

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

### How do I get more information about Part D claims data?

CMS is hosting an open door forum meeting for the public to learn more about the new Part D data regulation and how to request Part D data. The open door forum is scheduled for June 11, 2008. We will have more information posted soon on our website at:

[http://www.cms.hhs.gov/OpenDoorForums/05\\_ODF\\_SpecialODF.asp](http://www.cms.hhs.gov/OpenDoorForums/05_ODF_SpecialODF.asp)

### 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 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 researchers are described in the data availability chart located on our website at:

[www.cms.hhs.gov/PrescriptionDrugCovGenIn/08\\_PartDData.asp](http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/08_PartDData.asp).

### 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 Prescription Drug Event data?

The Part D data final rule allows the public to receive identifiable Part D 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 Part D 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 drug claims 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. There are about 17 million beneficiaries who are in Original Medicare with a stand-alone Part D prescription drug plan which means that Medicare Part A, B, and D claims data are available for research purposes. Only Part D data is 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](http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/01_Overview.asp).)

**What year of data is available now?**

Part D claims 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 are available will be posted on our website at: [www.cms.hhs.gov/PrescriptionDrugCovGenIn/08\\_PartDData.asp](http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/08_PartDData.asp) Please check back to learn when data are available. 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 de-identified, limited data sets 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 will be soliciting information from the public about what information would be useful to include in such files.

**When will the Chronic Condition Warehouse (CCW) be able to provide Part D drug event data to researchers?**

The CCW is not able to obtain Part D drug event data until 30 days after the Part D data regulation is published (the effective date). Once the regulation is effective, it will take about 5 months for the CCW to test and load the 2006 Part D data. 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 researchers who need to link the Part D data to other datasets.

**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 research community. ResDAC has a toll-free help desk and comprehensive web-site 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.

ResDAC will inform the research community about how to obtain Part D data.

**How do I request Part D data?**

CMS will be developing guidelines and workshops to inform researchers on how they can access this new database. Additional information is available from our research data assistance center at: <http://www.resdac.umn.edu/>

An open door forum to review the final rule, discuss the Part D claims data release process, and answer questions from the public has been scheduled for June 11, 2008. To participate in the open door forum, please visit:

[http://www.cms.hhs.gov/OpenDoorForums/05\\_ODF\\_SpecialODF.asp](http://www.cms.hhs.gov/OpenDoorForums/05_ODF_SpecialODF.asp).

**Is CMS going to sponsor training for Part D data requestors?**

Yes. CMS will sponsor training for Part D requestors via the ResDAC contract.

**How much does the Part D data cost?**

CMS sets data file costs to recover the actual amount expended in the data distribution process. This is 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 Part D data to link to my current Part A and B claims data?**

Yes, if you submitted a research protocol that required Part D drug claims data as part of your original data request, but were waiting for publication of this rule. You will first need to modify your Data Use Agreement (DUA) with CMS to add Part D data. If you have new research that you can now pursue with the availability of Part D data, you will have to submit a data reuse request, along with a Part D data request.

**Can I get Part D data to link to my clinical trial data?**

Yes. This request would require the release of sensitive beneficiary identifiers, and would undergo a heightened level of scrutiny at CMS to ensure you have procedures in place to protect the privacy of the data. Such protections include storing data files in a locked secure area, allowing password protected access for a limited number of members of the research team to beneficiary identifiable data, creation of study-specific identifiers that are not derived from Medicare identifiers and destruction of personal identifiers once the data linkage has been made.

**Is CMS going to sponsor a Part D data users group?**

No. CMS will not sponsor a Part D data users group.

**Why do these data only reflect benefit year 2006? Why don't they include 2007 and when will 2007 data be available?**

2006 is the only full year of data that is complete. 2007 information includes payment and prescription drug event data reported by the plans that has not been finalized and reconciled with CMS. We plan to have the 2007 data available once our reconciliation process is completed and we have had time to prepare data files for non-payment uses.

**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 to researchers. We anticipate that 2007 Medicare Parts A/B data will be available later this summer.