Chronic Conditions Warehouse

Your source for national CMS Medicare and Medicaid research data

Chronic Conditions Warehouse Technical Guidance

Summarizing and Describing Prescription Drug Utilization

MAY 2022 | VERSION 1.6

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Revision Log

Date	Changed by	Revisions	Version
May 2022	K. Schneider	Adjusted references to conditions data files to reflect the	1.6
		addition of the 30 CCW Chronic Conditions file	
March 2022	K. Schneider	Transferred to 2020 template. Inserted information regarding	1.5
	R. Van Gilder	availability of Medicare Advantage encounter data, and	
	M. Richardson	updated language to active voice	
July 2021	M. Richardson	Updated help email addresses with @gdit.com to	1.4
		@ccwdata.org	
January 2018	K. Schneider	MBSF A/B references updated to include C/D; updated data	1.3
	R. Van Gilder	source information to reflect CME instead of EDB	
September 2015	K. Schneider	Adjusted information regarding encryption of plan, prescriber,	1.2
	B. O'Donnell	and pharmacy identifiers	
November 2014	K. Schneider	Updated document template. Added code examples related to	1.1
	B. O'Donnell	benefit phases	
	J. O'Donnell		
	C. Powers		
	C. Alleman		
February 2014	K. Schneider	Created initial document	1.0
	M. Roozeboom		
	M. Brenton		

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Chapter 1. Introduction

The Centers for Medicare & Medicaid Services (CMS) launched the Chronic Conditions Warehouse (CCW), a research database, in response to the Medicare Modernization Act (MMA) of 2003. Section 723 of the MMA outlined a plan to improve the quality of care and reduce the cost of care for chronically ill Medicare beneficiaries. An essential component of this plan was to establish a data warehouse that contains Medicare claims data and assessments linked by beneficiary across the continuum of care. Part of the MMA (Section 101) established a prescription drug benefit, which is a voluntary benefit offered though the Medicare Part D program. CMS automatically enrolls Medicare beneficiaries were able to purchase Part D coverage through private plans. Medicare Part D data became available to researchers in 2008.

Academic researchers and certain government agencies with approval under a Data Use Agreement (DUA) may request Research Identifiable Files or RIFs. The CCW Medicare data contain identifiable information and are subject to the Privacy Act and other Federal government rules and regulations (reference the <u>Research Data Assistance Center</u> [<u>ResDAC</u>] website for information on requesting Medicare data). To obtain a DUA to use the Part D data, researchers must select variables based on minimum data necessary and justify the need for each variable.

The CCW team publishes Part D enrollment and utilization counts on the <u>CCW website</u> (reference Table F1 for example). Depending on the assumptions researchers make when requesting and compiling variables, researchers may obtain different useable sample sizes.

The CCW team designed the data files to support a variety of research objectives. The <u>CCW Medicare Part D User</u> <u>Guide</u> provides background information regarding the Part D benefit and the data variables available for researchers. It is best to use this Technical Guidance paper in conjunction with the <u>CCW Medicare Part D User Guide</u>.

We designed this paper to help researchers more easily, efficiently, and accurately work with the Part D data files to summarize and describe prescription drug utilization.

A. Objectives

This Technical Guidance paper provides researchers with guidance to:

- 1. Specify a study cohort based on Medicare Part D coverage criteria
- 2. Link the cohort/enrollment file to the Part D utilization file (known as the Prescription Drug Event file) which describes the dispensed drug
- 3. Perform data tabulations to accurately calculate particular study metrics

The CCW team is pleased to offer some hints that we have found useful in working with Part D data to obtain the types of information commonly desired from these data files.

Chapter 2. Contents of CCW Part D Data Files

The CCW system contains data for 100% of Medicare-enrolled beneficiaries, not only those with a chronic condition. A standard data file available to researchers is the CMS 5% random sample. CCW documents the criteria for selection of the random 5% in Chapter 1 of the <u>CCW Medicare Administrative Data User Guide</u>. Alternatively, CCW data are available upon request for specific researcher-defined cohorts. Medicare Part D enrollment information is available within the CCW Master Beneficiary Summary File (MBSF) beginning in 2006.

The CCW database contains Medicare A and B fee-for-service (FFS) claims from 1999 forward. It also includes Medicare Advantage (Part C) encounter data from 2015 forward. For Medicare Part D, all prescription drug events (PDEs) are present, regardless of whether the beneficiary enrolled in managed care or an FFS plan. PDEs are available for all filled prescriptions that Medicare Part D covers as part of the Part D benefit. The PDE file may include a small number of non-covered drugs (e.g., supplemental drugs reported by enhanced alternative plans or over-the-counter drugs).

For 2006–2011, the CCW team extracted the PDE file from an annual standard analytic file (SAF) with Part D data that CCW obtained from CMS. Starting with 2012 data, the CCW team created our own version of the SAF¹ from weekly CMS PDE Tap data feeds where we applied a SAF final-action process. The shift to a CCW-produced annual PDE file allows for the CCW team to release Part D Event data several months earlier. Researchers should consider all PDE data disseminated by the CCW team "final action," as they represent the final status of a drug event record at the conclusion of CMS' payment reconciliation process (i.e., the records account for post-transaction adjustments).² Each prescription fill appears in the data file as a unique PDE.

The PDE includes services for beneficiaries enrolled in Medicare Advantage Prescription Drug Plans (MA-PD — managed care and prescription drug coverage integrated with provided health care coverage under Medicare Part C), stand-alone prescription drug plans (PDPs), which offer only prescription drug coverage, and employer plans. Although retiree insurance plans may offer services equivalent to a Part D benefit through Retirement Drug Subsidy (RDS) plans or other creditable plans (e.g., the Veterans Administration [VA]), Part D events data are not available for these enrollees.

The CCW team processes the PDE and other Part D data to create several derived variables and some supplemental Part D characteristics data files. Researchers may request the "drug characteristics" variables, which describe the drug. These fields include the brand name, generic name, dosage form, and strength and the CCW team appends them to the PDE file.

The researcher can use key variables within the data files to join the CCW files. The linkage keys vary depending on which files researchers are attempting to join; however, for the purposes of this paper, the primary linkage will be at the beneficiary (person) level. It is important to note that CCW encrypts two of the Part D data fields using DUA-specific criteria. These encrypted variables include the CCW-assigned unique beneficiary ID (BENE_ID) and a unique key for each prescription drug fill, that is, each PDE (PDE_ID).

¹ Analyses performed demonstrate our final action processing results in an annual PDE data file that is nearly identical to the CMS PDE SAF file.

² Additional details regarding final action for PDEs are in a CCW Medicare Data white paper <u>Medicare Claims Maturity</u>. Available on the ccwdata.org site.

NOTE: Before the 2013 data release, CMS required the CCW team to encrypt or use CCW-assigned ID values to protect some of the sensitive Part D data fields. CMS determined that researchers could use these sensitive fields to identify the prescriber, the pharmacy, the plan, or the plan's formulary. CMS no longer requires encryption of these variables. Additional details regarding Part D data files are in the <u>CCW Medicare Part D Data User Guide</u>.

The CCW team provides requested data extracts and SAS[®] read-in statements to researchers in a user-friendly format. The variable names used for examples in this document are the long names found in the SAS v8 read-in file.

Chapter 3. Defining a Cohort

Throughout this paper, the assumption is that we begin with a Medicare 1% random sample of beneficiaries who, in 2011, had at least one month of Part D coverage. We are using the CCW Master Beneficiary Summary File Part A/B/C/D segment (also referred to as the Base Master Beneficiary Summary File) as well as the PDE File for this population for 2011. The CCW team creates the MBSF for each calendar year. The MBSF contains demographic entitlement and enrollment data for beneficiaries who: 1) the CCW team documented as alive for some part of the reference year; and 2) enrolled in the Medicare program during the file's reference year.

A. Denominator Selection

The MBSF Part A/B/C/D segment contains the Medicare Part D enrollment/eligibility status for each Medicare-eligible beneficiary. This information is present regardless of the type of Medicare Part D plan the beneficiary might select (i.e., enrollment data are present for managed care participants as well as those enrolling in stand-alone prescription drug plans). Information is also available for Medicare beneficiaries who did not obtain Part D coverage. Researchers can find a description of the variables contained within each CCW data file on the <u>Data Dictionaries</u> page of the CCW website. Most investigators will want to include information from the MBSF A/B/C/D segment related to Medicare Parts A/B/C coverage and demographic information. There is a single row of data for each beneficiary in the population, identified by a unique encrypted beneficiary identification number (BENE_ID).

The additional segments of MBSF are:

- 1. CCW Chronic Conditions
- 2. Other Chronic or Potentially Disabling Conditions
- 3. Cost and Use
- 4. National Death Index (NDI) for cause of death segment, available through 2016.

These segments of the MBSF easily join together using the BENE_ID.

NOTE: When the CCW team delivers the data files, they are already pre-sorted and indexed by BENE_ID.

Researchers may use the MBSF to determine whether a beneficiary has a sufficient surveillance period (i.e., months of Medicare coverage) for inclusion in the study. Variables contained in this file include: the number of months of Medicare Part A, B, C, and D coverage; whether the beneficiary died during the year; Part D plan type; whether the beneficiary received Part D subsidies; as well as other beneficiary demographic and geographic information. Reference the CCW website for the complete <u>record layout</u>.

1. Length of Part D Coverage

From the universe of Medicare beneficiaries, you may wish to limit your study population to beneficiaries "at risk" for events of interest to you. For example, not all Medicare beneficiaries will elect to purchase Part D coverage. You may wish to limit your cohort to beneficiaries with Part D coverage — perhaps a certain minimum number of months of Part D coverage during the time frame of interest.

Decide whether other considerations are important for your cohort, such as the type of Part D coverage, Medicare Part A/B, fee-for-service coverage, and presence of chronic conditions.

2. Type of Part D Coverage

Do you need to understand the benefit structure for the Part D plan selected by the members of your cohort? If so, you may wish to subset the data to keep members of specific types of plans or organizations. CMS does not require some types of Part D plans to report their benefit details (e.g., Program of All-inclusive Care for the Elderly [PACE] and employer direct plans). Researchers can identify the employer direct plans in 2007 forward by the first digit of the Part D contract ID (monthly PTD_CNTRCT_ID_<MM> on the MBSF-ABCD segment; the first digit is "E"). More detailed information regarding the type of benefit offered by each contract that a Part D plan has with CMS is available in the plan characteristics data file (reference particularly variables such as ORGANIZATION_TYPE or PLAN_TYPE).

NOTE: CMS identifies a particular plan benefit package using a combination of both the contract and plan benefit package identifiers, which have different variable names in the PDE and plan characteristics data files (i.e., PLAN_CNTRCT_REC_ID and PLAN_PBP_REC_NUM in the PDE file, CONTRACT_ID and PLAN_ID in the plan characteristics file, and monthly PTD_CNTRACT_ID_<*MM>* and PTD_PDP_ID_<*MM>* in the MBSF).

3. Length of Medicare Part A and/or B Fee-for-Service Coverage

Do you need to be able to observe treatment/receipt of care or to accurately ascertain diagnoses and comorbid conditions? If so, you may wish to select beneficiaries who had both Medicare Part A and B coverage. Variables within the Base MBSF A/B/C/D indicate the type of Medicare coverage obtained each month (using the monthly MDCR_ENTLMT_BUYIN_IND_<*MM*>). If you wish to observe claims/encounter records for only beneficiaries enrolled in FFS or in Medicare Advantage (MA) plans, use the monthly MA enrollment indicator (BENE_HMO_IND_<*MM*>) to do this. Note that MA encounter data is available starting with 2015.

4. Presence of Chronic Conditions

Some researchers may wish to bring in additional information, such as clinical data regarding the patient, to specify a cohort. For example, researchers wishing to select a cohort based on presence of medical conditions of interest may wish to merge information from the Chronic Conditions segments of the MBSF. There are two types of conditions segments: 1) the CCW Chronic Conditions, and 2) the CMS Other Chronic or Potentially Disabling Conditions (OTCC).

- CCW Chronic Conditions the CCW contains two versions of the Chronic Conditions: 30 CCW Chronic Conditions (2017 forward) and 27 CCW Chronic Conditions (1999–2020). CMS developed the CCW Chronic Conditions variables using a multi-stage process.³ and
- 2. CMS (OTCC) CMS developed additional condition measures specifically to enhance research of the Medicare-Medicaid dually enrolled population.

The predefined conditions use FFS claims-based algorithms to indicate that treatment for a condition appears to have taken place. To observe health service utilization information for patients within the FFS claims files, the Medicare beneficiary must have Medicare Part A and/or Part B FFS coverage. Those enrolled in Medicare Advantage (i.e.,

³ CMS developed the 27 CCW Chronic Condition variables using a multi-stage process. Initially, ResDAC used CMS and other national data sources to identify candidate conditions which they could define using claims-based algorithms. Next, ResDAC conducted extensive literature reviews to gather diagnosis code sets for each candidate condition. Finally, CMS engaged other federal agencies in a series of conversations to vet the proposed category definitions. In 2020, CMS contracted an expert panel to validate the algorithms following the change from ICD-9 to ICD-10-CM. CMS also asked the expert panel to refine these algorithms and identify additional conditions to add to the CCW, resulting in the 30 CCW Chronic Condition algorithms.

Medicare managed care plans) do not have FFS claims; therefore, no information regarding their care or clinical diagnoses or procedures is available in the CCW FFS Medicare claims files or in the MBSF.⁴

Researchers may wish to restrict the cohort to those with a certain number of A/B coverage months (rationale described above). A Technical Guidance paper called <u>Getting Started with CMS Medicare Administrative Research Files</u> on the CCW website explains methods to address applying coverage criteria in greater detail.

Although Medicare encounter data have recently become available for 2015+, the CCW team has not yet considered encounter service records for CCW Chronic Conditions. Reference the MBSF data file documentation on the CCW website for additional information regarding the CCW Chronic Conditions and the OTCC file segments.

Coding specifications for the <u>condition algorithms</u> are located on the CCW website. For more information about using the conditions variables for various purposes, please reference a CCW paper called <u>Technical Guidance for Calculating</u> <u>Medicare Population Statistics</u> on the CCW website.

B. Aggregating Data to Summarize Coverage Variables

Within the MBSF, there are several variables that describe the Medicare coverage the beneficiary selected. These include the Part D plan's contract and benefit package identifiers, the segment (market area) for the plan, the cost share group, and the retiree drug subsidy. Each of these variables has 12 monthly indicators for every beneficiary (reference Table 1).

Variables with monthly values	SAS variable name(s)
	The last two <mm> digits are sequential 01–12</mm>
Contract ID*	PTD_CNTRCT_ID_ <mm></mm>
Benefit package ID*	PTD_CNTRCT_ID_ <mm></mm>
Segment ID*	PTD_SGMT_ID_ <mm></mm>
Cost share group	CST_SHR_GRP_CD_ <mm></mm>
Retiree drug subsidy	RDS_IND_ <mm></mm>
Dual Medicare-Medicaid enrollment status	DUAL_STUS_CD_ <mm></mm>
HMO indicator	HMO_IND_ <mm></mm>
Medicare buy-in indicator	MDCR_ENTLMT_BUYIN_IND_ <mm></mm>

Table 1. Part D monthly coverage variables in MBSF

* Prior to the 2013 data release, the CCW team encrypted these variables.

This level of detail may be important for researchers studying the effect of plan changes during the year; however, researchers who are not studying these issues in-depth may wish to generalize the monthly coverage information. For

⁴ There are a couple of exceptions where FFS claims appear for MA enrolled beneficiaries. CMS always pays hospice care through FFS Medicare; MA plans do not cover hospice. Additionally, there may be a small number of claims for inpatient and skilled nursing facility services for beneficiaries enrolled in certain MA plans that CMS reimburses based on costs. These plans have the option of getting CMS to process those claims.

example, it may be sufficient to select a cohort based on having at least one month of Part D coverage, or perhaps you would like to require coverage for the full year or until time of death.

Researchers may select variables from the MBSF as key study variables of interest, — such as whether the beneficiary had dually enrolled in Medicare and Medicaid. For other researchers, a more summarized version of this information may suffice (e.g., knowing that the beneficiary was dually eligible for at least one month of the year).

There are many options for summarizing beneficiary coverage information:

- Select a particular month of coverage researchers may take a "snapshot" of the monthly coverage information and look at one month in the year as an indicator of the coverage status for the beneficiary. For example, the midpoint of the year (i.e., coverage for July, using PTD_CNTRCT_ID_07) or the end of the year (i.e., using PTD_CNTRCT_ID_12).
- Any month of coverage the MBSF contains a few summary variables that summarize the number of months of coverage and the types of coverage for each beneficiary during the year. These include the number of months of Part D plan coverage (PTD_PLAN_CVRG_MONS), dual eligibility (i.e., enrolled in both Medicare and Medicaid; DUAL_ELGBL_MONS), and retiree drug subsidy (RDS_CVRG_MONS). Using these variables, it is simple to obtain denominator counts, which take into consideration the number of beneficiaries who EVER had Part D coverage during the year.
- Use a "majority of months" perspective or count member months of enrollment consider every month of Part D coverage for every beneficiary and accumulate this information for each covered month. Depending on study objectives, you may either determine the type of coverage the beneficiary had for most months enrolled in Part D or count total member months for rate calculations. A CCW paper called <u>CCW Technical Guidance: Calculating</u> <u>Medicare Population Statistics</u> on the CCW website, presents an illustrative example of what this type of analytic code might look like.

Once you have selected a cohort based on the parameters of interest, decide whether you want to keep all the variables in this file — some of them may not be of interest for your study.

NOTE: The MBSF records can become quite wide if you are combining variables from the different segments (e.g., merging A/B/C/D and the Conditions segment). Furthermore, your data file can become very long if you are intending to merge information regarding utilization or information from other data files.

Chapter 4. Examining Prescription Drug Utilization

Once you have selected your cohort, you can merge in the subset of PDE data that is for your population. Note that not all Part D eligible beneficiaries will have prescription drug event data (i.e., if they did not fill a prescription during the year).

The PDE is a large file, with a row of data for each prescription fill. Therefore, there is a many-to-one relationship to the MBSF; a single beneficiary may have hundreds of PDEs (reference <u>Table 2</u>). We recommend extracting only the PDEs for your cohort of interest — however, you have specified your study group, as discussed above.

Table 2. Part D file size

Data file	Number of records in 1% (2011)
MBSF base (A/B/C/D)	517,322
PDE file	11,552,645

For the examples presented in this paper, we select our cohort as a random 1% sample of Medicare enrollees in 2011 with at least one month of Part D coverage.

A. Merging PDE file to Cohort File

You will likely wish to obtain demographic and Medicare enrollment information for your cohort from the MBSF-ABCD segment. Keep only the variables of interest and merge these two files by BENE_ID. Before attempting to merge the PDE file with the denominator/cohort file, you will need to sort both data files by BENE_ID.

NOTE: When the CCW team delivers the data files, they are already pre-sorted and indexed by BENE_ID (the PDE file sorts by BENE_ID, SRVC_DT, and PDE_ID). Therefore, if you have only subsetted the files and not performed other types of data processing, then you may not need to sort the files.

For some studies the PDE file will be extremely large; therefore, efficient data management is prudent. For example, an alternative to managing the large data file is to partition the PDE data file into smaller files (e.g., monthly files based on service date, files based on types of National Drug Codes (NDCs), or files for people in certain population subsets), then sort each file and loop through all the small files, extracting only the PDEs of interest. There may also be times when it is appropriate to restrict your enrollment/cohort data file only to PDE users to examine patterns of use more efficiently.

Some researchers may wish to use SAS PROC SQL (rather than a SAS DATA step) to handle this sorting and-merging process more efficiently. This type of processing negates the need for a separate sorting step. Some sample code is below.

NOTE: For all the coding examples, the variable name appears in all capital letters if it is directly from the source (CCW) data file; all other derived variable names may be a combination of upper- and lower-case letters.

Code Example 1. Join Part D event data with pre-defined study denominator or cohort file

This code example assumes you have already created a denominator file using variables of interest from the MBSF-ABCD segment. It also assumes that when you made your CCW data request, you had the "drug characteristics" variables appended to the PDE.

The following SAS code assumes that you are developing a new merged data file (a working file called "cohort2011") created by linking the cohort you established (e.g., using whatever denominator specifications you deemed appropriate — vis-à-vis the <u>A. Denominator Selection</u> section of this paper or a source file we called "work.coverage", with the Part D events for this study population (called PDE_2011). The LEFT JOIN is important in keeping only PDE records for your specific study cohort.

```
proc sql;
  create table work.cohort2011 as
   select c.*, p.*
    from work.coverage c
        left join PDE2011.PDE_2011 p
   on c.BENE_ID = p.BENE_ID;
   quit;
   run;
```

You may prefer to use a SAS DATA step to merge these files.

The following example produces the same data file as the SQL code above. To merge using a data step, the researcher may need to sort files first using BENE_ID. However, since CCW has presorted the CCW data files, researchers can omit the sort for the PDE file. Then, when you merge the files, you specify (using the "in" statements and a subsetting "if") your intention to keep only the PDEs for the beneficiaries in your cohort.

```
proc sort data=work.coverage out=work.benes;
by BENE_ID;
    run;
data work.cohort2011;
merge work.benes (in=b) PDE2011.PDE_2011 (in=p);
by BENE_ID;
    if b;
    run;
```

B. Tabulating or Summarizing PDEs

Researchers have many options for exploring and describing Part D prescription drug utilization. Numerous variables in the PDE make it possible to classify the types of drugs used. There are also many options for the unit of analysis (e.g., prescription use for enrolled beneficiaries, use per member months of enrollment or average quantity of fills per person who used at least one PDE). Some common methods for counting and summarizing prescription drug utilization are below.

1. Tabulating Prescription Drug Utilization

Some beneficiaries will not have any PDE utilization information, indicating no prescription drug fills during the time frame of interest. Other beneficiaries will have a very large volume of PDEs. The following examples use the PDE_ID variable, which assumes that you do not need to know what drug the beneficiary obtained, but only that a prescription drug event (fill) took place. You may modify the code, for example, to use NDC (using the variable PROD_SRVC_ID) or generic name (using the generic name [GNN] variable, which is available as a Part D drug characteristics field), if your study requires you to tabulate the number of distinct drugs or drug products/entities.

a. Total PDE Counts

In the simplest case, researchers may wish to identify the number of Part D enrollees in the cohort and determine the average number of prescription drug fills per enrolled beneficiary. First, take the number in your Part D enrolled cohort from the <u>A. Denominator Selection</u> section. Next, one must determine the total PDEs for the cohort. There are several ways to accomplish this task. Perhaps the simplest approach is to obtain record counts from the cohort file that included linked PDE records (e.g., use the work.cohort2011 file, from Code Example 1 above). This file will have one record for each PDE. Use this information for your numerator and denominator to calculate the average number of prescription fills per beneficiary (reference <u>Table 3</u>).

Average number of prescription fills = $\frac{\text{Total PDEs for the cohort}}{\text{Total PDEs for the cohort}}$

Number of unique beneficiaries in cohort

Table 3. PDE counts for 2011 (1% beneficiary sample)

Measure	Ν
Number of PDEs for cohort	11,552,645
Number of unique beneficiaries in cohort	517,322
Beneficiaries with PDEs	291,163

Another option is for researchers to create a counter variable to tally each of the PDEs so that they can obtain per beneficiary (or per user) counts.

b. Per Beneficiary PDE Counts

To tabulate the per-beneficiary number of prescriptions more discretely, we can obtain beneficiary-specific (i.e., Part D enrollee-level or per capita) counts of PDEs.

Code Example 2. Calculate number of PDEs per beneficiary

The following SAS code sorts the PDEs for each beneficiary and creates a small data file, so that the researcher can obtain beneficiary-level prescription fill counts. We use the SAS keywords "first" and "last" for this new counter variable called numPDE and create a skinny file called "work.PDEslim2011" that is specific to this purpose.

NOTE: We also use the SAS key word "retain" so that SAS does NOT automatically re-initialize our new variable, numPDE, as SAS works through sequentially processing the data file. While technically not required for this sort of counter variable, it is a good coding practice that will allow users to easily adapt this sample code. This "retain" statement allows for variables that do not appear on the input statement to retain or hold the current value while SAS moves on to process the next row of data.

Finally, we use a PROC MEANS statement to calculate the number of PDEs per beneficiary in our sample.

```
data work.PDEslim2011;
set work.PartD;
by BENE_ID PDE_ID;
retain numPDE;
if first.BENE_ID then numPDE =0;
if PDE_ID ~=' ' then numPDE + 1;
if last.BENE_ID then output;
label
numPDE = 'per bene count of PDEs';
run;
proc means data=work.PDEslim2011 N mean median max min sum;
var numPDE;
title 'average number of prescriptions filled per bene';
run;
```

Those who prefer to use SQL statements for this type of processing may accomplish the same objectives through using something like the following:

The following SQL code produces a similar file as the DATA step above. With SQL code, you must have an additional data step to handle the BENE_IDs with null PDE_IDs; that is, those without any PDEs.

Summarize the data as above, using the PROC FREQ and/or MEANS.

```
proc sql;
    create table work.PDEslim2011 as
    select BENE_ID,
        count(PDE_ID) as pde_count
        from PartD
        group by BENE_ID;
        quit;
        *recodes to accommodate beneficiaries without PDEs;
        data work.PDEslim2011;
        if pde_count = . then pde_count=0 ;
        if pde_count >0 then user='y';
        else user='n';
        run;
```

c. Per Prescription Drug User PDE Counts

Researchers can address different questions related to Part D utilization by limiting the sample to those who have used the benefit (i.e., those who had one or more PDEs during the time frame). Researchers can easily perform this sort of analysis using a slight variation on the PROC MEANS statement shared previously.

Code Example 3. Calculate number of PDEs per Part D prescription drug user

In the PROC MEANS statement, limit the analysis to beneficiaries who had a PDE by using a WHERE statement.

```
proc means data = work.PDEslim2011 N mean median max min sum;
    var numPDE;
    where PDE_ID ~=' ';
    title 'average number of PDEs per user';
run;
```

Results from this processing are in <u>Table 4</u>.

Table 4. Per beneficiary and per Part D user PDE counts

Measure	Number of beneficiaries	2011 Random 1%
Average PDE fills per bene	517,322	mean = 22.33
		median = 7
		max = 726
Average PDE fills per user	291,163	mean = 39.68
		median = 29
		max = 726

2. Describing Prescription Drug Utilization

a. Total Prescription Fills by Drug or Generic Name

There are many potential ways researchers may wish to count Part D prescription drug utilization. Researchers may be interested in the total number of drug fills as illustrated above. Other options include determining the number of fills by NDC (e.g., distinct national drug codes with all 11 digits or a subset of the digits, such as the first nine digits) or by generic drug names. Note that a beneficiary may obtain drugs that have the same active ingredients with multiple NDCs. For example, researchers may consider hundreds of unique NDC codes as antibacterials, many of which may contain the same active ingredients. Researchers must determine the appropriate level of aggregation for the study.

- The PROD_SRVC_ID field contains the NDCs.
- The GNN field within the Drug Characteristics file contains the generic drug name.

Code Example 4. Determine number of different drugs and refills obtained per beneficiary

This SAS code is a variation on the PDE counting code above. Here, we sift through the PDEs and count the occurrences of each NDC. We set up variables to accumulate counts for the distinct NDCs.

First you must sort your data file by NDC (PROD_SRVC_ID) or GNN, depending on your variable of interest. This is the file (called "work.pdendc) we use as our input source for the DATA step below.

proc sort data=work.cohort2011 (keep=PROD_SRVC_ID GNN) out=work.pdendc;

```
by PROD_SRVC_ID;run;data work.ndc_fills;
set work.pdendc;
by PROD_SRVC_ID;
retain ndcfillcnt;
if PROD_SRVC_ID ne '';
if first.PROD_SRVC_ID then ndcfillcnt=0;
ndcfillcnt+1;
if last.PROD_SRVC_ID then output;
label ndcfillcnt='Number of fills per NDC';
run;
proc univariate data=work.ndc_fills;
var ndcfillcnt;
title 'Number of Fills per NDC';
run;
```

This data file will allow researchers to understand the most frequently observed types of drugs in the PDE file. Results from this processing are in <u>Table 5</u>, <u>Table 6</u>, and <u>Table 7</u>.

b. Per Prescription Drug User Counts by Drug or Generic Name

Researchers may wish to know which prescriptions a beneficiary has received and the number of refills for each type of drug. This analysis concerns only those beneficiaries who had at least one prescription drug fill.

Code Example 5. Determine number of different drugs and refills obtained per Part D prescription drug user

The following SAS code is a variation on the NDC counting code above. Here, we process every row of PDE data and count the occurrences of each NDC for each beneficiary. We set up variables to accumulate counts for both the distinct NDCs per beneficiary and the frequency of each NDC (e.g., number of fills for each NDC) for the beneficiary.

First you must sort your data file by BENE_ID and NDC (PROD_SRVC_ID). This is the file (called "work. pdefills) we use as our input source for the data step below.

To accurately tabulate the number of NDCs per beneficiary, we need to identify the last of the NDC records for each beneficiary. This is the utility of the "L" variable.

```
proc sort data=work.cohort2011(keep=BENE ID PROD SRVC ID GNN PDE ID)
out=work.pdefills;
by BENE ID PROD SRVC ID;
run;
data work.beneNDC;
 set work.pdefills;
 by BENE ID PROD SRVC ID;
  retain numNDC numfills;
   if first.BENE ID then do;
         numNDC =0; L=0;
       end;
     if PDE ID NE ' ' then do;
         if first.PROD SRVC ID then do;
        numNDC + 1; numfills=0;
         end;
         if PDE ID NE ' ' then do;
            numfills+1;
               if last.BENE ID then L=1;
            output;
        end;
       end;
label
   numNDC = 'per bene count of unique NDCs'
   numfills = 'number of fills per bene per NDC'
   L='last NDC record per bene';
run;
```

An example of the values for the new variables produced by the DATA step are in Table 5.

Obs	BENE_ID	PROD_SRVC_ID	PDE_ID	NumNDC	Numfills	L
number						
1	ааааааааааааааааа	12345678910	Xxxxxxxxxxxxx1	1	1	0
2	ааааааааааааааааа	12345678910	Xxxxxxxxxxxxx2	1	2	none
3	ааааааааааааааааа	12345678910	Xxxxxxxxx1xxxx	1	3	none
4	ааааааааааааааааа	2222233333	Xxxx5xxxxxxxx1	2	1	none
5	ааааааааааааааааа	2222233333	XxxxxxxQxxxxx	2	2	none
6	ааааааааааааааааа	55667788991	xhxxxfxxxxxxxxXX	3	1	1
7	bbbbbbbbbbbbbbbbbbbbbbbbbbbbbbbbbbbbbbb	4444444444	X1xxxxxxxxxxxxxxx	1	1	0
8	bbbbbbbbbbbbbbbbbbbbbbbbbbbbbbbbbbbbbbb	4444444444	X1xxxxxxxxxxxxxxx	1	2	1
9	000000000000000000000000000000000000000	07070707071	Xnxxxxxxx3xx	1	1	1

Table 5. Example of data row — variables for number of NDCs and number of fills

For each PDE, there is a combination of values to indicate whether it is a new NDC or a refill of an NDC already obtained. <u>Table 5</u> illustrates that for the first beneficiary (observations 1-6 indicating six rows of data for the six PDEs), there were three different NDCs dispensed (highest value for numNDC is 3 — reference Row 6); we obtained the first

NDC three times (highest value for numfills for NDC 1 is 3 - reference Row 3). The record where L = 0 is the first PDE record for the beneficiary, when L = 1 it is the last PDE record for the beneficiary. For NDCs with a single fill, L = 1.

Using this data file, the researchers can tabulate the per user number of NDCs.

```
proc means data=work.beneNDC N mean median max min sum;
where L=1;
var numNDC;
run;
```

Results display in Table 6.

Table 6. Number of NDCs per user NDC and fill totals

Measure	N	2011 Random 1%
Average number of fills per NDC	21,145 different NDCs	mean = 546.35
		median = 29
		max = 66,190
Average number of different NDCs	291,163 beneficiaries	mean = 12.23
(11-digit) per user		median = 10
		max = 111

In our study population, there were 21,145 different NDCs dispensed. An NDC appeared, on average, 546 times in our data file, although one NDC had over 66 thousand PDEs in our sample.

Code Example 6. Calculate per capita and per user statistics for prescription drug cost and use

The following SAS code is a variation on the NDC counting code above, except here we use SAS SQL rather than a DATA step and we count the number of unique drug products, using the generic name of the drug (variable called GNN). During a single SQL submit, we can sift through the PDEs and count the occurrences of each GNN for each beneficiary. We also set up a variable to accumulate total drug costs for the PDEs to demonstrate we can handle multiple processing steps in a single PROC.

When using SAS SQL, it is not necessary to sort the input data file first. We use a DATA step to include the null counts for beneficiaries without PDEs to allow for flexibility in producing summary statistics (i.e., per beneficiary counts or per user counts).

proc sql;

```
create table work.Drugs11 as
select
BENE_ID,
count(PDE_ID) as pde_count,
count(distinct GNN) as drug_count,
sum(TOT_RX_CST_AMT) as gross_cost_sum
from work.cohort2011
group by BENE_ID;
quit;
*recodes for non-users;
```

```
data work.Drugs11;
       set work.Drugs11;
           if pde_count = . then pde_count=0 ;
           if drug count = . then drug count=0;
           if gross cost sum = . then gross cost sum=0 ;
     if pde count>0 then user='y';
       else user='n';
  run;
proc means data=work.Drugs11 n mean median max min sum;
           var pde count drug count gross cost sum;
           title 'average utilization and cost per beneficiary';
           run;
proc means data=work.Drugs11 n mean median max min sum;
           var pde_count drug_count gross_cost_sum;
                where user='y';
           title 'average utilization and cost per PDE user';
           run;
```

Results are in Table 7.

Table 7. Number of drugs (GNN — Generic Drug Products) per beneficiary and per Part D user

Measure	N	2011 Random 1%
Average number of different drug	517,322 beneficiaries	mean = 5.24
products (GNNs) per bene		median = 3
		max = 79
Average number of different drug	291,163 beneficiaries	mean = 9.32
products (GNNs) per user		median = 8
		max = 79

Researchers may wish to be very specific regarding whether prescription drug fills indicated that beneficiaries likely used an "effective" dose, or whether the beneficiary was taking a medication as often as necessary to manage a particular condition (note that these data indicate only that the beneficiary filled the prescriptions and are not proof that the beneficiary was taking the medications as directed). The PDE file contains information regarding the quantity of the medication dispensed during the fill (QTY_DSPNSD_NUM) and the number of days' supply provided by the fill (DAYS_SUPLY_NUM). Additionally, information regarding the dosage form (GCDF and GCDF_DESC) and strength (STR) are available as Part D Drug Characteristics fields.

3. Describing Costs of Prescription Drugs

The Part D benefit is a risk-adjusted prospective capitated benefit, with Part D plans generally receiving a fixed annual payment for each enrolled beneficiary. Note that a final reconciliation at the end of the year may occur, whereby Medicare may alter the final amount paid to plans based on actual payments. The costs shown on the PDEs do not correspond with plan payments (i.e., sum of drug costs for all beneficiaries enrolled in a plan does not equal plan payments).

There are times when it may be helpful to know how much the beneficiary paid for specific prescription drugs or to understand the gross (total) cost of drugs for a beneficiary during the year. The PTNT_PAY_AMT is the data field that indicates the amount the beneficiary paid for the prescription drug. The TOT_RX_CST_AMT is the gross drug cost, which is the sum of three fields: 1) ingredient cost, 2) dispensing fee, and 3) sales tax.

Within this document, we previously shared a sample of some SQL code to calculate the total costs for PDEs in Code Example 6 of this paper. We then summed the TOT_RX_CST_AMT field for each beneficiary. Results are in <u>Table 8</u>.

Table 8. Gross drug costs

Measure	n	2011 Random 1%
Average gross drug costs per beneficiary	517,322 beneficiaries	mean = \$1636
		median = \$158
Average gross drug costs per user	291,163 beneficiaries	mean = \$2907
		median = \$1480

4. Describing Experience with the Part D Benefit Structure

Researchers may wish to understand how many beneficiaries experienced particular phases of the Part D benefit. The BENEFIT_PHASE variable is a CCW-derived field that considers the plan benefit structure for each beneficiary at the time of the fill and indicates where in the benefit cycle each PDE occurred. This variable is in the Part D Event File. For a standard Part D benefit, there are four phases that a beneficiary may experience: 1) the deductible, 2) pre-initial coverage limit (ICL) or pre-coverage gap, 3) the ICL (coverage gap), and 4) catastrophic coverage.

Different data manipulation will be necessary depending on the specific question to address. Also, this data field will occasionally contain unexpected information (e.g., a phase that appears to be out of sequence) because a small number of beneficiaries may switch plans during the year, in which case the benefit phase sequencing "clock" starts over.

Code Example 7. Ordering Part D benefit phases

The BENEFIT_PHASE values contain intelligence but are not ordinal; therefore, it may be helpful to create a recoded ordinal variable containing benefit phase. There are a couple of different ways to do this — using the first digit of the variable to indicate the starting benefit phase for the fill or using the second digit of the variable to indicate the ending benefit phase for the following examples, we use the ending benefit phase for the fill.

The following SAS code creates an ordinal benefit phase variable called "bpord". We use a PROC FORMAT statement to classify the ordinal benefit phase variable into the four standard benefit phases based on the last digit of the benefit phase variable. For most purposes, researchers may wish to hard code the four phases, rather than maintaining a very granular bpord variable; this would provide for a cleaner way of counting the number of beneficiaries to reach each distinct standard phase.

The analysis includes beneficiaries without PDEs in this file to allow for flexibility in calculating rates.

```
data work.phase;
  set work.cohort2011 (keep=BENE_ID SRVC_DT BENEFIT_PHASE PDE_ID);
  if BENEFIT_PHASE='DD' then bpord=11;
  else if BENEFIT_PHASE='DP' then bpord=21;
```

```
else if BENEFIT_PHASE='DI' then bpord=31;
else if BENEFIT_PHASE='DC' then bpord=41;
else if BENEFIT_PHASE='PP' then bpord=22;
else if BENEFIT_PHASE='PI' then bpord=32;
else if BENEFIT_PHASE='PC' then bpord=42;
else if BENEFIT_PHASE='II' then bpord=43;
else if BENEFIT_PHASE='IC' then bpord=43;
else if BENEFIT_PHASE='CC' then bpord=44;
else bpord=0;
proc format;
value order low-9='no phase'
10-19 ='deductible'
20-29 ='pre-ICL'
30-39 ='ICL'
40-high='catastrophic';
```

run;

This data file contains information for every benefit phase experienced by each beneficiary. Since we included all beneficiaries in this data file, we counted members of our population without any PDEs as having bpord = 0. For several of our analyses, we will want to remove these rows (i.e., where there is a record but not a PDE_ID).

/*tabulate after excluding records for beneficiaries without any PDES*/

```
proc freq data =work.phase;
    tables bpord;
    where PDE_ID ~=' ';
    format bpord order.;
run;
```

Results are in Table 9.

Table 9. Benefit phases for each PDE

PDEs in each benefit phase	Number	Percentage
n=11,552,645 PDEs		
No phase (phases not applicable)	965,625	8.4
Deductible	783,971	6.8
Pre-ICL	6,900,926	59.7
ICL	1,894,985	16.4
Catastrophic	1,007,138	8.7

A total of 8.7% of all PDEs were in the catastrophic coverage phase of the Part D benefit.

a. Number of Beneficiaries to Reach Each Phase

To determine the range of benefit phases experienced by members of our study population, we will want to keep only the first prescribing event in each benefit phase for each beneficiary in the cohort. We may count beneficiaries in multiple phases. You may be as granular as you would like in defining these phases; for simplicity, we use the four standard phases.

Code Example 8. Determining Part D benefit phases for each beneficiary

For this code, we must use a more specific benefit phase variable than we used in the prior analyses. Here we will use only the four distinct standard benefit phases. We also eliminate rows of data for beneficiaries without any PDEs (i.e., where there is not a PDE_ID).

Next, we sort the data file so that the PDEs are in order of service date for each beneficiary. We use the SAS keyword "first" to keep the first PDE record for each beneficiary in each of the benefit phases applicable. This file outputs a record for each beneficiary-phase combination. Researchers may also wish to partition the data into smaller files based on the specific benefit phase of interest.

```
data work.b phase;
set work.phase;
if PDE ID ~=' ';
if bpord in (0) then BP=0;
   else if bpord in (11) then BP=1;
   else if bpord in (21,22) then BP=2;
   else if bpord in (31, 32, 33) then BP=3;
   else if bpord in (41,42,43,44) then BP=4;
proc format;
  value b 0='no phase'
          1='deductible'
          2 ='pre-ICL'
          3 ='ICL'
          4-high='catastrophic';
        run;
  proc sort data=work.b phase out=work.small;
   by BENE ID bp SRVC DT;
  run;
 data work.benephase;
 set small;
 by BENE ID bp;
 if first.bp;
 run;
proc freq data=work.benephase;
 tables bp;
 format bp b.;
 title 'first event each phase';
  run;
```

Results are in <u>Table 10</u>. For the 291,163 beneficiaries with one or more PDEs, there were 489,635 benefit phases (i.e., beneficiary: phase combinations).

Table 10. Each benefit phase for each beneficiary

Benefit phase	Number*
Total beneficiary: phase combinations	489,635
No phase (phases not applicable)	38,030
Deductible	104,273
ICL	78,419
Catastrophic	25,802

*Beneficiaries may fall into multiple phase categories during the year.

Note that 38,030 beneficiaries had a PDE, and the benefit phases were not applicable. Another 78,419 beneficiaries had a PDE in the ICL phase. Also, we use this code primarily to show how to identify the first event in each phase, which allows for calculation of some timing variables (e.g., Code Example 11).

b. Highest Benefit Phase Reached by Each PDE User

Researchers will want to keep only the highest (worst) benefit phase reached by each beneficiary.

Code Example 9. Determining highest Part D benefit phase for each beneficiary

For this analysis, we use the data set sorted previously (above) by BENE_ID bp and SRVC_DT. This time we look at the last event for each beneficiary.

```
data work.bp_last;
set work.small;
by bene_id ;
if last.BENE_ID;
run;
proc freq data =work.bp_last;
tables bp;
title 'for last event';
format bp b.;
run;
```

The processing above limits the sample to those with at least one PDE. Results appear in Table 11.

Table 11. Highest benefit phase for each PDE user

Highest (or worst) benefit phase for each beneficiary with PDEs n = 291,163 beneficiaries (PTD users)	n	Percentage
No phase (phases not applicable)	38,896	9.9
Deductible	18,529	6.4
Pre-ICL	164,917	56.6
ICL	53,019	18.2
Catastrophic	25,802	8.8

A total of 8.8% of beneficiaries who used any Part D drugs reached the catastrophic coverage phase; an additional 18.2% reached the coverage gap (i.e., the ICL).

c. Time to Reach a Phase

Researchers may wish to determine how long it took beneficiaries to use enough prescription drugs to cross into a particular phase of the benefit. Similarly, it may be desirable to know the length of time a beneficiary was in a particular benefit phase.

• In general, researchers may wish to calculate "time to event" in terms of calendar time, which corresponds to the Part D benefit year. For example, we could use the following code to calculate the time to reach the ICL (initial coverage limit and coverage gap).

Code Example 10. Determining time to reach a benefit phase (time to coverage gap)

We make use of the ordinal benefit phase variables we created in Code Example 8 and leverage the data file we created (file called "work.b_phase") during that step.

The following SAS code keeps only the subset of beneficiaries that reached the benefit phase of interest (this example uses the ICL benefit phase). We can create a small file such as this, which is specific to any benefit phase of interest. We use the SAS "first" function as well as the "intck" function.

/*time to reach the coverage gap -or ICL benefit phase*/

The frequency output is below in <u>Table 12</u>.

Table 12. Month to reach coverage gap (ICL benefit phase)

Gaptime	Frequency	Percent	Cumulative frequency	Cumulative percent
1	1291	1.65	1291	1.65
2	3543	4.52	4834	6.16
3	5951	7.59	10785	13.75
4	6602	8.42	17387	22.17
5	8095	10.32	25482	32.49
6	8414	10.73	33896	43.22

Gaptime	Frequency	Percent	Cumulative frequency	Cumulative percent
7	8066	10.29	41962	53.51
8	8142	10.38	50104	63.89
9	7476	9.53	57580	73.43
10	7661	9.77	65241	83.20
11	6914	8.82	72155	92.01
12	6264	7.99	78419	100.00

In the first month of 2011, 1.65% of beneficiaries who would eventually experience the coverage gap (the ICL) benefit phase had done so. The month of June (i.e., where gaptime = 6) was when the largest number of people reached the ICL phase.

d. Time in a Phase

A variation on this code will allow researchers to examine the amount of time spent in each benefit phase.

Code Example 11. Determining duration of Part D benefit phases for each beneficiary

We begin with the input data file (file called "work.small") created in Code Example 9 above. The system has already sorted the file by beneficiary (BENE_ID) and benefit phase (bp). We create several new variables that key in on the particular dates of certain events for each beneficiary. We use the "retain" statement to keep the resulting dates of interest.

```
/*highest BP per beneficiary*/
data work.bp2011;
     length bp bppdecnt 3 bp start dt bp end dt 4 bp days
days2phase 3;
     set work.small;
     by BENE ID bp;
     retain bp start dt;
     if first.bp then
           do;
                 bp_start_dt=SRVC_DT;
                 bppdecnt=0;
           end;
     bppdecnt+1;
     if last.bp then
           do;
                 bp end dt=SRVC DT;
                 bp days=intck('day',bp start dt,bp end dt)+1;
      days2phase=intck('day',mdy(1,1,2011),bp start dt);
                 output;
           end;
     label
           bp='Benefit Phase'
           bppdecnt='Number of PDEs in Phase'
```

```
bp_start_dt='Earliest Service Date of Phase'
bp_end_dt='Latest Service Date of Phase'
bp_days='Number of Days in Phase'
days2phase='Calendar Days to Start of Phase';
format bp_start_dt bp_end_dt mmddyy10.;
```

run;

Then, to find counts and averages for selected analysis variables, we can perform the following:

```
/*tabulations*/
proc sort data=work.bp2011 out=temp;
    by bp;
run;
proc means data=temp maxdec=2;
    by bp;
    var bppdecnt bp_days days2phase;
    run;
```

The output of this step is below in <u>Table 13</u>.

Table 13. Time to reach coverage gap (ICL) and time in gap

Variable	Label	Ν	Mean	Std Dev	Minimum	Maximum
bppdecnt	Number of PDEs in phase	78419	24.16	19.26	1.00	269.00
bp_days	Number of days in phase	78419	106.24	64.17	1.00	357.00
days2phase	Calendar days to start of phase	78419	201.75	91.50	0	364.00

Another way to examine time to a phase (as "time to event") is to look at the number of benefit months before
hitting a particular phase; that is, the member months of enrollment before the benefit phase event first occurred.
This type of analysis may be helpful if you have a cohort that includes a large population of those newly enrolled in
Medicare.

Readers may reference a CCW Technical Guidance paper <u>CCW Technical Guidance: Getting Started with CMS Medicare</u> <u>Administrative Data Research Files</u> on the CCW website for considerations and examples for constructing member months of enrollment variables.

Chapter 5. Conclusions

Researchers have a variety of hypotheses and objectives. The CCW team does not intend to be prescriptive, but rather descriptive of some useful tools for combining data files and tabulating Part D prescription drug data. Our objective is to make it easy for researchers to accomplish their study objectives and to ensure they can do so with a thorough understanding of the data available from the CCW team. Researchers can gain a better understanding of prescription drug use and the effect on the population through appropriate and accurate data analysis techniques as demonstrated in this paper.

Chapter 6. Further Assistance with CCW Data

Researchers interested in working with CCW data should contact ResDAC. They offer free assistance to researchers using Medicare data for research. The ResDAC website provides links to descriptions of the CMS data available, request procedures, supporting documentation, such as record layouts and SAS input statements, workshops on how to use Medicare data, and other helpful resources. Visit the ResDAC website at <u>http://www.resdac.org</u> for additional information.

ResDAC is a CMS contractor and researchers should first submit requests to ResDAC for assistance in the application, obtaining, or using the CCW data. Researchers can reach ResDAC by phone at 1-888-973-7322, email at resdac@umn.edu, or online at http://www.resdac.org.

If a ResDAC technical advisor cannot answer your question, the technical advisor will direct the researcher to the appropriate person. If you require additional CMS data (data not available from the CCW) to meet research objectives, or the researcher has any questions about other data sources, the researcher should first visit the ResDAC website.

The CCW Help Desk provides assistance between 8:00 am to 5:00 pm ET, Monday through Friday (excluding most federal holidays). Contact the CCW Help Desk at <u>ccwhelp@ccwdata.org</u> or 1-866-766-1915.

Acronym	Definition
CCW	Chronic Conditions Warehouse
CMS	Centers for Medicare & Medicaid Services
DUA	Data Use Agreement
FFS	Fee-for-Service
GNN	Generic name
ICL	Initial Coverage Limit
MA	Medicare Advantage
MA-PD	Medicare Advantage-Prescription Drug Plan
MBSF	Master Beneficiary Summary File
MMA	Medicare Modernization Act of 2003
NDC	National Drug Code
PACE	Program of All-inclusive Care for the Elderly
PDE(s)	Prescription Drug Event(s)
PDP	Prescription Drug Plan
RDS	Retirement Drug Subsidy
RIF	Research Identifiable File
ResDAC	Research Data Analytic Center
SAF	Standard Analytic File
VA	Veteran's Administration

Appendix A — List of Acronyms and Abbreviations