicable law, including the Privacy Act and the Health Insurance Portability and Accountability Act. In order to secure data that reside in a CMS Privacy Act System of Records; in order to ensure the integrity, security, and confidentiality of information maintained by the CMS; and to permit appropriate disclosure and use of such data as permitted by law, CMS and _____ *(Requestor)* _____ enter into this agreement to comply with the following specific paragraphs.

1. This Agreement is by and between the Centers for Medicare & Medicaid Services (CMS), a component of the U.S. Department of Health and Human Services (HHS), and _____ *(Requestor)* _____, hereinafter termed "User."

2. This Agreement addresses the conditions under which CMS will disclose and the User will obtain, use, reuse and disclose the CMS data file(s) specified in section 5 and/or any derivative file(s) that contain direct individual identifiers or elements that can be used in concert with other information to identify individuals. This Agreement supersedes any and all agreements between the parties with respect to the use of data from the files specified in section 5 and preempts and overrides any instructions, directions, agreements, or other understanding in or pertaining to any grant award or other prior communication from the Department of Health and Human Services or any of its components with respect to the data specified herein. Further, the terms of this Agreement can be changed only by a written modification to this Agreement or by the parties adopting a new agreement. The parties agree further that instructions or interpretations issued to the User concerning this Agreement or the data specified herein, shall not be valid unless issued in writing by the CMS point-of-contact or the CMS signatory to this Agreement shown in section 20.

3. The parties mutually agree that CMS retains all ownership rights to the data file(s) referred to in this Agreement, and that the User does not obtain any right, title, or interest in any of the data furnished by CMS.

4. The User represents, and in furnishing the data file(s) specified in section 5 CMS relies upon such representation, that such data file(s) will be used solely for the following purpose(s).

Name of Study/Project

CMS Contract No. *(If applicable)*

The User represents further that the facts and statements made in any study or research protocol or project plan submitted to CMS for each purpose are complete and accurate. Further, the User represents that said study protocol(s) or project plans, that have been approved by CMS or other appropriate entity as CMS may determine, represent the total use(s) to which the data file(s) specified in section 5 will be put.

The User agrees not to disclose, use or reuse the data covered by this agreement except as specified in an Attachment to this Agreement or except as CMS shall authorize in writing or as otherwise required by law, sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement. The User affirms that the requested data is the minimum necessary to achieve the purposes stated in this section. The User agrees that, within the User organization and the organizations of its agents, access to the data covered by this Agreement shall be limited to the minimum amount of data and minimum number of individuals necessary to achieve the purpose stated in this section (i.e., individual's access to the data will be on a need-to-know basis).

5. The following CMS data file(s) is/are covered under this Agreement.

File	Years(s)	System of Record

6. The parties mutually agree that the aforesaid file(s) (and/or any derivative file(s)) including those files that directly identify individuals and those that can be used in concert with other information to identify individuals may be retained by the User until, *Date* hereinafter known as the "Retention Date." The User agrees to notify CMS within 30 days of the completion of the purpose specified in section 4 if the purpose is completed before the aforementioned retention date. Upon such notice or retention date, whichever occurs sooner, the User agrees to destroy such data. The User agrees to destroy and send written certification of the destruction of the files to CMS within 30 days. The User agrees not to retain CMS files or any parts thereof, after the aforementioned file(s) are destroyed unless the appropriate Systems Manager or the person designated in section 20 of this Agreement grants written authorization. The User acknowledges that the date is not contingent upon action by CMS.

   The Agreement may be terminated by either party at any time for any reason upon 30 days written notice. Upon notice of termination by User, CMS will cease releasing data from the file(s) to the User under this Agreement and will notify the User to destroy such data file(s). Sections 3, 4, 6, 8, 9, 10, 11, 13, 14 and 15 shall survive termination of this Agreement.

7. The User agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it.The safeguards shall provide a level and scope of security that is not less than the level and scope of security requirements established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III--Security of Federal Automated Information Systems **(http://www.whitehouse.gov/omb/circulars/a130/a130.html)** as well as Federal Information Processing Standard 200 entitled "Minimum Security Requirements for Federal Information and Information Systems" **(http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf);** and, Special Publication 800-53 "Recommended Security Controls for Federal Information Systems" **(http://csrc.nist.gov/publications/nistpubs/800-53-Rev2/sp800-53-rev2-final.pdf)**. The User acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable or deducible information derived from the file(s) specified in section 5 is prohibited. Further, the User agrees that the data must not be physically moved, transmitted or disclosed in any way from or by the site indicated in section 17 without written approval from CMS unless such movement, transmission or disclosure is required by a law.

8. The User agrees to grant access to the data to the authorized representatives of CMS or DHHS Office of the Inspector General at the site indicated in section 17 for the purpose of inspecting to confirm compliance with the terms of this agreement.

9. The User agrees not to disclose direct findings, listings, or information derived from the file(s) specified in section 5, with or without direct identifiers, if such findings, listings, or information can, by themselves or in combination with other data, be used to deduce an individual's identity. Examples of such data elements include, but are not limited to geographic location, age if > 89, sex, diagnosis and procedure, admission/discharge date(s), or date of death.

   The User agrees that any use of CMS data in the creation of any document (manuscript, table, chart, study, report, etc.) concerning the purpose specified in section 4 (regardless of whether the report or other writing expressly refers to such purpose, to CMS, or to the files specified in section 5 or any data derived from such files) must adhere to CMS' current cell size suppression policy. This policy stipulates that no cell (eg. admittances, discharges, patients) less than 11 may be displayed. Also, no use of percentages or other mathematical formulas may be used if they result in the display of a cell less than 11. By signing this Agreement you hereby agree to abide by these rules and, therefore, will not be required to submit any written documents for CMS review. If you are unsure if you meet the above criteria, you may submit your written products for CMS review. CMS agrees to make a determination about approval and to notify the user within 4 to 6 weeks after receipt of findings. CMS may withhold approval for publication only if it determines that the format in which data are presented may result in identification of individual beneficiaries

10. The User agrees that, absent express written authorization from the appropriate System Manager or the person designated in section 20 of this Agreement to do so, the User shall not attempt to link records included in the file(s) specified in section 5 to any other individually identifiable source of information. This includes attempts to link the data to other CMS data file(s). A protocol that includes the linkage of specific files that has been approved in accordance with section 4 constitutes express authorization from CMS to link files as described in the protocol.

11. The User understands and agrees that they may not reuse original or derivative data file(s) without prior written approval from the appropriate System Manager or the person designated in section 20 of this Agreement.

12. The parties mutually agree that the following specified Attachments are part of this Agreement:

    _____

13. The User agrees that in the event CMS determines or has a reasonable belief that the User has made or may have made a use, reuse or disclosure of the aforesaid file(s) that is not authorized by this Agreement or another written authorization from the appropriate System Manager or the person designated in section 20 of this Agreement, CMS, at its sole discretion, may require the User to: (a) promptly investigate and report to CMS the User's determinations regarding any alleged or actual unauthorized use, reuse or disclosure, (b) promptly resolve any problems identified by the investigation; (c) if requested by CMS, submit a formal response to an allegation of unauthorized use, reuse or disclosure; (d) if requested by CMS, submit a corrective action plan with steps designed to prevent any future unauthorized uses, reuses or disclosures; and (e) if requested by CMS, return data files to CMS or destroy the data files it received from CMS under this agreement. The User understands that as a result of CMS's determination or reasonable belief that unauthorized uses, reuses or disclosures have taken place, CMS may refuse to release further CMS data to the User for a period of time to be determined by CMS.

    The User agrees to report any breach of personally identifiable information (PII) from the CMS data file(s), loss of these data or disclosure to any unauthorized persons to the CMS Action Desk by telephone at (410) 786-2850 or by e-mail notification at **cms_it_service_desk@cms.hhs.gov** within one hour and to cooperate fully in the federal security incident process. While CMS retains all ownership rights to the data file(s), as outlined above, the User shall bear the cost and liability for any breaches of PII from the data file(s) while they are entrusted to the User. Furthermore, if CMS determines that the risk of harm requires notification of affected individual persons of the security breach and/or other remedies, the User agrees to carry out these remedies without cost to CMS.

14. The User hereby acknowledges that criminal penalties under §1106(a) of the Social Security Act (42 U.S.C. § 1306(a)), including a fine not exceeding $10,000 or imprisonment not exceeding 5 years, or both, may apply to disclosures of information that are covered by § 1106 and that are not authorized by regulation or by Federal law. The User further acknowledges that criminal penalties under the Privacy Act (5 U.S.C. § 552a(i) (3)) may apply if it is determined that the Requestor or Custodian, or any individual employed or affiliated therewith, knowingly and willfully obtained the file(s) under false pretenses. Any person found to have violated sec. (i)(3) of the Privacy Act shall be guilty of a misdemeanor and fined not more than $5,000. Finally, the User acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641 if it is determined that the User, or any individual employed or affiliated therewith, has taken or converted to his own use data file(s), or received the file(s) knowing that they were stolen or converted. Under such circumstances, they shall be fined under Title 18 or imprisoned not more than 10 years, or both; but if the value of such property does not exceed the sum of $1,000, they shall be fined under Title 18 or imprisoned not more than 1 year, or both.

15. By signing this Agreement, the User agrees to abide by all provisions set out in this Agreement and acknowledges having received notice of potential criminal or administrative penalties for violation of the terms of the Agreement.

16. On behalf of the User the undersigned individual hereby attests that he or she is authorized to legally bind the User to the terms this Agreement and agrees to all the terms specified herein.

Name and Title of User *(typed or printed)*		
Company/Organization		
Street Address		
City	State	ZIP Code
Office Telephone *(Include Area Code)*	E-Mail Address *(If applicable)*	
Signature	Date	

17. The parties mutually agree that the following named individual is designated as Custodian of the file(s) on behalf of the User and will be the person responsible for the observance of all conditions of use and for establishment and maintenance of security arrangements as specified in this Agreement to prevent unauthorized use. The User agrees to notify CMS within fifteen (15) days of any change of custodianship. The parties mutually agree that CMS may disapprove the appointment of a custodian or may require the appointment of a new custodian at any time.

    The Custodian hereby acknowledges his/her appointment as Custodian of the aforesaid file(s) on behalf of the User, and agrees to comply with all of the provisions of this Agreement on behalf of the User.

Name of Custodian *(typed or printed)*		
Company/Organization		
Street Address		
City	State	ZIP Code
Office Telephone *(Include Area Code)*	E-Mail Address *(If applicable)*	
Signature	Date	

18. The disclosure provision(s) that allows the discretionary release of CMS data for the purpose(s) stated in section 4 follow(s). (To be completed by CMS staff.) _____

19. On behalf of _____ the undersigned individual hereby acknowledges that the aforesaid Federal agency sponsors or otherwise supports the User's request for and use of CMS data, agrees to support CMS in ensuring that the User maintains and uses CMS's data in accordance with the terms of this Agreement, and agrees further to make no statement to the User concerning the interpretation of the terms of this Agreement and to refer all questions of such interpretation or compliance with the terms of this Agreement to the CMS official named in section 20 (or to his or her successor).

Typed or Printed Name	Title of Federal Representative
Signature	Date
Office Telephone *(Include Area Code)*	E-Mail Address *(If applicable)*

20. The parties mutually agree that the following named individual will be designated as point-of-contact for the Agreement on behalf of CMS.

    On behalf of CMS the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

Name of CMS Representative *(typed or printed)*		
Title/Component		
Street Address		Mail Stop
City	State	ZIP Code
Office Telephone *(Include Area Code)*	E-Mail Address *(If applicable)*	
A. Signature of CMS Representative		Date
B. Concur/Nonconcur — Signature of CMS System Manager or Business Owner		Date
Concur/Nonconcur — Signature of CMS System Manager or Business Owner		Date
Concur/Nonconcur — Signature of CMS System Manager or Business Owner		Date

Appendix C - Requesting Minimum Data Necessary Under 42 CFR 423.505(m)

The CMS Privacy Policy requires that disclosure of personally identifiable information be restricted to the minimum amount of data necessary to accomplish the task. This requirement pertains to all requestors of CMS data whether internal or external to CMS. (For more information, see Section 4B Disclosure and Use of Personal Information at http://www.cms.hhs.gov/SystemLifecycleFramework/downloads/privacypolicy.pdf).

There is currently a process in place for reviewing external data requests involving identifiable Medicare and Medicaid data to determine minimum necessary disclosure at the cohort and file level. We are building on this process for all Part D PDE data requests, including requests from external entities and other government agencies.

CMS will review requests for PDE claims data to ensure that disclosure is limited to those data required for the project. In addition to the existing data request processes, requestors of PDE data need to provide the information on the attached worksheet. PDE requestors include other HHS and non-HHS executive branch governmental agencies, Congressional agencies (when *not* acting on behalf of a congressional committee in accordance with 2 U.S.C. § 166(d)(1)), States, and external entities. This worksheet will be submitted to ResDAC for triage and completeness prior to ResDAC forwarding the package to CMS.

In addition to the minimum necessary policy, to further protect sensitive data, CMS will also impose the following restrictions. 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
- 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).

(For purposes of the above-listed protections, an external entity would not include States, executive branch governmental agencies, or Congressional support agencies. The Congressional support agencies are defined as: the Congressional Budget Office, the Government Accountability Office, the Medicare Payment Advisory Commission, and the Congressional Research Service when acting on behalf of a congressional committee in accordance with 2 U.S.C. § 166(d)(1).)

[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.

On the worksheet included as Appendix D:

- Requestors need to justify why a particular PDE element or group of PDE elements are necessary for the research/project, identify the literature or 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.
- Requestors need to 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 to ensure that unintentional disclosures are not made with respect to the published results of the study, if applicable.
- Requestors need to affirm that they will protect identifiers (beneficiary, plan, prescriber, and pharmacy) from disclosure.

Appendix D - Prescription Drug Event (PDE) Data Request Worksheet

Prescription Drug Event (PDE) Data Request Worksheet

Requestor name, title, and institution:

Funding Source (if a Federal contract include Project Officer name):

Title of the research study or project:

Data requested (include years requested, sample size, whether linked files are needed, such as Part A or B data, and if so, which files):

Brief description of the study or project:

A data request checklist, an Executive Summary, study protocol (Appendix E), and detailed description of how the data will be managed must be attached. The Executive Summary should include a highly condensed version of the project objectives, background, importance, project design (including requested data files and years and whether a sample or extract is required), and funding organization/agency of the project. The data management section should address all security and privacy issues associated with the data (how the data will be stored, accessed, managed and processed).

Prescription Drug Event Data Variable Selection & Justification Worksheet	
Date:	
Requester Name:	
Requester Institution:	
Study Title:	

'x' to request	#	PDE Data Element	Reason for Requesting PDE Element (In a few sentences, provide detailed justification for each element)	Risk of not receiving element (high, medium, low). If risk is high, or medium, please provide explanation.
		IDENTIFIERS		
	1	Beneficiary ID (includes the Health Insurance Claim Number (HICN), Cardholder ID, and Patient Date of Birth) *(*Not available to external entities, unless needed to link to another data set)*		
	2	Plan ID (includes contract number and plan benefit package id) *(*Not available to external entities)*		
	3	Prescriber Identifier *(*Not available to external entities, unless needed to link to another data set)*		
	4	Pharmacy Identifier (Service Provider identifier) *(*Not available to external entities, unless needed to link to another data set)*		
	5	Qualifying Identifiers (Service & Prescriber Identifier Qualifiers)		

Prescription Drug Event Data Variable Selection & Justification Worksheet	
Date:	
Requester Name:	
Requester Institution:	
Study Title:	

'x' to request	#	PDE Data Element	Reason for Requesting PDE Element (In a few sentences, provide detailed justification for each element)	Risk of not receiving element (high, medium, low). If risk is high, or medium, please provide explanation.
	6	Internal Plan/Pharmacy Prescription Identification Numbers (claim control number & prescription/service reference number) (**Not available to other non-HHS executive branch agencies, states and external entities.)*		
		DRUG UTILIZATION INFORMATION		
	7	Date of Service		
	8	Drug Information (includes Product/Service Identifier, Quantity Dispensed, Days Supply, Compound Code, Fill Number, Dispensing Status)		
	9	Other utilization information (includes Dispense as Written/Product Selection Code and Drug Coverage Status Code)		

Prescription Drug Event Data Variable Selection & Justification Worksheet	
Date:	
Requester Name:	
Requester Institution:	
Study Title:	

'x' to request	#	PDE Data Element	Reason for Requesting PDE Element (In a few sentences, provide detailed justification for each element)	Risk of not receiving element (high, medium, low). If risk is high, or medium, please provide explanation.
		DRUG COST INFORMATION		
	10	Total Drug Costs (contains aggregation of Ingredient Cost, Dispensing Fee, and Total Amount Attributed to Sales Tax, except that sales tax may be pulled out if requested.) (**HHS entities & Congressional support entities may request disaggregated information if needed.)*		
		COVERAGE INFORMATION		
	11	Date Paid		
	12	Plan Paid Amounts (includes Covered D Plan Paid Amount and Non-Covered Plan Paid Amount)		
	13	Beneficiary Cost Sharing (patient pay amount)		

Prescription Drug Event Data Variable Selection & Justification Worksheet	
Date:	
Requester Name:	
Requester Institution:	
Study Title:	

'x' to request	#	PDE Data Element	Reason for Requesting PDE Element (In a few sentences, provide detailed justification for each element)	Risk of not receiving element (high, medium, low). If risk is high, or medium, please provide explanation.
	14	Other Payer Amounts (includes Other True Out of Pocket Amount and Patient Liability Due to Other Payer Amount)		
	15	Low-Income Cost-Sharing Subsidy Amount		
	16	Other Financial Information (includes Gross Drug Cost Below Out of Pocket Threshold and Gross Drug Cost Above Out of Pocket Threshold)		
		OTHER DESCRIPTIVE DATA		
	17	Patient Gender		

Prescription Drug Event Data Variable Selection & Justification Worksheet	
Date:	
Requester Name:	
Requester Institution:	
Study Title:	

'x' to request	#	PDE Data Element	Reason for Requesting PDE Element (In a few sentences, provide detailed justification for each element)	Risk of not receiving element (high, medium, low). If risk is high, or medium, please provide explanation.
	18	Catastrophic Coverage Indicator (Catastrophic Coverage Code)		
	19	In-Network versus Out of Network or MSP Claim (Pricing Exception Code)		
	20	Electronic versus Paper Claim (Non-standard format code)		
	21	Original versus Adjusted PDE (Adjustment/Deletion Code) (**Final action claims will be provided; thus, this element should not be needed for other executive branch agencies, States and external entities.)*		

Appendix E - Requestor's Executive Summary and Study Protocol

The requestor's Executive Summary, a detailed description of how the data will be managed, and a research or other project protocol must be attached to the PDE Data Request Worksheet (Appendix D). The Executive Summary should include a highly condensed version of the project objectives, background, importance, project design (including requested data files), and funding organization/agency of the project. This summary will be the cover page of the project/research protocol and should be detailed enough to allow any CMS representative reviewing the executive summary to understand the project being proposed. The Executive Summary should also be submitted as the cover page to the federal grant proposal.

Additionally, the Executive Summary should *briefly* address each of the following:

1. How the project has the potential to improve the quality of life for Medicare beneficiaries or Medicaid recipients, or improve the administration of the CMS programs.
2. The measures to be taken to ensure that the use of these data involves no more than minimal risk to individuals and the steps to be taken to assure that identifiers (beneficiary, plan, prescriber, or dispenser) are not disclosed. A more comprehensive overview may be presented in the Database Management section of the protocol.
3. Whether the project could be conducted without individual level authorization. Explain.
4. Whether the project could be conducted without access to these individually identifiable data. Explain.

Example text: Understanding factors that influence the utilization of prolonged mechanical ventilation in the elderly Medicare population will be important to ensuring rational and optimal care of these patients. The research could not be conducted without access to these individually identifiable data since the investigation will require identifying dates of service at the beneficiary level. The volume of subjects and retrospective nature of the project would make it impractical to perform if informed consent and authorization were required. The measures outlined in the project protocol will ensure that no more than minimal privacy risk is imposed upon individuals.

5. List of the data files and years being requested.

Example text: We are requesting the research identifiable files (RIFs) from CMS, specifically the2004-2006Denominator and MedPAR files. The RIFs are needed for this analysis (as opposed to the limited data set (LDS) Files) because our analysis requires that we identify the exact date the procedure occurred, since the quarter and year are not sufficient. Per our project objectives, we must identify individuals who have age-related macular degeneration (AMD) and have received IVT-injection, and must use the individually identifiable data to link these individuals to any of their claims that have a diagnosis code for acute endophthalmitis over the four-year project period.

6. Brief summary that this is minimum data necessary, including a brief justification of why the LDS files could not be used.

Example text: To the best of our knowledge, this research cannot be conducted without individual level data and the individually identifiable data. We have requested only the data needed for our analysis. Per our project objectives, we must identify individuals who have AMD and have received IVT-injection, and must use the individually identifiable data to link these individuals to any of their claims that have a diagnosis code for acute endophthalmitis over the four-year project period.

Database Management:

The protocol should explicitly address how the data files will be held, managed, and processed. For example, who will have the main responsibility for organizing, storing, and archiving the data? Who will maintain computer data media and make needed work files available to those who will analyze the data? How will the privacy information be safeguarded? What is the plan for destroying/returning data at the end of the DUA period? If multiple organizations are involved, is a copy of the data being requested? If the funding source is commercial, requestors should indicate that the commercial entity will not receive any individual data and that the requestor would have full editorial control over any publication regardless of the project findings.

The following is an example of a well constructed data management section:

To ensure the privacy and confidentiality of data for this project we will store and use the identifiable data at the following locations: 1) a password-protected stand-alone PC at the offices of Dr. X at the University of XX; or 2) an alternate server at the University of XX IT Facility under the direction of Dr. Johnson, who has signed the DUA signature addendum. The stand-alone PC will be password-protected and resides in a locked office within a building having limited, electronic passkey access. The IT systems analyst, under the supervision of Dr. Johnson, who has signed the DUA signature addendum, will upload the data onto the secure production servers (the main Oracle database server and the Protected Health Information (PHI) server), which are accessible only to key personnel, who are under the direction of Dr. Johnson and will be monitored regularly. The database management at University of XX's IT facility is built with multiple layers of security and follows best practices for securing sensitive data. The main levels of security are fourfold and include: CD physical security in the offices of Dr. X and machine physical security in the IT facility, data directory access controls, physical server security, and virtual server security. Project computers are all password protected, are protected by the University of XX firewall, and are in locked offices within a building having limited, electronic passkey access.

Password protection will be used in additional places at the server and web portal levels for all transactions that allow entry and editing of data, provide access to sensitive subject data or administrative privileges. Passwords will be managed to

require all users to change their password within 90 days and strict rules will be implemented to require strong passwords. Additionally, all PHI data hosted on the PHI server, which is privately networked to the main database server for authorized integration by PIs, will be encrypted within the Oracle database with de-encryption keys activated only by a user password for which a member of the research team has been given permission to access these sensitive data (the PI and project staff who are under the direct supervision of the PI and have yet to be named). PHI data access will be limited to PIs and key members of the IT facility. Prior to receiving PHI access, requestors must demonstrate completion of HIPAA training and abide by security procedures developed by the IT facility.

The production servers at the University of X IT facility (the main Oracle database server and the PHI server), running the Sun Microsystems Solaris 9 operating system, will be housed in a dedicated computer machine room containing emergency backup power, an uninterruptible power source (UPS), a non-liquid fire suppression system and authorization-based limited access. The computer and corresponding Raid-5 disk storage will be locked in a computer cabinet within the computer room with keys to the server and rack only distributed to key personnel under the supervision of Dr. Johnson. According to industry best practices, all software services and corresponding ports on the servers that are known to be substantial security risks and which are not used by the project data management resources will be disabled, including telnet, ftp, r commands and sendmail. Administrative access to databases and corresponding data will be limited to the IT facility team using Secure Shell (SSH) and/or Virtual Private Network (VPN). Furthermore, all databases will reside behind industry-strength firewalls, with the PHI server being protected by yet another layer of firewalls. Data, query tools and reports published via web interfaces will be encrypted using a secure web server and SSL certificates that provide a minimum of 256-bit encryption.*

The electronic data files for this project will be processed on this dedicated, layered-security system, which can be accessed only by the PI and designated project staff that are under the direct supervision of the PI and have yet to be named on an as-needed basis. Since the system is behind multiple firewalls, is monitored regularly, and is accessible only to key personnel, the risk of unlawful penetration is not a significant data safeguard concern.

All applications are run on the server, thereby eliminating the need to house data on laptop computers that are generally more of a security risk.

As indicated in the Data Use Agreement, individually identifiable or deducible data will not be transmitted by unsecured telecommunications, which include the Internet, email, and electronic File Transfer Protocol (FTP). Further, the data will not be physically moved or transmitted in any way from the University without written approval from CMS.

At the conclusion of this project, or by the date of retention identified in the Data Use Agreement, a CMS "Certification of Destruction" certifying the proper destruction of all data obtained will be sent to CMS.

Lastly, all output containing individual identifiable information, as well as plan, prescriber, and dispenser identifiers, is treated as confidential data. This information is never transferred electronically via email or other protocols. Shredders are used on any printed material containing individual identifiers. Printed materials such as tables and manuscripts will not contain cell sizes less than 11.

Finally, although this project is funded by Pfizer, inc., as illustrated in the contract with Pfizer and in the project protocol, Pfizer and its employees/consultants will not have any access to the CMS raw data. Instead, they will receive only summary results from the analyses. It is the policy of University of X and our academic tradition that the requestors are free to publish their research results without any influence by the funding agency. In addition, publication of this project's results is at the sole direction of the project PI, independent of any influence by Pfizer and its employees or consultants, regardless of whether the results will be potentially "beneficial" or "harmful" to Pfizer and its products.

Key Staff –Title, Responsibilities, and Role

To the extent possible, persons the requestor believes are crucial to a successful project should be named in this section. This section specifically identifies the institution and the role in this project. The requestor and custodian should be named in this section at a minimum.

For government requests, this section may identify key contractor staff assisting with the project, as applicable

Example Text:
Robert Smith, M.D., Chief, Division of General Internal Medicine, University of United States School of Medicine. Dr. Smith will serve as the requestor of the data, overseeing the project and personnel on the project.

IMPLEMENTATION POTENTIAL

In this section, requestors should address the generalizability, applicability, and dissemination of the work. Include a sentence that you acknowledge that by signing the DUA, you agree to the cell suppression policy of not publishing or presenting tables with cell sizes less than 11. Include a sentence that you acknowledge that by signing the DUA you agree to the identifier masking policy of not publishing or presenting findings that identify specific beneficiaries, plans, prescribers, or dispensers.

Requestors may use the following proposed structure when providing their project protocol:

INTRODUCTION

Title:

The requestor should be succinct in titling their project. Use keywords, phrases, or descriptors that will highlight the population of interest, the medical problems of concern, and the health policy issues of importance.

Objectives:

The objectives should pinpoint what the requestor plans to do and expects to achieve. The number of objectives should be relatively few and listed in approximate order of priority or importance. The objectives listed should underscore the major elements of work that are realistically achievable.

Background:

For research requests, the background should succinctly highlight gaps in the current knowledge or practice in the field of study. The requestor must show that he or she understands the important studies that form the foundation for the protocol and indicate how the project will go beyond them. Please include a literature review. The literature review need not be lengthy, but it should be reasonably comprehensive and up-to-date. The requestor is not expected to review all the relevant literature in great detail; if he or she is conversant with other bibliographies or literature reviews, they should be cited. If there is no literature or body of knowledge in the area proposed for the project, this should be stated.

For government requests that are not research in nature, the background should describe how the project is consistent with the mission of the agency.

Importance:

There are two main points that should be addressed here: the significance of the question or project issue proposed and the significance of the requestor's particular project. This is the place to make a strong case for the importance of the project being proposed. For example, the proposed project may add to the general body of knowledge, expand the possible ways to organize and deliver health services to meet a particular human need, or it may do both. The point is to deliver a credible, straightforward argument for the contributions that the work will make.

RESEARCH QUESTIONS AND METHODS

Hypotheses/Study Issues:

If there are hypotheses to test, they should be stated explicitly. If there are no specific hypotheses, the application should discuss the issues that prompted the requestor to undertake the project.

Project or Study Design:

The basic objective is to describe how the project will operate. In some studies or projects, Medicare or Medicaid data will be used to supplement other data. In such instances, the requestor should briefly state the design of the overall project and then describe in detail how the CMS data being requested will be used in the project. Uppermost in the reviewers' minds are the questions of how each piece of information relates to the project or hypotheses to be tested, issues to be studied, or program(s) to be demonstrated.

For research projects, it is a good idea to consult an epidemiologist, statistician, econometrician, or some other person well acquainted with basic research methodology when planning the design and analysis of the project. The project design must present a solid chain of reasoning. The project design, at a minimum, should:

- List the data files and years being requested, including any conversion or crosswalk files needed.
- Describe the sample population to be studied and the method to be used to select or identify the project population in the data files;
- Discuss the issue of precision or power of the study/project and the strength of its eventual conclusions. If applicable, indicate whatever power calculations might have been done to justify the sample size and comment whether the sample size will permit accurate generalization to larger populations;
- Give a specific description of the match between what is to be investigated and the data files and variables to be used in the analysis;
- Briefly state the dependant (or response) variables, the independent (treatment or explanatory) variables, and the factors that may need to be measured or accounted for because they might otherwise confound the analyses;
- If relevant, discuss the project's cross-sectional aspects (comparisons in one time period) and longitudinal aspects (comparisons over time).
- If CMS data are to be linked to other CMS data files or other data sources, specify the data that will be linked. Per section 10 of the DUA, the requestor can not link CMS data files without noting this request in the project protocol.

Data Limitations:

It is important to note potential limitations of the data in relation to the proposed project and to identify the efforts that will be made to address those issues. For example, noting that the data does not contain information regarding services not covered by, or billed to, Medicare and how that might affect the results. Also, note that for the most part, CMS data do NOT include information for beneficiaries enrolled in a Medicare managed care plan. It is better to show that consideration has been given to what the potential limitations are rather than have reviewers assume that the requestor was not aware any existed.

EVALUATION AND ANALYSIS PLAN

Analysis Plan:

In this section, the application should explain, as clearly as possible, how the data would be analyzed. This section should convince reviewers that the proposed methods are consistent with the hypotheses/issues to be studied and the data to be collected, and it should persuade them that the data will support the level of analysis planned.

Analytic Methods:

This section should discuss specifically what analytic methods are expected to be used. It is often helpful to give examples of the analyses or to show what the tables of results might look like. Often, discussing hypothetical findings based on likely values of the data which will eventually be collected is a useful device for making the analysis plan seem less abstract. The goal is to try to aid reviewers in visualizing the data set that will be compiled, so that they can think along with the requestor about what methods of analyses seem appropriate and reasonable to address the hypotheses/issues to be studied.

WORK PLAN

Description of Tasks:

The proposed work should be sufficiently well planned so that the requestor can specify a set of tasks that will cover all the activities needed to complete the project. The aim is to identify all the tasks to be under the project design. In addition, note that one task will probably involve producing a final report. Every task noted here should have some corresponding description in the project design and/or analysis plan section(s) to show how it will be accomplished; every major activity targeted for completion should have a corresponding task.

Time Schedule:

The application should provide a Gantt chart or some other diagram to illustrate when the tasks outlined above will be completed, in what order, and how long they are expected to take. This is commonly done in terms of elapsed months (e.g., for a 2-year project, months 0 through 24 would be one axis of your chart). It is helpful to adopt

some conventional symbols, such as an asterisk or triangle, to show when specific milestones are to be achieved. The time schedule should extend to date that is listed in the Data Use Agreement retention period. CMS will allow for a maximum of a 5 year retention period. Be sure to include a task of seeking CMS approval of release of findings, per the DUA, prior to submitting manuscripts for publication review or conference presentations.

	Year 1			Year 2-5
Task	**Month 0-3**	**Month 4-5**	**Month 6-12**	**Month 13-60**
Request CMS Data				
Receive data tapes & load data				
Data Cleaning				
Data Analysis				
Prepare manuscript				
Retention of data for presentations and to answer follow-up questions				

Level of Effort of Personnel:

This section is commonly shown as a table, in which the requestor lists the key individuals (by name or by task) and the number of full time equivalent (FTE) or days they will devote to each task.

For multi-year projects, the requestor should show total days in each year. Total days per year should be equivalent to whatever percentage of time is shown for these individuals in the budget document. Note that reviewers pay attention to these figures. Too little time for key personnel suggests that the requestor may have an unrealistically optimistic view of what can be accomplished.