Chronic Condition Data Warehouse

Your source for national CMS Medicare and Medicaid research data

CCW Medicare Part D Data User Guide

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Overview

The Medicare Part D prescription drug benefit was authorized through the Medicare Prescription Drug, Improvement, and Modernization Act MMA of 2003 (MMA, Section 101). The Medicare prescription drug benefit, which is a voluntary benefit offered though the Medicare Part D program, is optional drug coverage that beneficiaries may purchase through private plans. Coverage of prescription drugs through Medicare Part D began in 2006. The Chronic Condition Data Warehouse (CCW) contains all Part D events, regardless of whether the beneficiary was enrolled in a managed care plan that includes coverage for prescription drugs or a stand-alone prescription drug plan. More information about the CCW can be found at http://www.ccwdata.org. Beneficiaries who qualify for both Medicare and Medicaid (full-benefit dual eligibles) will automatically receive the Medicare drug benefit. The MMA also provides for assistance with premiums and cost sharing to eligible low-income beneficiaries.

As of June 2008, a federal rule allowed for the release of Part D data to researchers. This rule established stringent protection for beneficiary and commercially-sensitive data, while allowing researchers to obtain minimum data necessary to conduct approved studies. In 2014, the Centers for Medicare & Medicaid Services (CMS) broadened the rule to allow for the release of additional variables and also unencrypted identifiers for the plan, formulary, pharmacy and prescriber[1]. The Part D data contained within the CMS CCW is the official data source for external requests for Part D research data files. The data in the CCW contains all of the Part D program enrollment and utilization information.

The CCW contains CMS Medicare beneficiary data (from multiple data sources) linked by a unique identifier, allowing researchers to analyze information across the continuum of care. The CCW makes it easy to study chronic diseases by incorporating a broad range of pre-defined condition category variables which indicate treatment for a condition of interest; however, it is important to note that this database is representative of the entire Medicare population, and is not limited to those with a chronic condition. The CCW contains data for Medicare enrollment/eligibility, fee-for-service (FFS) institutional and non-institutional claims, and managed care encounter data is available for people enrolled in Medicare Advantage (MA) plans in 2015 (the data dictionary for this file is available on ccwdata.org). CCW also contains assessment data (i.e., *Minimum Data Set, Outcome and Assessment Information Set, Swing bed assessments,* and *Inpatient Rehabilitation Facility Patient Assessment Instrument*) from January 1, 1999 forward and Medicaid eligibility and claims data from 1999 through 2012[2], which are available to researchers as the Medicaid Analytic eXtract (MAX) data files.

[1]US Department of Health and Human Services. CMS. 42 CFR Parts 417, 422, 423, et al. See: http://www.gpo.gov/fdsys/pkg/FR-2014-05-23/pdf/2014-11734.pdf

[2] MAX is being phased out. The last calendar year that uses the MAX data format is 2013; 28 states have MAX files for 2013 and 17 have files for 2014. States have converted to Transformed Medicaid Statistical Information System (T-MSIS).

The CCW Medicare administrative claims files are provided to academic researchers and certain government agencies, which have been approved under a Data Use Agreement (DUA) to obtain Medicare administrative data for research purposes. The CCW Medicare data contain identifiable information, and are subject to the Privacy Act and other Federal government rules and regulations; see the Research Data Assistance Center (ResDAC) web site for information on requesting Medicare data (http://www.resdac.org/).

Researchers interested in obtaining Medicare Part A and B data in addition to the Part D data, may obtain the standard random 5% sample of Medicare beneficiaries. However, for researchers interested only in Part D data, a random 10% or 20% Part D beneficiary sample is the standard data extract available to approved researchers (based on minimum data necessary standards). Alternatively, CCW data are available upon request for specific researcher-defined cohorts. These may include chronic condition cohorts, using the pre-defined chronic disease indicator variables to identify a study cohort. Please see the condition algorithm documentation on the CCW web site (http://www.ccwdata.org) for more information. Data may also be requested for beneficiaries with other clinical conditions or other cohort(s) of interest. For example, researchers interested in studying a particular drug or therapeutic class of drugs, would identify a cohort based on national drug codes (NDCs). For documentation on requesting CCW data, please visit the ResDAC website at www.resdac.org.

This manual provides users with information that may be helpful in understanding and analyzing the CCW Part D data.

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Chapter 1. Medicare Part D Enrollment Data

All Medicare Part D prescription drug benefits are provided through private plans (a.k.a. plan sponsors). Generally, Part D coverage is provided under Prescription Drug Plans (PDPs), which offer only prescription drug coverage, or through Medicare Advantage Prescription Drug Plans (MA-PD) plans, which offer prescription drug coverage that is integrated with the health care coverage they provide to Medicare beneficiaries under Part C.

The Medicare Part D enrollment data are found in the Master Beneficiary Summary File (MBSF), and delivered as part of the Base Beneficiary Summary File (also known as the MBSF_ABCD segment). It 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. A description of the variables contained within each CCW data file can be found on the Data Dictionaries page of the CCW web site (https://www.ccwdata.org/web/guest/data-dictionaries).

Note that through 2015, the Part D enrollment information was delivered via the original Master Beneficiary Summary File (MBSF) – Part D segment that used the CMS Enrollment Database (EDB) as the source. For this legacy MBSF, there were sometimes timing differences in terms of when CMS data sources were updated with Part A and B coverage - versus Part D enrollment information. As a result there were occasionally a small number of beneficiaries where there was an inconsistency between Part D enrollment indicators and other Medicare entitlement indicators. As of March 2017, the MBSF was updated to use the CMS Common Medicare Environment (CME) as the source. As a result, this issue no longer exists in the current MBSF.

Part D plan sponsors have flexibility to design a prescription drug benefit within certain parameters set by CMS. Plans must offer at least a "basic" benefit in terms of deductibles, copayments, formularies, and prior authorization requirements for certain drugs. Part D plans may choose to offer Part D coverage with enhanced benefits (e.g., lower deductibles/copayments, expanded formulary, prescription coverage during the gap, etc.) via supplemental premiums. The Medicare Prescription Drug, Improvement, and Modernization Act MMA of 2003 (MMA, Section 101) also provides for subsidy payments to sponsors of qualified retiree prescription drug plans (the retiree drug subsidy, or RDS) to encourage retention of non-Part D employer-sponsored benefits.

Additional information regarding Part D coverage options can be found at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html. Beneficiaries enroll in a plan for a calendar year, with open enrollment occurring annually October 15 – December 7. There is a late enrollment penalty for those who are eligible for Part D but choose not to enroll for any given

year and do not have creditable coverage for that time. A number of Medicare-eligible beneficiaries may have access to other types of prescription drug plans. Creditable prescription drug coverage includes, but is not limited to: employer-based prescription drug coverage, including the Federal Employees Health Benefits Program (FEHB); qualified State Pharmaceutical Assistance Programs (SPAPs); military-related coverage (e.g., VA, TRICARE); and certain Medicare supplemental (Medigap) policies. For additional details regarding the creditable coverage provision of the Part D benefit, please refer to the CMS website at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/CreditableCoverage/index.html?redirect=/CreditableCoverage/.

Note: We would not expect to see Part D prescription drug events (PDEs) during the months when the beneficiary did not have Part D coverage even if he/she had some form of creditable coverage.

The key Part D enrollment and coverage variables contained in the MBSF_ABCD include:

SAS Variable name	Variable description	Brief definition*
PTD_CNTRCT_ID_{*MM*}	Part D Contract ID (01-12)	The unique number CMS assigns to each contract that a Part D plan has with CMS (12 monthly occurrences). The first character of the contract ID is a letter representing the type of plan, e.g., Managed Care Organizations, Regional PPO, Regional PPO, PDP, Not Part D Enrolled, Employer Direct Plan (beginning in 2007)
PTD_PBP_ID_{*MM*}	Part D Plan Benefit Package ID (01-12)	The unique number CMS assigns to identify a specific Part D plan benefit package within a contract (12 monthly occurrences).
PTD_SGMT_ID_{*MM*}	Part D Segment ID (01-12)	The segment number CMS assigns to identify a geographic market segment or subdivision of a Part D plan benefit package within a contract (12 monthly occurrences).
CST_SHR_GRP_CD_{*MM*}	Part D Low Income Cost Share Group (01-12)	Monthly indicator of beneficiary liability of Part D low-income cost-sharing. Includes values to indicate whether the beneficiary was deemed to be eligible or whether there was a LIS subsidy (12 monthly occurrences).
RDS_IND-{*MM*}	Retiree Drug Subsidy Indicators (01-12)	Monthly indicator of whether employer-sponsored drug plan was in effect and should be subsidized for beneficiary (12 monthly occurrences).
DUAL_STUS_CD_{*MM*}	State Reported Dual Eligible Status Code (01-12)	Monthly indicator of dual eligibility status; where beneficiary is enrolled in both Medicaid and Medicare (12 monthly occurrences).
PTD_PLAN_CVRG_MONS	Part D Plan Coverage Months	Total number of months of Part D plan coverage
RDS_CVRG_MONS	Retiree Drug Subsidy Months	Total number of months employer is entitled to Retiree Drug Subsidy for beneficiary
DUAL_ELGBL_MONS	Medicaid Dual Eligible Months	Total number of months of dual eligibility status

* More detail regarding the meaning of these fields in terms of the Part D benefit appears below this table; furthermore, additional variable descriptions and code values are available in the CCW data dictionary.

Part D Contract ID – This field indicates the type of Part D plan, if any, the eligible beneficiary selected. This field contains the unique number CMS assigns to each contract that a Part D plan has with CMS. There are 12 monthly occurrences of this field. The first character of the contract ID is a letter or number representing the type of plan:

H = Managed Care Organizations other than Regional PPO (i.e., local MA-PDs), 1876 Cost plans, National Program of All-inclusive Care for the Elderly [PACE] plans, Private Fee-for-Service plans, or Demonstration Organization plans
R = Regional preferred provider organization (PPO)
S = Stand-alone prescription drug plan (PDP)
E = Employer Direct Plan (beginning in 2007)
X = Limited Income Newly Eligible transition (LINET)
N = Not Part D Enrolled
0 = Not Medicare Enrolled for the month
* = Enrolled in Medicare A/B, but no information regarding Part D enrollment

All employer plans (Employer Sponsored Plans and Employer/Union Only Direct Contract Plans) could have plan types of H, R, or S. Beginning in 2007, Employer/Union Only Direct Contract Plans were given their own plan type designation of "E". Researchers may identify the employer direct plans through use of the EGWP_INDICATOR field in the Plan Characteristics file, described later in this document.

Part D Plan Benefit Package ID – This field indicates the unique number CMS assigns to identify a specific Part D plan benefit package (PBP) within a contract. For a single Part D contract, there may be more than one different PBPs offered (e.g., silver and platinum-level benefits). There are 12 monthly occurrences of this field. This information can be linked to Part D Plan characteristics data to better understand the nuances of the benefit available through the plan (see Chapter 3).

Part D Segment ID – This field indicates the segment number CMS assigns to identify a geographic market segment or subdivision of a Part D plan benefit package within a contract. There are 12 monthly occurrences of this field. This information can be linked to Part D Plan characteristics data (see Chapter 3).

Part D Low Income Cost Share Group – The Part D benefit includes cost-sharing provisions. State Medicaid and other government-sponsored subsidized premiums and/or copayments/coinsurance for low-income individuals are allowed. Additionally, unlike Medicare A and B, the Part D benefit allows for means-testing. The low-income subsidy (LIS) provides assistance to certain low-income individuals to supplement the premium and cost-sharing (including deductibles and cost-sharing during the coverage gap) associated with the Part D benefit. Subsidies may also be provided to employers to cover eligible beneficiaries. All of these cost sharing provisions are indicated within this variable. There are 12 monthly occurrences of this field. Additional details regarding the LIS provisions within the Part D benefit can be found on the CMS website at: http://www.cms.gov/Medicare/Eligibility-and-Enrollment/LowIncSubMedicarePresCov/index.html?redirect=/LowIncSubMedicarePresCov/.

Retiree Drug Subsidy – Some employers offer prescription drug plans to their retirees. CMS has allowed qualified retiree plans to purchase D coverage, at a subsidized rate, on behalf of their retirees. Monthly indicators document whether retiree drug subsidies were used. Since this program operates as a Part D subsidy rather than as a Part D contract, PDEs are not available during the RDS months. There are 12 monthly occurrences of this field.

State Reported Dual Eligible Status Code – State reported Medicaid coverage; indicates entitlement to Medicare and concurrent eligibility for a Title XIX benefit (i.e., Medicaid or a Medicare Savings Program). An individual is deemed to be eligible for a full subsidy if he/she is entitled to Medicare and:

- A full benefit dual eligible individual (eligible for full Medicaid benefits);
- A recipient of Supplemental Security Income (SSI) benefits; or
- Eligible for full Medicaid benefits, and/or the Medicare Savings Program as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or Qualifying Individual (QI) under a State's Medicaid plan.

There are 12 monthly occurrences of this field. Additional details regarding methods for identifying beneficiaries who are dually enrolled in Medicare and Medicaid is available in a CCW Technical Guidance document (see https://www.ccwdata.org/web/guest/technical-guidance-documentation).

Monthly coverage variables:

Part D Plan Covered Months – Number of months during the year of Part D coverage; values = 0 through 12. This variable accumulates all monthly occurrences where the Part D plan type (the first character in PTD_CNTRCT_ID_<month>) is H, R, S, E, or X.

RDS Months – For beneficiaries with a retiree drug subsidy (RDS), the number of months during the year with RDS coverage; values = 0 through 12. This variable accumulates all monthly occurrences where RDS (RDS_IND_<month>) is 'Y'.

Medicaid Dual Eligible Months – For beneficiaries with a state-reported Medicaid dual-eligible indicator, the number of months during the year with dual coverage; values = 0 through 12. This variable accumulates all monthly occurrences where DUAL_STUS_CD_<month> is equal to '01','02','03','04','05','06','08','09', or '99') and the beneficiary has Medicare enrollment.

Beginning with MBSF using CME as the source

- The variable indicating that beneficiary was not enrolled in Part D but had other creditable coverage for any month of the year, e.g., FEHB, TRICARE, VA, SPAP, or active workers (i.e., ESRD, disabled, aged) had been included in the original MBSF that used EDB as the source (variable called CRDTBL_CVRG_SW). It is not available in the current MBSF that uses CME (i.e., the MBSF ABCD) due to differences in the source data.

Chapter 2. Part D Prescription Drug Event Data

Claims for prescription drugs are submitted by pharmacies to the Part D health plans for beneficiaries enrolled in Medicare Part D. This information is transmitted to CMS, and administrative data files called prescription drug event (PDE) data files are created. The PDE data are created from point-of-service transactional data at the time a prescription is filled. Data for prescriptions which are ordered but not filled do not exist in this database (i.e., data are not prescribing data, but rather reflect filled prescriptions).

The CCW contains all of the Medicare Part D Prescription Drug Event (PDE) data beginning with the inception of the Part D benefit in 2006. For 2006 – 2011, the PDE file is extracted from an annual standard analytic file (SAF) with Part D data that CCW obtained from CMS. Starting with 2012 data, CCW created our own version of the SAF[3] 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 Part D Event data to be released several months earlier.

All PDE data disseminated by CCW are considered "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). Plans may adjust or delete PDEs until six months after the benefit year, when the PDE file is locked down for final processing. Then, CMS performs reconciliations which may result in edits to various fields on the record to reflect beneficiary eligibility changes or Part D plan switching that may have occurred during the benefit year. PDE data are not considered final until all of these types of adjustments have been completed.

Not all Medicare-enrolled beneficiaries elect to purchase Part D coverage. PDE data are not submitted by plans which receive RDS, or for other types of plans which are considered to be Part D creditable coverage (e.g., VA, TRICARE, FEHBP).

The complete PDE record is obtained by CCW. This includes information such as the specific drug, cost, pharmacy, provider, and benefit information. To obtain a CMS data use agreement (DUA) to use the PDE, researchers are required to select variables based on minimum data necessary and justify the need for each variable.

Note: Prior to the 2013 data release, CCW was required to encrypt or use CCW-assigned ID values to protect some of the sensitive data fields. These sensitive fields were those which could be used to identify the beneficiary, the prescriber, the pharmacy, the plan, or the plan's formulary. We are no longer required to encrypt the prescriber, pharmacy, plan or formulary identifiers; however, the Pharmacy Characteristics data file may only be released if investigators agree to forgo the unencrypted pharmacy identifier (i.e., the service provider ID – variable called SRVC_PRVDR_ID. In its place, the investigator will receive the

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

National Council for Prescription Drug Programs (NCPDP) identifier (variable called NCPDP ID) as the linkage variable between the PDE and the Pharmacy Characteristics file).

Additional details regarding these Characteristics files are available in Chapter 3.

A. PDE Variables

A description of the variables contained in the PDE file can be found on the Data Dictionaries page on the CCW website (https://www.ccwdata.org/web/guest/data-dictionaries). This section of the document primarily identifies linkage variables, which can join the PDE with other files. In addition we highlight some key variables and also some variables created by CCW.

Nearly all of the variables stored by CMS as part of the PDE are available to researchers. Researchers may request any number and combination of variables, and a variable-by-variable justification must be provided as part of the data request packet obtained through ResDAC. Pricing for the data file is based on the size of cohort (e.g., 250,000 beneficiaries, 1 million beneficiaries, etc.). There is an additional cost for obtaining the FDB variables which describe the drug; these variables are available in the Part D Drug Characteristics File.

1. Identifier and Linkage Variables

Some fields contain CCW-assigned unique IDs in lieu of the actual identifiers, some of which are encrypted uniquely for each DUA:

Variable name	Variable description	Data File(s)
PDE_ID*	CCW PDE event ID (encrypted)	PDE
BENE_ID*	CCW beneficiary ID (encrypted)	PDE; MBSF
FRMLRY_RX_ID	CCW Identifier for a Drug Product	PDE; Formulary Characteristics

* Field is uniquely encrypted for each DUA.

Historically, the plan, prescriber and pharmacy identifiers were considered sensitive and CCW could not release them prior to 2013. For current data files, investigators may obtain the actual identifiers that appear in the PDE file (e.g., the Part D plan contract identifier and plan benefit package identifier – variables called PLAN_CNTRCT_REC_ID and PLAN_PBP_REC_NUM, respectively). The exception is that, for those who wish to obtain Pharmacy Characteristics files, they must choose between the pharmacy identifiers on the PDE (the service provider ID, variable called SRVC_PRVDR_ID), or a proprietary NCPDP ID that will allow linkage between the PDE and the Part D Pharmacy Characteristics Files. The changes in Part D data due to this loosening of the regulation are summarized later in this section (Table 1).

2. Commonly Used PDE Variables

Product Service ID (PROD_SRVC_ID) – This field is the National Drug Code (NDC). Researchers may select some optional data fields to append to the PDE.

Drug Characteristics - Through a special licensing agreement with First Databank, CCW is able to provide the brand name (BN), generic name (GNN), strength (STR), dosage form (GCDF), and the dosage form description (GCDF_DESC) for the NDC on the PDE. There is an additional fee for these variables; they are not included in the PDE price.

Alternatively, there are a variety of commercially available drug databases, which researchers may use to identify the NDC.

QTY_DSPNSD_NUM – This is the quantity of the drug that was dispensed. This field indicates the number of units, grams, milliliters, or other quantity dispensed in the current drug event. For example, the value might be 30.000 for a prescription dispensed as tablets, indicating a one-month supply of pills, or 22.000 if the prescription was dispensed as an ointment, indicating the number of grams. The dosage form description variable (GCDF_DESC) will often explain the units used for the PDE.

DAYS_SUPLY_NUM – This is the number of days supplied by the PDE. The value consists of the amount a pharmacist or pharmacy personnel enters for the prescription.

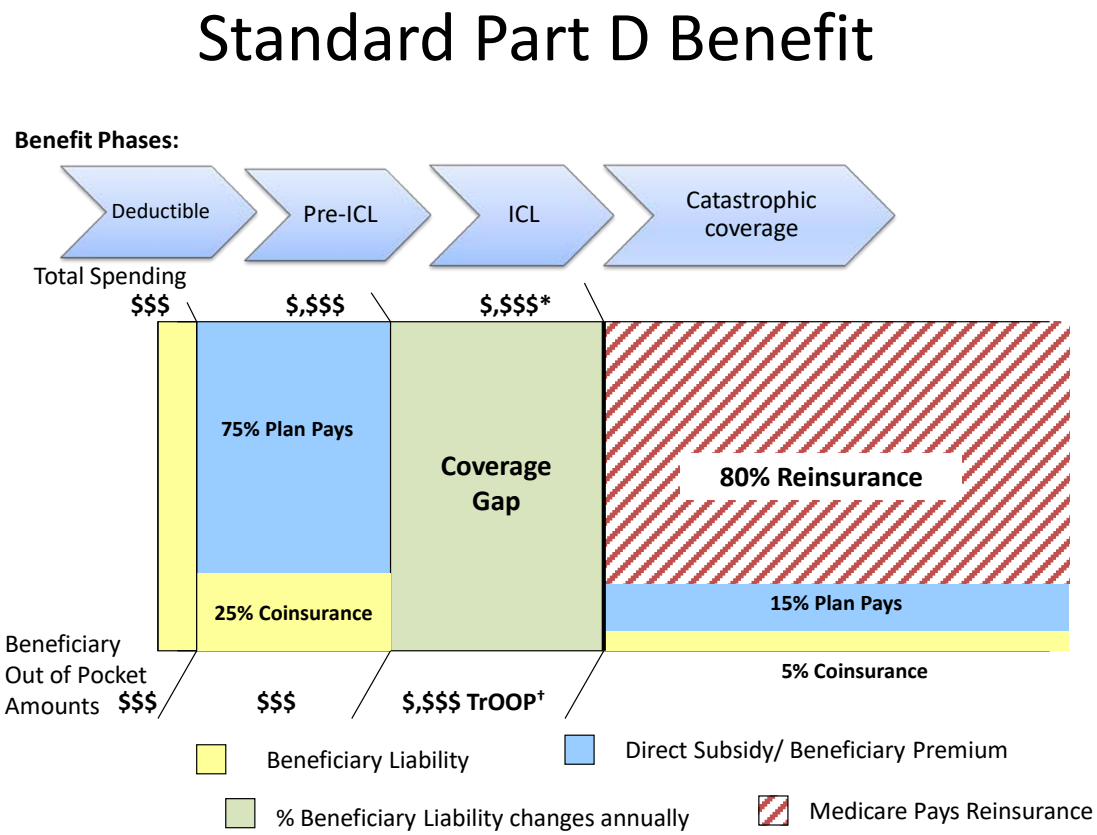
SRVC_DT – This is the date on which the prescription was filled.

3. Phases of the Part D Benefit

Benefit Phase (BENEFIT_PHASE) – This is a CCW derived field that considers the specific plan benefit structure for each beneficiary, and indicates where in the benefit phase this PDE occurred (deductible, pre-initial coverage limit [ICL], ICL, or catastrophic phase). This is an optional data field which researchers may elect to purchase. Please refer to Figure 1 for an illustration of the standard benefit phases, and Figure 2 for an illustration of how the ICL phase is altered for 2011 forward. If a beneficiary is not enrolled in a Part D plan with a Defined Standard benefit, but rather has an alternative benefit type (e.g., Basic Alternative or Enhanced Alternative Plan) then the benefit parameters used for benefit phase determination may be different than what is illustrated below. For example, alternative plans may have no deductibles or a modified ICL amount that effectively eliminates the coverage gap.

The benefit phase determination for every covered Part D event is made by accumulating (1) the total drug costs and (2) the true out-of-pocket (TrOOP) spending for the beneficiary to date, and comparing these amounts to the beneficiary's plan-specific benefit parameter amounts (deductible, ICL and out-of-pocket threshold [OOPT]), which change each year. If the accumulated TrOOP spending is below the OOPT then the accumulated total drug costs determine whether the beneficiary is in the deductible, Pre-ICL or ICL (gap) phase. Otherwise, TrOOP spending has exceeded the OOPT and the beneficiary has reached the catastrophic phase. Refer to the table below Figure 1 for the dollar amounts of these parameters.

Figure 1. Part D Standard Benefit Phases



* In 2010 a $250 rebate was provided to beneficiaries who reached the ICL. 2011 and later may have discounts and rebates, as well as reduced beneficiary cost-sharing provisions.

† True Out-Of-Pocket (TrOOP) amount; includes beneficiary payments (or payments made on behalf of a beneficiary from a third party) for covered Part D drugs.

Benefit Threshold Parameters (shown as spending at end of benefit phase):

Year	Type of costs	Deductible phase	Pre-ICL phase	** ICL phase
2006	Total Drug Costs	$250	$2,250	$5,100
	TrOOP *	$250	$750	$3,600
2007	Total Drug Costs	$265	$2,400	$5,451.25
	TrOOP	$265	$808.75	$3,850
2008	Total Drug Costs	$275	$2,510	$5,726.25
	TrOOP	$275	$833.75	$4,050
2009	Total Drug Costs	$295	$2,700	$6,153.75
	TrOOP	$295	$896.25	$4,350
2010	Total Drug Costs	$310	$2,830	$6,440
	TrOOP	$310	$940	$4,550
2011	Total Drug Costs	$310	$2,840	$6,483.72
	TrOOP	$310	n/a	$4,550
2012	Total Drug Costs	$320	$2,930	$6,730.39
	TrOOP	$320	n/a	$4,700
2013	Total Drug Costs	$325	$2,970	$6,954.52
	TrOOP	$325	n/a	$4,750
2014	Total Drug Costs	$310	$2,850	$6,690.77
	TrOOP	$310	n/a	$4,550
2015	Total Drug Costs	$320	$2,960	$7,061.76
	TrOOP	$320	n/a	$4,700
2016	Total Drug Costs	$360	$3,310	$7,515.22
	TrOOP	$360	n/a	$4,850
2017	Total Drug Costs	$400	$3,700	$8,071.16
	TrOOP	$400	n/a	$4,950

** True out-of-pocket (TrOOP) costs are payments for covered Part D drugs that are made by the beneficiary, by a third party on behalf of the beneficiary, or by the Part D low-income subsidy.

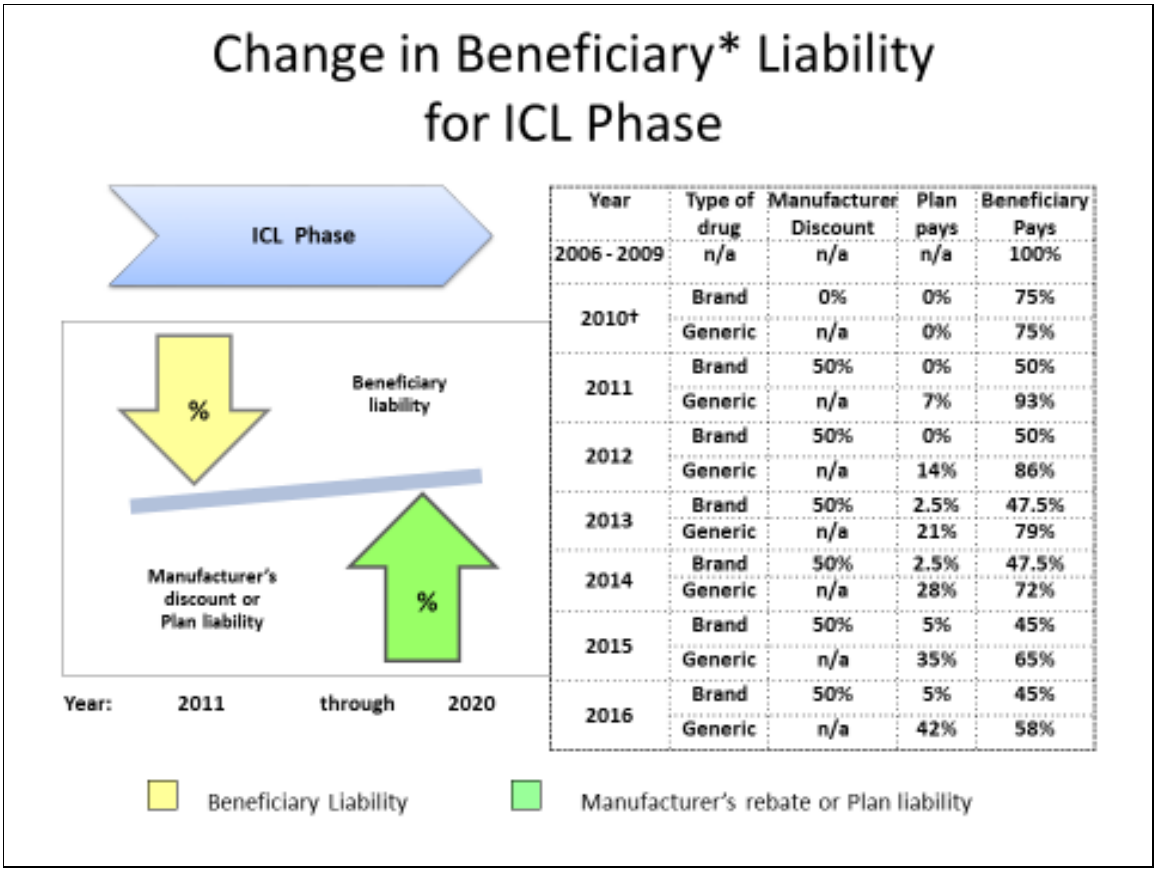
† In 2010, this includes a $250 rebate to beneficiary. The figures shown for total drug costs are for a beneficiary with no other form of third-party coverage. Starting in 2011, the value of any discounts that beneficiaries receive on brand-name drugs under the Medicare Coverage Gap Discount Program are included in their TrOOP costs. The figures shown here for total drug costs include the value of those discounts.

Starting in 2011 the coverage gap began to close through a combination of manufacturer discounts on brand name drugs and decreasing coinsurance percentages for beneficiaries. The Patient Protection and Affordable Care Act (HR 3590) required the Medicare Coverage Gap Discount Program to take effect January 1, 2011 (Sections 1860D-1 through 1860D-42). The Discount Program makes manufacturer discounts available to Medicare beneficiaries who are not eligible for LIS (called "applicable beneficiaries"), who obtain covered Part D drugs while in the coverage gap (more formally referred to as the ICL; see CMS website for additional details regarding this program http://www.medicare.gov/Pubs/pdf/11493.pdf). Beginning in 2011, manufacturers provide a 50% discount on brand-name drugs which is applied at the point-of-sale with those discounts contributing to the beneficiary's TrOOP accumulation. Additional legislation

made provisions for Part D sponsors to begin reducing coinsurance on generic drugs beginning in 2011 and on brand name drugs in 2013.

By 2020 the coverage gap will be closed and beneficiaries enrolled in standard benefit plans will have a 25% coinsurance once the deductible is met up until their TrOOP reaches the catastrophic threshold. These reductions in beneficiary coinsurance for brand-name drugs is achieved through a combination of manufactures' discounts (50% for applicable drugs) and increasing plan liability up to 25% by 2020. Plans will cover 75% of the costs for generics. We illustrate the impact of the Affordable Care Act (ACA) on beneficiary cost-sharing in the ICL phase in Figure 2, below.

Figure 2. Changes to ICL (or Gap) Phase, due to Affordable Care Act



Year	Type of drug	Manufacturer Discount	Plan pays	Beneficiary Pays
2006 - 2009	n/a	n/a	n/a	100%
2010†	Brand	0%	0%	75%
	Generic	n/a	0%	75%
2011	Brand	50%	0%	50%
	Generic	n/a	7%	93%
2012	Brand	50%	0%	50%
	Generic	n/a	14%	86%
2013	Brand	50%	2.5%	47.5%
	Generic	n/a	21%	79%
2014	Brand	50%	2.5%	47.5%
	Generic	n/a	28%	72%
2015	Brand	50%	5%	45%
	Generic	n/a	35%	65%
2016	Brand	50%	5%	45%
	Generic	n/a	42%	58%

* Illustration represents cost-sharing for "applicable beneficiaries".

† In 2010 only, beneficiaries who reached the coverage gap received a $250 rebate from the government.

The beneficiary cost-sharing provisions, the manufacturer's discounts for brand name drugs during the ICL, and the plan liability for brand and generic drugs during the ICL phase of the benefit vary by year, as displayed in the figure above.

The *BENEFIT_PHASE* field differs somewhat from the information in the catastrophic coverage code field on the PDE (CTSTRPHC_CVRG_CD) in that it has greater detail regarding the range of benefit phases available for most Part D plans.

Note: Since PDE data contained in the CCW represent "final action", the catastrophic coverage code field in the PDE data may have occasional discrepancies in the timing of the "A" and "C" codes due to interim adjustments to individual PDE records (e.g., post-transaction modifications or deletion of PDE records may cause a change as to when a beneficiary reaches the attachment point or catastrophic threshold) or due to information lags between Part D sponsor for beneficiaries who switch plans (i.e., True Out-Of-Pocket [TrOOP] balance transfer issues). Beginning in 2011, the catastrophic coverage code was not required to be populated by plans.

The two-digit benefit phase variable uses intelligence for both digits. The 1st digit = benefit phase at the start of fill, 2nd digit = phase once the drug has been dispensed (e.g., DD indicates that the beneficiary was in the deductible phase of the benefit, DI indicates that this PDE occurred partly in the deductible phase – and partly in the ICL phase). The two digits are necessary since the benefit phases depend on specific dollar amounts, which may not split exactly between prescription fills; that is, a particular PDE may "straddle" more than one benefit phase. It is possible that some non-standard combinations of benefit phases might appear, particularly if a beneficiary has changed plans during the year. CCW codes this benefit phase variable according to what the beneficiary's plan benefit package indicates should have occurred (i.e., according to the plan and contract of record – which appear in the MBSF) at the time of the PDE fill in terms of accumulated costs based on date of service ordering. For a small number of beneficiaries, particularly those who made a plan change around the time of the fill, the benefit phase value may not be representative of the beneficiary experience at the point-of-sale.

4. Changes in PDE data over time

Beginning with 2010 data

- The variable indicating the gross drug cost (TOT_RX_CST_AMT) has historically included the drug ingredient cost, the dispensing fee, and sales tax. Beginning with 2010 PDE, this variable also includes a vaccine administration fee, when applicable.
- The prescription origin code (RX_ORGN_CD) variable became available. It indicates whether the prescription was transmitted as an electronic prescription, by phone, by fax, or as a written paper copy.
- Two additional linkage variables were added to the PDE: the formulary ID (FORMULARY_ID) and formulary drug ID (FRMLRY_RX_ID). Using the two variables in combination, the PDE data can be linked to the Formulary Characteristics file (also new in 2010) to obtain the utilization management (UM) variables (tier, step, prior authorization, and quantity limits). The linkage rate between the Formulary Characteristics file and PDE is 96.5% in 2010. The UM variables are present in the 2006-2009 PDE data, since the Formulary Characteristics file had not yet been developed. Refer to Chapter 3 for details.

Beginning with 2012 data

- The plan-reported brand/generic code (BRND_GNRC_CD) became available. It indicates whether the plan processed the PDE as a brand or generic drug.
- The plan-reported amount of the gap discount at the point of sale for applicable brand drugs (variable called RPTD_GAP_DSCNT_NUM). This amount is included in the beneficiary's TrOOP accumulation (note that this amount is still part of the total drug cost amount – the TOT_RX_CST_AMT variable).
- Use of the CCW-created PDE SAF file, rather than CMS PDE SAF as the source data. For 2012, the CCW-created PDE annual file may not reflect the final plan-to-plan reconciliation processing performed by CMS for approximately 0.01% PDEs. This affects only the plan and contract identifiers, and would not affect inferences regarding the drug dispensed (i.e., the NDC) or the payment fields.

Beginning with 2013 data

- Most of the previously-encrypted variables are no longer required to be encrypted. Part D Plan, Contract, Segment, and formulary IDs are delivered without encryption. The BENE_ID and PDE_ID will remain encrypted specifically to each DUA (no change).
- For the prescriber and pharmacy ID, these were available without encryption, depending on whether the Part D Characteristics Files were requested. Additional details appear in the next section (5. Historical PDE Linkage Variables).
- For 2006 – 2013 years of data, researchers who would like to obtain the Prescriber Characteristics File are not able to obtain the prescriber ID due to the proprietary nature of the source data CCW uses to produce these characteristics files, and the CCW-created prescriber ID must be used.
- Three new plan-reported PDE variables became available: the type of pharmacy (PHRMCY_SRVC_TYPE_CD); patient residence code (PTNT_RSDNC_CD); and, for nursing facility residents, the submission clarification code (SUBMSN_CLR_CD) which is designed to explain why less than a ½ month supply of drugs may have been provided.

Beginning with 2014 data

- The prescriber identifier (PRSCRBR_ID) on the PDE is used regardless of whether the CCW Prescriber Characteristics file is desired. Since this field must be submitted on the PDE as an NPI (May 2013+), we no longer use a proprietary cross-walk to identify the prescriber.

5. Historical PDE Linkage Variables and Encryption

Historically, several fields were required to be encrypted prior to release of the Part D data to comply with CMS Privacy Regulations: the Part D plan contract ID (PLAN_CNTRCT_REC_ID), the plan benefit package ID (PLAN_PBP_REC_NUM), the plan segment ID (SEGMENT_ID), and the formulary ID (FORMULARY_ID). Beginning with the 2013 data release, these are no longer encrypted.

The 2013 Part D data release marked a transition year for CCW where additional unencrypted PDE variables could be requested. Specifically, researchers could obtain the prescriber and pharmacy identifiers from the source PDE (variables called PRSCRBR_ID and SRVC_PRVDR_ID). However, both the Prescriber and Pharmacy Characteristics files used proprietary cross-walks to create the CCW_PRSCRBR_ID and CCW_PHARM_ID, which were used in place of the actual PDE identifiers. Therefore, investigators who wished to obtain the CCW Part D Prescriber and Pharmacy Characteristics files received the CCW-created identifiers (CCW_PRSCRBR_ID and CCW_PHARM_ID) rather than the source PDE identifiers (PRSCRBR_ID and SRVC_PRVDR_ID).

Starting with the 2014 data release, CCW completed the transition to use unencrypted variables on the PDE. CCW re-specified some linkage variables to enable an additional source PDE field to be released. A summary of current and historical linkage variables appears in Table 1. Beginning with 2014 data files, investigators were allowed to obtain the prescriber's unique identification number (the PRSCRBR_ID), from the PDE and also obtain the CCW Prescriber Characteristics File. In general, the CMS-assigned National Provider Identifier (NPI) is used to populate the PRSCRBR_ID, especially after April 2013. Historically, the identification number could have been a Drug Enforcement Administration (DEA) number or state license number, which required a use of proprietary crosswalk. Additional details are available later in this document (see Chapter 3. Part D Characteristics Files). Researchers who receive the PRSCRBR_ID may also select the prescriber identifier qualifier code (variable called PRSCRBR_ID_QLFYR_CD), directly from the source PDE. This variable indicates which type of prescriber identification number was submitted on the PDE. However, CCW analysts have found that this variable is not always accurate, particularly for the early years of the Medicare Part D benefit.

For all years of Part D data, researchers have the option of receiving the actual pharmacy identifier and the associated qualifier code (variables on the PDE called the service provider identifier [SRVC_PRVDR_ID] and the service provider ID qualifier code [SRVC_PRVDR_ID_QLFYR_CD]); however, if the CCW Part D Pharmacy Characteristics File is requested – then the CCW_PHARM_ID (for 2006 - 2013 data) or NCPDP_ID (for 2014 + data) must be obtained instead to protect the proprietary source data for this file. Through a special licensing arrangement with the National Council for Prescription Drug Programs (NCPDP) for use of their dataQ™ product, CCW is able to provide researchers with the information in the Pharmacy Characteristics data file; the NCPDP_ID was the basis for the CCW_PHARM_ID.

The BENE_ID and PDE_ID will remain encrypted specifically to each DUA (no change).

Each of the aforementioned identifier variables is a "linkage" variable that enables data files to be joined together. Refer to Figure 4 for an illustration of the file linkages that are possible.

Table 1. Linkage Variable Changes between PDE and Characteristics Files

		Data File Years	
Variable Name	**Description**	**2006 - 2013**	**2014+**

Prescriber Identifiers			
CCW_PRSCRBR_ID	CCW-assigned Prescriber Identifier	Variable used to be required to link to Part D Prescriber Characteristic File; requestors not allowed to obtain the PRSCRBR_ID on the PDE	Retired (n/a)
PRSCRBR_ID	Prescriber Identifier on source PDE	Available on all PDEs; data populated with various types of identifiers (not historically the NPI). May obtain the **Prescriber Bridge File*** to cross-walk NPI to CCW_PRSCRBR_ID	Available on all PDEs (is populated with NPI)
Pharmacy Identifiers			
CCW_PHARM_ID	CCW-assigned Pharmacy Identifier	Variable is needed to link to Part D Pharmacy Characteristic File; requestors not allowed to obtain the SRVR_PRVDR_ID on the PDE	Retired (n/a)
NCPDP_ID	National Council for Prescription Drug Programs (NCPDP) Identifier	n/a on PDEs May obtain cross-walk to CCW_PHARM_IDs (available in the **Pharmacy Bridge File**†)	Variable is needed to link to Part D Pharmacy Characteristic File (and must forego the SRVR_PRVDR_ID)
SRVC_PRVDR_ID	Service Provider Identifier on source PDE	Populated on PDE, by default; not available if you obtain the Part D Pharmacy Characteristics File	Populated on PDE, by default; not available if you obtain the Part D Pharmacy Characteristics File
Plan and Formulary Identifiers			
PLAN_CNTRCT_REC_ID, PLAN_PBP_REC_NUM, SEGMENT_ID	Part D Plan contract ID, Part D Plan benefit package ID, Part D Plan segment ID	Actual identifiers on source HPMS and PDE data‡	Actual identifiers on source HPMS and PDE data
FORMULARY_ID	Formulary ID	Actual identifiers on source HPMS and PDE data‡	Actual identifiers on source HPMS and PDE data

* The Prescriber Bridge File was developed by CCW to provide information regarding the CCW_PRSCRBR_IDs used from 2006 – 2013. Additional details regarding this file are available in the (Prescriber Characteristics File section of this document).

† The Pharmacy Bridge File was developed by CCW to provide information regarding the CCW_PHARM_IDs used from 2006 – 2013. The associated NCPDP_ID is populated. Additional details regarding this file are available in the Pharmacy Characteristics File section of this document.

‡ For data files that were disseminated prior to the 2013 data release, these fields were always encrypted, to comply with CMS Privacy Regulations.

B. Limitations

The PDE differs from a "pharmacy claim" in several ways. Each PDE record is a summary record containing the final status of a drug claim sent by a pharmacy to a Part D sponsor accounting for any subsequent adjustments. Pharmacy claims rejected by the sponsor are not included in PDE data. For example, if a pharmacy submits an original claim to a plan sponsor which is rejected due to a prior authorization requirement and later, when the prior authorization criteria are met, resubmits the claim which is accepted by the sponsor, the sponsor would then submit only one PDE record to CMS reflecting the final status of the accepted claim. Similarly, if a pharmacy submits a claim to a plan sponsor and then soon after reverses (cancels) the claim, the sponsor would not submit a PDE record to CMS. Additionally, since the PDE data in the CCW represent "final action", all PDE adjustments received by CMS through the PDE submission deadline for payment reconciliation are accounted for in the data, including PDE adjustments, resubmissions, and deletions.

Not all drugs used by Part D enrolled beneficiaries are included in the PDE files. Data generally do not include Part D excluded prescription drugs (unless the plan covers excluded drugs as a supplemental benefit). Prescriptions obtained through a third party (e.g., VA) or those for which a claim is not submitted (e.g., if a beneficiary pays cash out-of-pocket) are not available. Similarly, free prescription fills offered by pharmacies or use of manufacturers' samples will not be captured in the PDE files. In addition, over-the-counter (OTC) drugs are excluded from Part D and typically are not included in the PDE files, unless they are part of an approved step therapy protocol or unless the plan covers some OTC drugs as part of their administrative cost structure.

There are some PDEs where Benefit Phase values cannot be determined:

- If the PDE is for a non-covered drug, the Benefit Phase value will be blank.
- Due to special waivers, some organization types are not required to submit details of their drug benefit package (e.g., employer, PACE, and LINET plans). The Benefit Phase value for PDEs associated with these plans will be "NA".
- If the plan information on the PDE cannot be linked to the HPMS plan information (i.e., the CCW Part D Plan Characteristics file), the value of "XX" is applied to Benefit Phase.

Limitations with 2011 data

- The variable indicating the gross drug cost (TOT_RX_CST_AMT) includes the full cost of the drug, and does not reflect any Coverage Gap Discounts which may have been applied. In general, for 2011 data, researchers can impute the value of coverage gap discounts for brand name drugs (e.g., the 50% manufacturer's discount applied in the coverage gap in 2011) by calculating the sum of the following variables and comparing the amount to the TOT_RX_CST_AMT:
    - Patient pay amount (PTNT_PAY_AMT) – which is actual payments from the beneficiary and may reflect coverage gap discounted amounts
    - Low income cost sharing amount (LICS_AMT)
    - Patient liability reduction due to other payer amount(PLRO_AMT)

- Other True Out of Pocket Amount (OTHR_TROOP_AMT)
- Covered Plan paid amount (CVRD_D_PLAN_PD_AMT)
- Non-covered Plan paid amount (NCVRD_PLAN_PD_AMT)

If the sum of these six variables is less than the TOT_RX_CST_AMT, and if the PDE was in the coverage gap phase of the benefit (i.e., either completely within the ICL or partially, as would be the case with a "straddle" claim), then the difference in these amounts can generally be assumed to be the gap discount amount for the portion of the PDE cost that falls within the coverage gap.

Starting with 2012 data, this limitation no longer exists since the PDE file includes the plan-reported gap discount amount (RPTD_GAP_DSCNT_NUM).

Chapter 3. Part D Characteristics Files

Researchers may wish to request supplemental characteristics files to link to the PDE or Part D enrollment data. For example, characteristics files include:

- Plan Characteristics (e.g., type of benefit/coverage provided by the plan) – UPDATED in 2015 to include Part C plans.
- Formulary Characteristics (e.g., the formulary tier for the drugs in the PDE and any associated utilization management associated with that drug in that formulary; also the FDB brand name, generic name, dosage and form)
- Pharmacy Characteristics (e.g., type of pharmacy that filled the prescription)
- Prescriber Characteristics (e.g., type of prescribing provider)
- Medication Therapy Management (MTM) (e.g., identification of beneficiaries receiving MTM) – for 2013+
- Part D Plan Election and Auto-Assignment Files

Data file layouts and descriptions for each file can be found on the CCW website, within the Data Dictionaries tab (https://www.ccwdata.org/web/guest/data-dictionaries).

Beginning with 2010 data, the Formulary Characteristics File became available, which resulted in a change in the data files researchers use to obtain the Utilization Management (UM) variables. In 2006-2009, these variables (tier, step therapy, quantity limits, and prior authorization) had been delivered as optional fields on the PDE. For 2010 forward, these variables are available only in the Formulary Characteristics File. Researchers interested in linking these variables to PDE data will need to purchase the Formulary Characteristics File for 2010 going forward and then link it to the PDE by FORMULARY_ID and FRMLRY_RX_ID to get the UM variables. Please refer below to section B. "Formulary Characteristics Files", as well as Figure 3, a linkage diagram below.

Additional information regarding linkage of data files is contained in Chapter 5.

A. Plan Characteristics Files

Medicare Part C (i.e., Medicare Advantage [MA] managed care plans) and Part D plan sponsors are required to submit to CMS, via the Health Plan Management System (HPMS), particular information regarding the structure of the benefit (i.e., the plan benefit package, or PBP) offered to Medicare consumers. This information is intended to help CMS review plan benefits for compliance with requirements. Information covers the plan benefit for a calendar year (e.g., information must generally be submitted and approved by October of the year prior to the start of the new benefit year).

Starting with the 2015 benefit year, the CCW has prepared a Plan Characteristics set of six files per year with detailed information on those plan characteristics, which can be joined to the Medicare Beneficiary Summary File (MBSF) to better understand the benefits available to enrollees. Note that these Plan Characteristics files are an enhancement to the original CCW Part D Plan Characteristics files, which are available for benefit years 2006 – 2014. Starting with the 2015 file, the updated Plan Characteristics File includes all Part C (i.e., Medicare Advantage) and Part D Plans, and there is an indicator in each file that enables investigators to filter for only Part D plans (or only Part C plans, or both), as desired. Those who have previously used the Part D Plan Characteristics files will also notice that a small number of duplicative variables were removed from the "base" file, and other minor changes – which we describe below.

> *Note:* To filter the 2015+ Plan Characteristics File so that it includes only the Part D Plans, use the Part C/D Plan Indicator (SAS variable called PTCD_INDICATOR). Part D plans are those where PTCD_INDICATOR=2 (Part D only plan) or 3 (Both Part C and D plan).

PDPs must offer a basic prescription drug benefit. MA organizations must offer either a basic benefit or broader coverage for no additional cost. If this required level of coverage is offered, MA-PDs or PDPs, may also offer supplemental benefits under enhanced alternative coverage for a supplemental premium. Organizations offering drug plans have flexibility in the design of the prescription drug benefit packages, including the establishment of formularies. The benefit offered by plans may change each year; therefore researchers interested in examining multiple years of benefit information should consider treating these files as annual cross-sectional files (i.e., the same contract and plan benefit package IDs are associated with a different plan benefit structure, and may serve different geographic areas, every year).

Information regarding plan characteristics is contained in six files per year (note that for the Part D Plan Characteristics files 2007-2014, there were five files per year), which are easily joined together, and/or to the PDE file and Part D Segment of the MBSF, using the contract ID and plan ID (note that the variable names are different on the PDE file). Starting in 2015 a variable within each of the files (except for the Cost Sharing Tier file and SNP file – which only include Part D Plans) can be used to filter out the plans that do not offer the Part D benefit (i.e., use the new variable with SAS name PTCD_INDICATOR). The six files which comprise Plan Characteristics

include: 1) Plan Benefit Base File, 2) Premium, 3) Cost Sharing Tier, 4) Service Area, 5) Plan Crosswalk, and, 6) Special Needs Plan (SNP) contracts file - starting in 2015. Each of these files is described in greater detail below.

Plan characteristic files are yearly files. Each year plans submit information to HPMS describing the benefit the plan offers – which may change annually. *Researchers using multiple years of data should treat each annual file as a cross-sectional file*. In addition, the variables in each year's data files can change from year to year, since the HPMS requirements for plans tend to evolve, in part because of provisions in the Affordable Care Act. In general, the Premium, Cost Sharing Tier and Service Area Files are quite stable; the main variability occurs in the plan benefit base file with regard to information obtained for supplemental benefits offered by alternative plans. The data in the annual plan files describe the way the benefit operated during the last month of the calendar year (as minor adjustments in the benefit might have occurred during the year). Variables that are the same from year to year have been named the same and every attempt has been made to standardize the values of common variables. However, this was not always possible. The data dictionary identifies the variables that are included in each annual set of plan characteristics files. Researchers should use caution when taking a longitudinal view of these plan characteristics, as there is variability in the content of these data files over time.

A Part C and/or Part D plan is uniquely determined by a CONTRACT_ID and PLAN_ID. The Plan Benefit Base File has one row of data for every plan. Plans operating in different geographic market areas, known as segments, will have multiple rows of data in the Plan Premium File (i.e., they have more than one row of data in the Plan Premium File – with a separate row for each segment ID [SEGMENT_ID]). The Cost Sharing Tier file has multiple tiers for each Part D plan, while the Premium and Service Area files will have some plans with more than one segment. Besides linking to the other plan files, for plans that offer the Part D benefit, the Plan Benefit Base file also links to the Formulary Characteristics file using the FORMULARY_ID (Formulary Characteristics file available starting with 2010 data). It is possible that more than one Part D plan may link to the same formulary. Please refer to Figure 3, a linkage diagram, later in this Chapter.

The Plan Characteristics data files are the same for all researchers. That is, the data are complete files which are not limited to plans serving the beneficiaries covered in the researcher's DUA.

1. Plan Benefit Base File

This file contains data regarding the type of benefit offered by the plan. Contents include information such as:

- the type of plan (e.g., HMO or PPO [MA-PD], PDP; special needs, PACE [programs of all-inclusive care for the elderly] or employer plan) the name of the plan and the organization marketing name
- whether plan enrollees receive a defined standard benefit (or an enhanced or alternative benefit)
- whether the plan has a deductible and other cost-sharing requirements (e.g., coinsurance or copays)

- whether the Part D plan offers any coverage during the gap

Plan benefit information is available for every Part C and Part D plan. Only the plans that offer Part D coverage will have a record in the Cost Sharing Tier File; however not every Part D plan will have a record in the files. This is because some Part D organization types are not required to submit PBP information to CMS (i.e., there are waivers) – these include LINET, PACE, and employer plans. These plans have basic information regarding the benefit and plan type, however information regarding details of the benefit package (e.g., formulary and tier for the covered drugs) are not available. CCW also does not include Tier-level information for MMP and other CMS demonstrations.

Note: Those who used the Part D Plan Characteristics files (2006-2014) should note that variables related to the Part D Tier, which redundantly appeared on the Tier File, have been removed from the Plan Benefit Base File (e.g., GAP_TIER_01-06 is in the Tier file as GAP_TIER, GAP_DRUG_TYPE_TIER_01-06 is in the Tier file as GAP_TIER_DRUG_TYPE).

2. Plan Premium File

Plan premiums will vary by plan and contract, and may also vary by *segment,* which constitutes a geographic service area covered by a particular benefit package. This Plan Premium data file contains a line of data for each Part C/D contract, plan and segment (i.e., CONTRACT_ID, PLAN_ID, and SEGMENT_ID). Therefore, unless the researcher is interested in questions regarding a particular segment within the plan's benefit structure, it will generally be wise to aggregate this file into the contract and plan level before merging with additional CCW data files. When aggregating, researchers will need to decide how to best aggregate (or roll up) the plan pricing information within this file for their study, as a small number of plan premiums do vary by segment.

The Plan Premium File contains premium pricing information. The Part D benefit allows for low-income beneficiaries to receive premium subsidies on a sliding scale, based on need. Data in this file include:

- basic pricing,
- premium amounts for enrollees who have a Part D low-income subsidy, and
- whether the Part D subsidy level is 25, 50, 75, or 100%.

3. Plan Cost Sharing Tier File

This file describes features of the Part D plan benefit package. Some researchers may wish to have detailed information regarding the various cost sharing options offered to Part D consumers for each tier of the plan's formulary. Plans have tremendous variation with regard to their benefit offerings in terms of the number of tiers included in their formulary, what types of drugs are covered on each tier, whether the tier is classified as a specialty tier, and payment structure for drugs within each tier.

We constructed a standardized plan tier cost sharing data file, however many of the data fields are null (and not applicable) for many plans. This allows for comparison of plans on several key dimensions of the benefit which may vary by tier. The file contains highly specific cost sharing information (co-payment amounts and co-insurance rates) for each tier along the dimensions of:

- benefit phase (i.e., pre- ICL, coverage gap [a.k.a. ICL], and catastrophic [post out-of-pocket threshold]),
- day supply amounts (i.e., one month supply, three month supply, and other), and
- type of pharmacy (e.g., in-network, out-of-network, mail order, etc.).

This file only includes information for plans that offer Part D coverage. This data file includes a row of data with cost sharing information for each drug tier within a Part D plan's formulary (i.e., one row per CONTRACT_ID, PLAN_ID, and TIER_ID combination); therefore there will be a different number of rows for plans which use different numbers of tiers for their benefit. LINET, PACE and employer plans are not required to submit a plan benefit package for approval to CMS; therefore these types of plans will generally not have data within this file. The data fields may vary somewhat from year-to-year, in accordance with HPMS reporting requirements. These changes are noted in the data dictionary.

In 2006-2007, plans using the defined standard benefit or other plans using the Medicare defined cost sharing in the pre-ICL phase had either no tier data or a single row of tier data, since there was no variation across tiers. Beginning with 2008, CCW duplicated the tier 1 cost sharing information across all tiers to make this information more explicit to users.

There may be instances where there are more TIER_ID values in this Cost Sharing Tier File than are found in the Formulary Characteristics File. This is due to a discrepancy by the plan sponsor between what they reported in their bid to CMS (reflected in the Plan Cost Sharing Tier file) and what was submitted on the final formulary file to the CMS HPMS. Any extra tiers in the Tier File may be ignored since no drugs will be dispensed on such a formulary tier.

Researchers may purchase the Formulary Characteristics File, described in the next section of this document, which may be joined to this Plan Cost Sharing Tier file. Since more than one plan could use the same formulary, researchers must obtain the appropriate cost-sharing information for each tier (TIER_ID) (which can vary for the same formulary), by linking together the plan, contract and tier IDs from the Plan Characteristics files (i.e., the CONTRACT_ID, PLAN_ID and TIER_ID from the Tier File). Please refer to the linkage diagram in Figure 4 below. The combined information from these files allows researchers to better understand the financial implications of various drug options.

4. Plan Service Area File

Some researchers may wish to understand the geographic areas covered by a particular plan's contract for a Part C and/or D benefit. This file contains information regarding the region, state, and/or county included in a plan benefit package service area. Additional information regarding Medicare Part D service areas is available on the CMS website (see, for example:

http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html).

This file contains information for every contract and plan benefit package that appears in the Plan Benefit Base File; starting in 2015 it includes all Part C and/or Part D plans (remember that you can filter by using the PTCD_INDICATOR variable). Plans with segmented service areas (i.e., the segment IDs [SEGMENT_ID] consist of multiple counties or states) will have more than one line of data per CONTRACT_ID, PLAN_ID, and SEGMENT_ID combination in this file. Each row of data defines a service area within the PBP's market segment (with service area defined using either a state or county SSA code). Note that plan premiums may vary by segment.

Data for local MA-PDs, 1876 Cost plans, Private Fee-for-Service plans, and Demonstration Organization plans (i.e., "H" and "E" contracts) are listed by state and county, regional MA-PD plans (i.e., "R" contracts) are listed by MA-PD region and state, and PDP (i.e., "S" contracts) are listed by PDP region and state. For MA-PD or PDP regions that contain multiple states, a row is listed for each individual state within the region. For employer plans that are national in scope, there may be more than 3,000 rows of data (i.e., one for each service area/county) in this file. There is no market segment information for LINET plans (they are nationwide).

Note: The first character of the contract ID is a letter or number representing the type of plan, as described in Chapter 1 of this document.

5. Plan Crosswalk File

The Plan Crosswalk file is useful for determining whether a new plan/contract ID is actually a new plan altogether, or simply a pre-existing plan which split into one or more plan/contract IDs. The Plan Crosswalk data files were created to allow researchers to examine consistency in plan offerings and enrollment over time. All plans which appear in the Plan Characteristics files for the year (i.e., all approved plans in HPMS) are included, as are all plans for the prior year. Note that starting with the 2015 data file, the Plan Crosswalk file includes all Part C/D plans.

Variable names include either the reference year (i.e., the year of the data file) or the previous year. Variables for the current year (aka reference year) are called the PLAN_ID_{YY} (YY=current year) and CONTRACT_ID_{YY}; variables for the prior year are called the PLAN_ID_{YY-1} (YY-1=year prior to reference year) and CONTRACT_ID_{YY-1}. For example, if you receive 2013 Part D data, and the Part D Plan Crosswalk file, then the variable for the contract ID for the prior year is called CONTRACT_ID_12 and the variable for the current year contract ID is called CONTRACT_ID_13. These plans are mapped to the plan and contract IDs from the prior year, to indicate whether the plan is new, renewed consolidated or terminated.

This file does not contain any information regarding the plan benefit package, rather it simply allows for mapping the plan and contract IDs from the current year to the prior year. Files

are available from 2007 forward (i.e., 2007 file includes 2006 plans – and indicates status *vis-à-vis* 2006). Details regarding the plan offerings are located in the Plan Benefit Base File.

6. Special Needs Plan (SNP) Contracts File

This file is new in 2015. The Special Needs Plan (SNP) Contracts file contains indicators to show which condition categories (e.g. heart failure, Diabetes) are covered in the SNP. SNPs are always MA-PD plans.

B. Formulary Characteristics Files

The Formulary Characteristics Files were created by CCW starting in 2010, to enable researchers to understand the types of drugs covered on the plan's formulary. Beginning in 2011 this also includes information for supplemental drugs that are generally excluded from the Part D benefit, or as over-the-counter (OTC) drugs for each plan's Part D plan benefit package (PBP). The same formulary may be used by more than one PBP within a contract. Formulary information is available for every Part D plan (note that CCW imputes an "open" formulary for PACE and other organization types that are not required to submit formulary information through HPMS).

Only Part D covered drugs will appear in the Formulary Base File. If plans offer a supplemental benefit under enhanced alternative Part D coverage then additional supplemental drugs, which are typically non-covered drugs, may be included in the plan's benefit package. These drugs that are normally excluded, but are being offered as supplemental drugs, appear in the Excluded Drug File (for 2011+). The definition of a Part D drug does not include OTCs. Therefore, Part D plan sponsors cannot cover OTCs under their basic prescription drug benefit. Plans that elect to cover OTC drugs as part of general drug utilization management or part of a step therapy protocol have identified the applicable drugs – and they appear in the OTC Drug file (for 2011+). Only a subset of plans will offer Part D enrollees any of the excluded drugs or OTC drugs; therefore these two types of Formulary Characteristics Files do not have records for every formulary and/or every Part D plan, only for those plans or formularies that include that type of coverage.

The Formulary Base File was made available with 2010 data. Beginning in 2011, three files are available as components of the Formulary Characteristics Files. The three files are:

1) Formulary Base File – identifies Part D covered drugs that are on the Part D plan's formulary. The file contains drug characteristics (i.e., FDB variables described below) and utilization management (UM) requirements for the formulary tier where the drug appears (i.e., UM variables described below)
2) Excluded Drug File – identifies non-covered Part D drugs that are on the plan's formulary. The file contains drug characteristics and formulary tier information.
3) OTC Drug File – identifies OTC drugs that are on the plan's formulary. The file contains drug characteristics variables, if the drug appeared in First Databank.

Part D Plans submit their formularies to CMS and identify drug products using the National Library of Medicine RxNorm Concept Unique Identifiers (RXCUIs). There can be several drug products submitted that are the same clinical formulation (same ingredients, strength, and dosage form) but different brand names. Each RXCUI corresponds to a unique brand name and clinical formulation.

The Formulary Characteristics Files are built from the CMS Approved Formulary Data found in the CMS' HPMS where a proxy NDC is assigned to each RXCUI. The proxy NDC for each drug product is mapped to a unique FDB brand name and proprietary clinical formulation identifier which is then assigned a CCW formulary drug identifier (FRMLRY_RX_ID). In order for a PDE record to link to the Formulary Characteristics Files, the drug product on the PDE must map to a FRMLRY_RX_ID in the formulary associated with the plan of record. A CCW formulary drug ID (FRMLRY_RX_ID) assigned to a particular PDE will link to only one of the three formulary files; the three files are mutually exclusive. In general, the PDE Drug Coverage Status Code value (i.e., from the variable DRUG_CVRG_STUS_CD) indicates which file the PDE should link to (value of C [indicating Part D covered] = refer to Base Formulary File; value of E [indicating excluded or non-covered by Part D] = refer to Excluded Drug File; and value of O [indicating OTC drug] = refer to OTC Drug File).

Note: Overall, more than 99% of PDEs are for covered drugs (according to the DRUG_CVRG_STUS_CD).

Plans offering OTC and/or Excluded drug coverage can be identified in the Plan Characteristics Base file (described previously) using the variables OTC_UM_PROGRAM and EXCLUDED_DRUGS, if the value for either of these variables is yes (or "Y").

Formulary and Drug Identifiers **-** The CCW Formulary Base File and OTC Drug File are uniquely keyed by a formulary ID (FORMULARY_ID) and a CCW-assigned formulary drug ID (FRMLRY_RX_ID). The Excluded Drug file is also keyed on these identifiers for 2012+. These are also the linking variables between the PDE records and the Formulary Characteristics Files.

Drug Characteristics Variables **-** Through a special licensing agreement with FDB, CCW is able to provide the brand name, generic name, strength, and dosage form for the CCW-assigned formulary drug ID (FRMLRY_RX_ID). Historically, the FDB variables describing the drug (the NDC) have been delivered as optional fields on the PDE, for a fee. For 2010 data forward, researchers have the option of having these variables appended to the PDE. Alternatively, the variables are available in the Formulary Characteristics Files (at the drug-level [the FRMLRY_RX_ID], which consists of all NDCs that have the same ingredients and are branded the same way). The FDB variables found in one of the three Formulary Characteristics Files do not describe PDEs which are not on the plan's formulary. Without requesting the FDB variables to be appended to the PDE, researchers would be missing this information for approximately 2.75% of PDEs.

The Formulary Characteristics Files are the same for all researchers. That is, the data are complete files which are not limited to plans serving the beneficiaries covered in the researcher's DUA.

1. Formulary Base File

Researchers using the Formulary Base File have access to information regarding Part D covered drugs on formulary for each plan, and the UM variables associated with each drug. Prior to 2010 data, this information was provided only for the filled drug prescriptions in the PDE.

In the Formulary Base File, we have one summary record for Part D covered diabetic supplies; FRMLRY_RX_ID = 99999999, and BN = DIABETIC SUPPLY. The GNN, STR, GCDF and GCDF_DESC will have null values for diabetic supplies.

Utilization Management (UM) Variables **-** The Formulary Base File includes four UM variables that plan sponsors are required to report to HPMS. These variables are based on the plan's formulary files, and may not exactly represent the beneficiary experience at the time of the prescription fill (e.g., no data are collected at the time of the transaction to indicate the actual beneficiary experience).

The four UM variables are:

a) Tier (TIER_ID) – on which tier of the formulary the drug (FRMLRY_RX_ID) appeared according to the plan's benefit design

b) Step (STEP) – whether the drug (FRMLRY_RX_ID) was subject to step therapy according to the plan's benefit structure

c) Quantity Limits (QUANTITY_LIMIT_YN) – whether the drug (FRMLRY_RX_ID) was subject to quantity limits according to the plan's benefit structure

d) Prior Authorization (PRIOR_AUTHORIZATION_YN) – whether prior authorization was required for the drug (FRMLRY_RX_ID)

In the Formulary Base File, drug products are not duplicated within a formulary. However, in the source formulary data there can be rare instances where a drug product is duplicated within a formulary. To address these situations, CCW de-duplicated records by choosing the lowest tier and the most restrictive step, quantity limit, and prior authorization values.

This file is at the formulary level (FORMULARY_ID). There are many rows of data for each formulary, indicating the various drugs (FRMLRY_RX_ID) covered on the formulary. Investigators may link to the PDE file using FORMULARY_ID and FRMLRY_RX_ID. For

almost all plans, the number of cost sharing tiers (i.e., in the Plan Cost Sharing Tier File) matches the number of formulary tiers. However, there a few plans where there are more cost sharing tiers in the Plan Cost Sharing Tier File than formulary tiers in the Formulary File. Refer to Figure 3 below. Investigators can assume in these cases that the Part D plan submitted more cost sharing tiers for approval than were actually used.

2. Excluded Drug File (available beginning with 2011 data)

Part D non-covered (or excluded) drugs may be included as a supplemental benefit under Enhanced Alternative Part D coverage. In 2011 there were 407 plans that covered some Part D non-covered drugs (19% of Enhanced Alternative plans). Across all these plans, there were 48 distinct excluded generic products that were covered by plans (e.g., barbiturates, benzodiazepines, erectile dysfunction drugs, and vitamins).

In 2011, the Excluded Drug file was at the plan level. There may be multiple rows of data for each plan, with each row indicating the various excluded drugs (FRMLRY_RX_ID) allowed on the formulary. The 2011 file links to the PDE file using Contract ID, Plan ID and formulary drug ID (variables called CONTRACT_ID, PLAN_ID, and FRMLRY_RX_ID).

Beginning in 2012, CMS required that plans report Excluded Drugs at the formulary level. Accordingly, the CCW Excluded Drug file is at the FORMULARY_ID level, and links to the PDE file using FORMULARY_ID and FRMLRY_RX_ID (not plan or contract IDs).

Investigators are cautioned that it is possible that some of the PBPs that use a particular formulary may not allow the excluded drugs. That is, many plans may use the same FORMULARY_ID; however some of these PBPs might choose to allow excluded drugs and others will not. To determine whether the formulary that is identified on the Excluded Drug file (the FORMULARY_ID) actually includes these drugs as a benefit, you must use the EXCLUDED_DRUGS variable from the Plan Benefit Base File. When EXCLUDED_DRUG='Y' then the excluded drugs that appear in the Excluded Drug File are plan-covered.

The Excluded Drug File did not include Step Therapy, Quantity Limit and Prior Authorization UM variables in 2011, but these were added starting in 2012. The tier value (variable called TIER_ID) enables researchers to investigate the cost sharing structure for these drugs (i.e., by linking this file to the Plan Cost Sharing Tier File, which is one of the Plan Characteristics files).

3. OTC Drug File (available beginning with 2011 data)

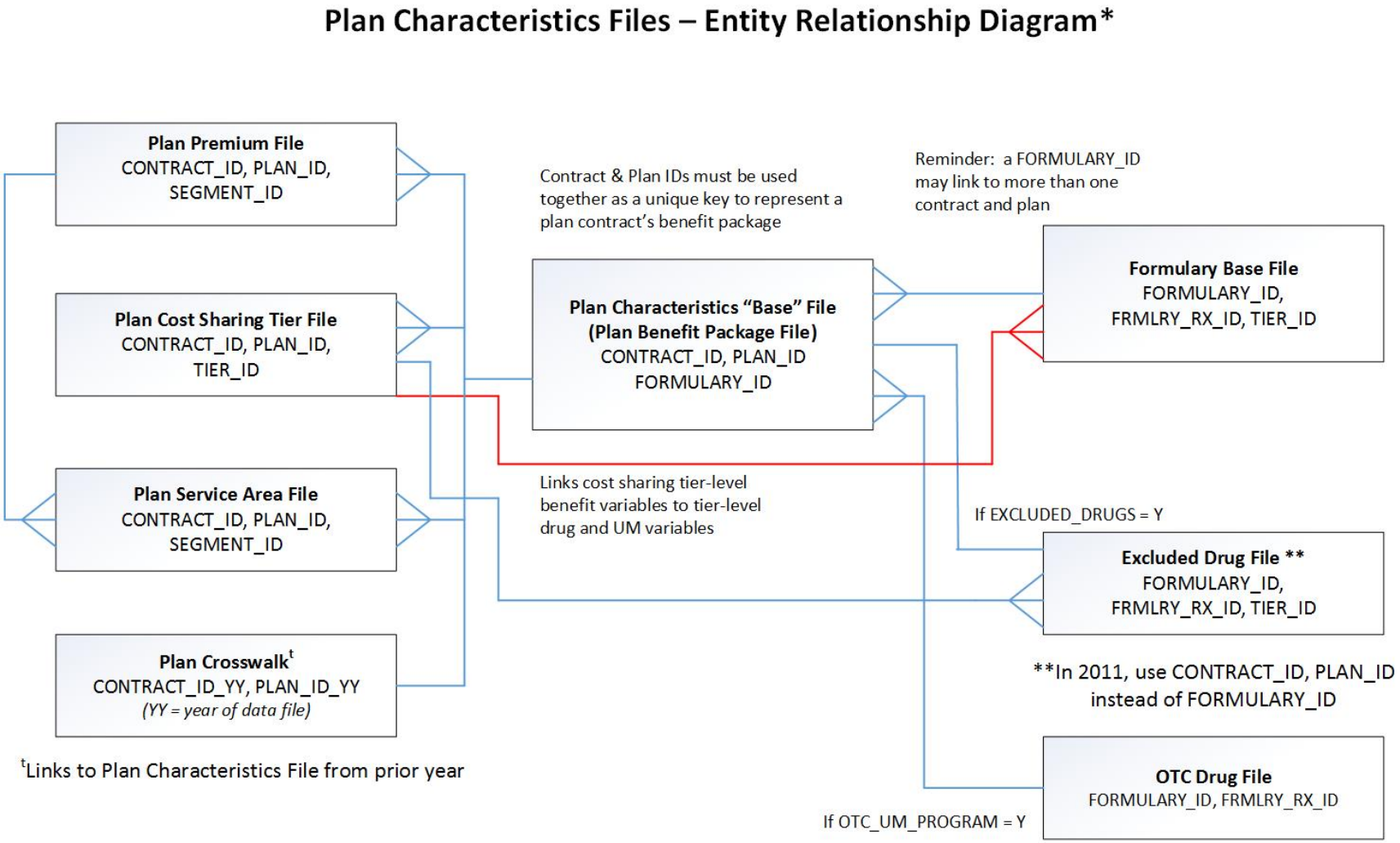
The OTC Drugs file is at the formulary level (as is the Formulary Base File). There may be more than one row of data for each formulary, indicating the various OTC drugs (FRMLRY_RX_ID) covered on the formulary. Note that the OTD Drug file is limited to OTC drugs where the NDC appeared in the PDE and could be linked to FDB. This file will link to the PDE file using formulary ID and formulary drug ID (variables called FORMULARY_ID and FRMLRY_RX_ID).

Investigators are cautioned that it is possible that some of the PBPs that use a particular formulary may not allow the OTC drugs. That is, many plans may use the same FORMULARY_ID; however some of these PBPs might choose to allow OTC drugs and others will not. As a result, to determine whether the formulary that is identified on the OTC Drug file (the FORMULARY_ID) actually includes these drugs as a benefit, you must use the OTC_UM_PROGRAM variable from the Plan Benefit Base File. When OTC_UM_PROGRAM='Y' then the over-the-counter drugs that appear in the OTC Drug File are allowed by the plan.

In 2011 there were 317 plans (8% of all plans) offering some OTC drug coverage. Across all these plans, there were 22 distinct OTC generic products identified (e.g., aspirin, allergy medications, acid reflux medications and smoking cessation products).

The Formulary Base File, or either of the Excluded Drug or OTC Drug Files, may be used in conjunction with the PDE file. Linkage of the any of the Formulary Characteristics files with the PDE file by using the FRMLRY_RX_ID and the plan's formulary number (FORMULARY_ID) enables researchers to learn how the dispensing event was handled by the formulary tier of the plan, in terms of UM variables (note that UM variables do not apply and are not available in the OTC File). The Formulary Characteristics File and the Excluded Drug File may also be used in conjunction with the Plan Characteristics file (e.g., the Plan file, described in the previous section) to better understand the medication therapy options available to enrollees, even if drugs were not dispensed.

Figure 3. Part D Plan Characteristics Files – Linkage Diagram



*Only key variables are listed; starting in 2015, the Plan Characteristics Files include all Part C and D plans.

C. Pharmacy Characteristics File

The objective of this file is to allow researchers to better understand the type of pharmacy (e.g., community/retail pharmacy, mail order, institutional pharmacy), the physical location of the pharmacy (i.e., state), and whether the pharmacy has a relationship with a common parent organization. Through a special licensing arrangement with the National Council for Prescription Drug Programs (NCPDP) for use of their dataQ™ product, CCW is able to provide researchers with this information.

Pharmacies participate with NCPDP in order to receive an industry-recognized pharmacy identifier that can be used for claims adjudication. As part of this relationship, pharmacies voluntarily report other information about their pharmacies such as other provider identification numbers (e.g., NPIs), location information, and type of pharmacy. The CCW Pharmacy Characteristics File is an end-of-year snapshot of the historical NCPDP data that is updated monthly. It only includes the information about the pharmacy in the historical NCPDP database at the end of the year. Changes throughout the year are not included.

The CCW Pharmacy Characteristics File is uniquely keyed by CCW Pharmacy ID (CCW_PHARM_ID for 2006-2013) or NCPDP_ID (for files 2014+), which links with the Pharmacy identifiers in the PDE file. Occasionally, a PDE record will have a null CCW_PHARM_ID/NCPDP_ID because a conclusive link could not be found between service provider identification number (variable called SRVC_PRVDR_ID) in the source PDE data and the provider identification numbers in the NCPDP dataQ™ source data. Usually the CCW_PHARM_ID/NCPDP_ID represents a unique pharmacy entity, which historically was a retail store. However, as the pharmacy services industry has evolved, some retail stores have added other lines of business such as filling prescriptions for long term care facilities. In these cases, the pharmacy can ask NCPDP to issue them more than one identification number to keep the billing separate for their multiple lines of business.

The CCW_PHARM_ID/NCPDP_ID is a more refined and unduplicated version of the SRVC_PRVDR_ID, because we use NCPDP dataQ™ to reconcile the different types of IDs a pharmacy may submit on the PDE. The value-added purpose of the CCW-assigned CCW_PHARM_ID/NCPDP_ID is that it can be used to link to the Pharmacy Characteristics File. This enables researchers to obtain descriptive information about the pharmacy.

For 2006-2013, the CCW_PHARM_ID was created and used to link between the PDE and the CCW Pharmacy Characteristics file; for 2014+ the CCW_PHARM_ID has been retired and NCPDP_ID is used as the linkage variable.

Starting with the 2013 data release when CMS began to allow the actual pharmacy identifier (variable called SRVC_PRVDR_ID) to be released on the PDE file, **the Pharmacy Characteristics File is only available if the CCW linkage variable (i.e., the CCW_PHARM_ID for 2006-2013 or the NCPDP_ID for 2014+ data files) is used in lieu of the actual pharmacy identifier on the PDE file**.

For all years of data, researchers wishing to obtain the actual pharmacy ID on the PDE file (the SRVC_PRVDR_ID) are not allowed to obtain the CCW Pharmacy Characteristics Files. Instead, those wishing to obtain the Pharmacy Characteristics file must obtain the CCW_PHARM_ID/ NCPDP_ID. This is due to licensing restrictions related to the NCPDP dataQ™ source data for the file rather than a CMS privacy concern (i.e., CMS has approved release of the actual prescriber and pharmacy identifiers as they appear in the PDE).

Note: The CCW Pharmacy ID Bridge File is available to researchers who have obtained the CCW_PHARM_ID. The purpose of this file is to provide information regarding pharmacies to researchers transitioning from CCW Part D files containing the CCW-created pharmacy identifier (the CCW_PHARM_ID; available 2006-2013) to using the industry-standard pharmacy identifier (the NCPDP ID) from the source Prescription Drug Event (PDE) data. For all seven years of data, the NCPDP_ID associated with each CCW_PHARM_ID is listed.

D. Prescriber Characteristics File

The PDE contains information regarding the practitioner who prescribed the drug for the patient. The objective of this file is to allow researchers to better understand the type of provider who prescribed the medication (e.g., type of provider and specialty). The HCIdea® Prescriber Database is the source of information for the CCW Prescriber Characteristics file. Through a special licensing arrangement with NCPDP, the CCW is able to provide researchers with this information.

HCIdea® obtains prescriber information from a variety of data sources, including the NPPES (National Plan and Provider Enumeration System, administered by CMS; assigns a unique NPI to each provider), DEA (Drug Enforcement Agency, data files known as the Controlled Substances Act Registrants), and SureScripts (a nationwide e-prescribing network). Using these input files, it is generally possible to identify a unique provider using an NPI, DEA number, and/or UPIN number. Note that there are a small number of instances where it was not possible to confidently identify a unique provider – however this occurred for less than 1% of the prescribers in the HCIdea® database.

A range of variables are collected, and different information may exist for providers at different points in time. CCW obtains monthly files from HCIdea®, and has created a CCW provider history database, from which an annual CCW Prescriber Characteristics File is extracted. The annual CCW Prescriber Characteristics File includes information for all Part D prescribers from the yearly PDE file who are found in the HCIdea® files. It is possible, although rare, for a provider to have more than five different values for taxonomy, credentials and/or state during a year. When this occurred, CCW used the most frequently occurring information for the time frame. Providers self-selected their taxonomy codes in NPPES, and designated a primary taxonomy code.

HCIdea® has limited their data files to those providers who are likely prescribers (i.e., not all NPIs from NPPES are included, rather the NPIs where taxonomy codes indicate a type of provider likely to have prescribing privileges). Organizational NPIs are generally not included.

Not all prescribers will have all of the data fields in the Prescriber Characteristics File populated (e.g., taxonomy code was not present for about 10% of providers). A description of the primary taxonomy code is provided in the data file. If researchers would like to append the descriptions for other taxonomy codes, they can obtain the National Uniform Claims Committee (NUCC) taxonomy descriptions from: http://www.nucc.org/index.php?option=com_content&view=article&id=14&Itemid=125

For 2006 – 2013 data, the CCW Prescriber Characteristics File is uniquely keyed by CCW Prescriber ID (CCW_PRSCRBR_ID), which links with the CCW Prescriber ID written to the PDE data. Starting in 2014, the Prescriber Characteristics File is uniquely keyed by NPI, which links with the actual prescriber identifier (variable called PRSCRBR_ID) on the PDE data.

The Prescriber Characteristics File links to a prescriber in the PDE data file about 94%-96% of the time, depending on the year of data used. Non-linkage would have occurred if the prescriber ID appearing on the PDE did not conform to a known NPI, DEA or UPIN format or if there was not a record for the prescriber in the HCIdea files. For 2006-2013, an event record might have a negative CCW Prescriber ID value when a conclusive link could not be found between the prescriber identification number in the source PDE data and the prescriber identification numbers in the HCIdea® source data. Occasionally, a null value was present in the CCW Prescriber ID field. This occurred when the source PDE data did not contain a prescriber identifier. Usually the CCW Prescriber ID represents a unique individual prescriber (i.e., a prescribing provider); however, on 1-2% of events, an entity or organization may be the prescriber (e.g., a clinic or specialized unit of a hospital, or a student).

For 2006 – 2013 data files, **the Prescriber Characteristics File is only available if the CCW-assigned CCW_PRSCRBR_ID is used in lieu of the actual prescriber identifier on the PDE file**. That is, due to source data licensing restrictions, researchers may not receive the PRSCRBR_ID on the PDE for 2006 – 2013 and also obtain the Prescriber Characteristics File. Starting in 2014, the CCW_PRSCRBR_ID has been retired, and researchers may obtain both the PRSCRBR_ID on the PDE and the Prescriber Characteristics File. As of May 2013, the PRSCRBR_ID is always populated with the prescriber's NPI.

For 2006 – 2013, the CCW prescriber ID (CCW_PRSCRBR_ID) may be linked to the CCW Prescriber Characteristics File, and for 2014+ the PRSCRBR_ID in the PDE file may be linked to the NPI (in the Prescriber Characteristics File), so that researchers interested in knowing more about the prescriber may do so.

Note: The CCW Prescriber ID Bridge File is available to researchers who have obtained the CCW_PRSCRBR_ID. The purpose of this file is to provide information regarding prescribers to data file users who are transitioning from CCW Part D files containing the CCW-created prescriber identifier (the CCW_PRSCRBR_ID; available 2006 – 2013) to using the actual prescriber identifier from the source Prescription Drug Event (PDE) data (i.e., the PRSCRBR_ID). For all seven years of data, the HCIdea® proprietary prescriber identification

number (variable called HCID) associated with each CCW_PRSCRBR_ID is listed, along with the NPI, if available.

Researchers who obtain the CCW_PRSCRBR_ID may also obtain the CCW-developed PDE Prescriber ID format code (variable on PDE file called PDE_PRSCRBR_ID_FRMT_CD). This variable was created to identify the type of prescriber identifier found on the original PDE. This field is populated by examining the format and length of the Prescriber ID variable (i.e., the combination of alpha and numeric characters in the PRSCRBR_ID); the value indicates whether the Prescriber ID appearing on the PDE was an NPI, DEA or UPIN.

E. Medication Therapy Management (MTM) File

Many researchers have expressed interest in studying the effects of Medicare Part D Medication Therapy Management (MTM) programs. Therefore, CMS has created a beneficiary-level MTM research identifiable file which is based on data submitted to CMS by Part D plan sponsors.

MTM Program Technical Specifications:

Under 42 CFR §423.153(d), a Part D sponsor must establish an Medication Therapy Management (MTM) program that: (1) Ensures covered Part D drugs are used to optimize therapeutic outcomes through improved medication use; (2) Reduces the risk of adverse events; (3) Is developed in cooperation with licensed and practicing pharmacists and physicians; (4) May be furnished by pharmacists or other qualified providers.

Eligibility Criteria: Part D enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual costs for covered Part D drugs that exceed a predetermined level are targeted for the MTM programs, as described in§423.153(d)(1). The CMS eligibility targeting requirements are established as the minimum threshold. Sponsors may also offer MTM services to an expanded population of beneficiaries who do not meet the eligibility criteria under §423.153(d). Sponsors are encouraged (but not required) to also offer MTM services to beneficiaries who meet the sponsors' internal criteria for retrospective identification of opioid overutilization, but do not otherwise qualify for MTM.

Method of Enrollment: (1) Sponsors must enroll beneficiaries using an opt-out method of enrollment only. (2) Sponsors must target beneficiaries for enrollment in the MTM program at least quarterly during each plan year.

General Requirements of Required MTM Services: Sponsors must offer a minimum level of MTM services to all eligible beneficiaries: (1) interventions for beneficiaries and prescribers; (2) an annual comprehensive medication review (CMR) -interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider for the beneficiary with an individualized, written summary in CMS' standardized format; and, (3) quarterly targeted medication reviews (TMRs) with follow-up interventions when necessary.

CMR Definition: (1) A CMR is a systematic process of collecting patient-specific information, assessing medication therapies to identify medication-related problems, developing a prioritized list of medication-related problems, and creating a plan to resolve them with the patient, caregiver and/or prescriber. (2) A CMR is an interactive person-to-person or telehealth medication review and consultation conducted in real-time between the patient and/or other authorized individual, such as prescriber or caregiver, and the pharmacist or other qualified provider and is designed to improve patients' knowledge of their prescriptions, over-the-counter (OTC) medications, herbal therapies and dietary supplements, identify and address problems or concerns that patients may have, and empower patients to self-manage their medications and their health conditions.

Annual Review: (1) A CMS-approved MTM program is one of several required elements in the development of a Medicare Part D sponsor's bid. (2) Annually, sponsors must submit an MTM program description to CMS for review and approval in the Health Plan Management System (HPMS). (3) CMS evaluates each program description as part of a Part D quality improvement requirement (42 CFR §423.153(d)), to ensure that it meets the current minimum requirements for the program year.

For additional details regarding MTM see: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.html

Data Validation: starting from 2011, CMS has made policy decisions and revisions to improve data validation (DV) guidance and standards/sub-standards to ensure reported data are accurate, reliable, and valid. It is important to note that reporting sections that are used for monitoring only are excluded from DV. CMS only releases data for contracts receiving at least the minimal DV score to pass. More information about the data validation standards can be found at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html.

F. Part D Beneficiary Plan Election and Part D Beneficiary Auto-Assignment Files

The Low-Income Subsidy (LIS) program for the Medicare Part D benefit provides subsidies that reduce or eliminate Part D premiums and deductibles and offers zero or reduced co-payments for low-income beneficiaries. Beneficiaries who qualify for Extra Help include Medicaid dual eligibles, Supplemental Security Income (SSI) recipients, and other low-income beneficiaries[4, 5].

[4] Medicare.gov "Find your level of Extra Help (Part D)." https://www.medicare.gov/your-medicare-costs/help-paying-costs/extra-help/level-of-extra-help.html. Accessed 11/2016.

[5] CMS.gov "Prescription Drug Benefit Manual. Chapter 13 – Premium and Cost-Sharing Subsidies." https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/partdmanuals.html. Accessed 11/2016.

The LIS program also established a strategy of auto- and facilitated enrollment. Under **auto-enrollment**, if a Medicare dual eligible who is deemed to be eligible for the full LIS subsidy does not select a plan, he or she is randomly assigned to a plan that qualifies for the full subsidy of the Part D premium. The **facilitated enrollment** process is similar, but applies to all other beneficiaries who are found to be eligible for LIS[6].

Full premium subsidies are available in plans whose bid for standard Part D coverage was at or below the average in that prescription drug plan (PDP) region. The average premium associated with such bids is called the regional low-income benchmark premium amount.

During the Medicare Part D annual open enrollment period from October 15 to December 7, Medicare Part D beneficiaries can review and compare stand-alone prescription drug plans (PDPs) and Medicare Advantage plans (MA-PDs) and switch plans if they choose. Beneficiaries who are eligible for the full LIS will pay zero premiums if they are enrolled in an at- or below-benchmark plan. If they enroll in above-benchmark plans, they are responsible for paying the amount of the premium above the benchmark. Because benchmarks are recalculated on an annual basis, some plans may be at or below the benchmark in one year but not in the following year. Any full subsidy beneficiary who was originally auto/facilitated enrolled into one of these plans is **reassigned** by CMS to another plan that will be at or below the benchmark in the following year, unless the beneficiary opts to stay in the original plan or selects a different plan[7].

Passive enrollment is a process by which a beneficiary is informed that he or she will be considered to have made a request to enroll in a new Part D plan by taking no action. Passive enrollment is permitted by CMS in specific, limited circumstances generally associated with either immediate plan terminations or in other situations where CMS determines that remaining enrolled in the plan would pose potential harm to members. Passive enrollment must follow rigorous procedures to ensure beneficiaries retain their rights, including opting out and choosing other Medicare options[8].

In some parts of the US, beneficiaries may be enrolled either voluntarily or through passive enrollment, into **CMS' Financial Alignment (FA) Demonstration** for Medicare-Medicaid enrollees[9]. In **passive enrollments**, the State or CMS notifies the Medicare-Medicaid dually

[6] CMS.gov https://www.cms.gov/Medicare/Prescription-Drug-Coverage/LimitedIncomeandResources/downloads/11186.pdf. Accessed 11/2016.

[7] CMS.gov Medicare. Low Income Subsidy for Medicare Prescription Drug Coverage. "Reassignment." https://www.cms.gov/Medicare/Eligibility-and-Enrollment/LowIncSubMedicarePresCov/Reassignment.html. Accessed 11/2016.

[8] CMs.gov "Medicare Prescription Drug Benefit Manual. Chapter 3. Eligibility, Enrollment, and Disenrollment." (updated Aug. 2014) https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicarePresDrugEligEnrol/Downloads/CY-2015-PDP-Enrollment-and-Disenrollment-Guidance.pdf. Accessed 11/2016.

[9] CMS.gov "Medicare=Medicaid Plan Enrollment and Disenrollment Guidance. Released on: June 14, 2013." https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MMPFinalEnrollGuidance.pdf. Accessed 11/2016.

eligible individual that he or she will be considered to have made a request to enroll in a Medicare-Medicaid Plans (MMP) by taking no additional action.

Medicare's Limited Income Newly Eligible Transition (**LINET**) Program, effective January 1, 2010, provides temporary Part D prescription drug coverage for low income Medicare beneficiaries not already in a Medicare drug plan[10].

LIS Part D plan enrollees (i.e., those who qualify for Extra Help, including those in MMPs), unlike non-LIS enrollees, are also permitted to switch plans at any time outside the annual open enrollment period.

Two research identifiable files, the "Part D Beneficiary Plan Election File" and the "Part D Beneficiary Auto-Assignment File", have been created utilizing information from the "Part D Enrollment Type Code" variable in the Medicare enrollment database. These files provide researchers with information required to identify LIS beneficiaries subject to the auto-assignment and reassignment policies. The key information in this data file is obtained from the Part D Enrollment Type Code, which is associated with each change in the beneficiary's Part D plan.

Values for the **Part D Enrollment Type Code are:**

A = Part D Auto Enrolled by CMS
B = Beneficiary Election (Beneficiary Made Plan Choice)
C = Part D Facilitated Enrollment by CMS
D = System Generated Enrollment (Rollover)
E = Plan Submitted Auto Enrollment
F = Plan Submitted Facilitated Enrollment
G = Point of Sale (POS) submitted enrollment (i.e., pharmacy enrolled beneficiary in a LINET plan)
H = CMS or Plan Submitted Re-assignment Enrollment
I = Assigned to Plan Submitted Transactions with Enrollment Source Other than any of the Following: B, E, F, G, H and blank
J = State Submitted Passive Enrollment
K = CMS Submitted Passive Enrollment
L = Financial Alignment (FA) Demonstration Beneficiary Election

The files are partitioned into two annual files, starting with the onset of the Part D benefit in 2007. Data dictionaries are available on the ccwdata.org website.

1. Part D Beneficiary Plan Election File

The "Part D Beneficiary Plan Election File" provides detailed information on Part D plan enrollment transactions including the reasons why beneficiaries were enrolled in specific

[10] CMS.gov "Medicare Limited Income NET Program." Medicare Limited Income NET Program - Centers for Medicare & Medicaid Services. Accessed 11/2016.

plans (as indicated by the Part D Enrollment Type Codes). There are 9 variables in the Part D Beneficiary Plan Election data file.

The source data contain separate records for each plan to which the beneficiary was enrolled – even if multiple selections were made prior to the benefit year (i.e., even if they were never the valid/active plan, these choices would be recorded in the source data).

There is at least one record for each beneficiary enrolled in Part D during the reference year (aka Part D benefit year). There are additional rows of data when more than one plan election occurred during the reference year. Note that there may be circumstances when a beneficiary has a record in the file, yet the beneficiary was never actively enrolled in Part D for the benefit year (i.e., a Part D plan selection was made, but it did not result in Part D coverage for any month of the benefit year).

2. Part D Beneficiary Auto-Assignment File

The "Part D Beneficiary Auto-Assignment File" contains a single summary row for each Medicare Part D enrolled beneficiary that indicates whether the beneficiary was in a plan in the year due to an auto-enrollment or a re-assignment or whether the beneficiary chose his/her own plan. There are 7 variables in the data file.

These files may be used in combination with our other CCW data files – such as the Master Beneficiary Summary File (MBSF ABCD segment), when joined by the BENE_ID. The Part D plan and contract ID are included in the MBSF. In addition, the Part D plan and contract IDs can be joined to the Plan Characteristics File to obtain detailed information regarding the plan benefit package.

G. Limitations

Plan Characteristics Files and the Formulary Characteristics File may be missing a small number of plans or contracts which appear on either PDE or in the MBSF. There are a few reasons why this might occur: 1) if the plan sponsor is waived from providing plan benefit information to CMS (e.g., employer direct plans, PACE plans), 2) if there was not a valid link between the plan appearing on the PDE and a plan ID in the source HPMS data, or 3) the version of HMPS data used in CCW is the end-of-the year snapshot. A small number of Part D contracts are terminated during the course of the year, and may not be captured in this annual source data file although the contract appears on the PDE.

All PDEs have a formulary ID; however some PDEs will not have formulary drug IDs (FRMLRY_RX_ID). Missing FRMLRY_RX_IDs occur for PDEs which do not appear in the plan's formulary (e.g., over-the-counter, or excluded drugs that are not covered by the plan), drugs that were removed or added to formularies through the year but weren't captured in our end-of-the-year file, and branded generics where the brand listed in the formulary doesn't correspond with what beneficiaries actually purchased.

Chapter 4. CCW Part D Sample Population

The CCW Part D data are available for services beginning January 1, 2006 through the most current year of Medicare data available. Researchers have tremendous flexibility to define a study cohort, as 100% of Medicare enrollment and PDEs are loaded to CCW.

The standard CCW PDE file includes events for a random 10% or 20% of Medicare Part D beneficiaries, as well as the standard 5% Medicare sample. Not all Medicare beneficiaries have Part D coverage, as it is an optional benefit (refer to CCW data regarding proportion of Medicare enrollees who obtain Part D coverage: Table F.1 at https://www.ccwdata.org/web/guest/medicare-tables-reports). However, all beneficiaries who are dually enrolled in Medicare and Medicaid have Part D coverage. The health status and prescription drug needs of beneficiaries enrolled in Part D may not be representative of all Medicare beneficiaries.

Researchers may define their own study cohort or population of interest to be extracted from the PDE. Researchers may choose to select a sample using finder files of populations previously studied, cohorts of beneficiaries with certain conditions or treatment patterns, users of certain prescription drugs, or unique cohorts defined by the researcher.

The 20% sample includes those eligible and enrolled for Medicare Part D on or after January 1, 2006 through the most current period covered by the release, who had a Health Insurance Claim (HIC) number equal to the Claim Account Number (CAN) plus Beneficiary Identity Code (BIC) (HIC=CAN+BIC) where the last digit of the CAN is either a 0 or 5. The 10% sample is a subset of the 20% sample, which includes Medicare Part D enrollees where the last 2-digits of the CAN are: 05, 20, 45, 70, 95, 10, 35, 60, 85, or 00.

Medicare beneficiary Health Insurance Claim numbers (HICs) are removed from the data files delivered to researchers (unless otherwise specified/approved in the Data Use Agreement). A unique CCW beneficiary identifier is included in each data file delivered as part of the output package, thus allowing linkage of an individual's data across data files. Additional details regarding the CCW beneficiary identifier can be found in Chapter 5 – Linkage of the CCW Data and Data Limitations. If a researcher needs to obtain the HIC in order to link to outside data sources or extract claims not part of the CCW database, then the researcher must submit justification for this information in the study protocol as part of the data request application packet. The HIC to CCW beneficiary identifier crosswalk would be delivered as a separate file.

Requests for control populations or comparison groups should be made at the time of the initial data request. The inclusion/exclusion criteria for the control population should be specified by the researcher completing the data request form. The standard, modified standard, or custom definitions explained above for research populations can also be applied to control populations. Alternatively, the researcher can request a control population lacking in any particular drug use, if desired. Researchers can request a standard sample or customize the control population as

needed. Specifications should include type(s) of data files, applicable drug codes, diagnosis or procedure codes or DRGs, time periods, and any related demographic selection criteria.

Chapter 5. Linkage of CCW Data and Data Limitations

A. CCW Beneficiary Identifiers

The unique CCW beneficiary identifier field (variable called BENE_ID) is specific to the CCW (not applicable to any other identification system or data source). This identifier is encrypted prior to delivering the data files to researchers. In addition, all data files delivered to researchers are encrypted (see Encryption Information in Chapter 6 for details). Each research request employs a different encryption key for the beneficiary identifier field and the data files.

For each Medicare beneficiary enrolled and eligible for Medicare during the given time period, a unique CCW identifier provides a common link across all applicable types of data available. Based on the approved research request, the CCW data delivered may or may not include any patient identifying information beyond the CCW beneficiary ID. Regardless of whether patient identifying information is included, the unique patient identifier provides researchers with the ability to analyze information across the continuum of care for a particular beneficiary or chronic condition cohort.

The unique CCW BENE_ID is created from the Medicare unloaded enrollment database (EDB) file, using the EDB Link Number, HIC number, and other beneficiary identifiers (i.e., gender, Social Security Number [SSN], date of birth). Analysis is performed to ensure that the beneficiary is not represented multiple times in the CCW HIC history table. If the beneficiary already exists in the CCW HIC history table, the table is updated with the new HIC information corresponding to the existing CCW BENE_ID. If they do not already exist in the CCW HIC history table, the record will be added and the beneficiary will be assigned a new unique CCW BENE_ID. All cross reference records for this beneficiary will be assigned this unique ID.

B. Part D Identifiers

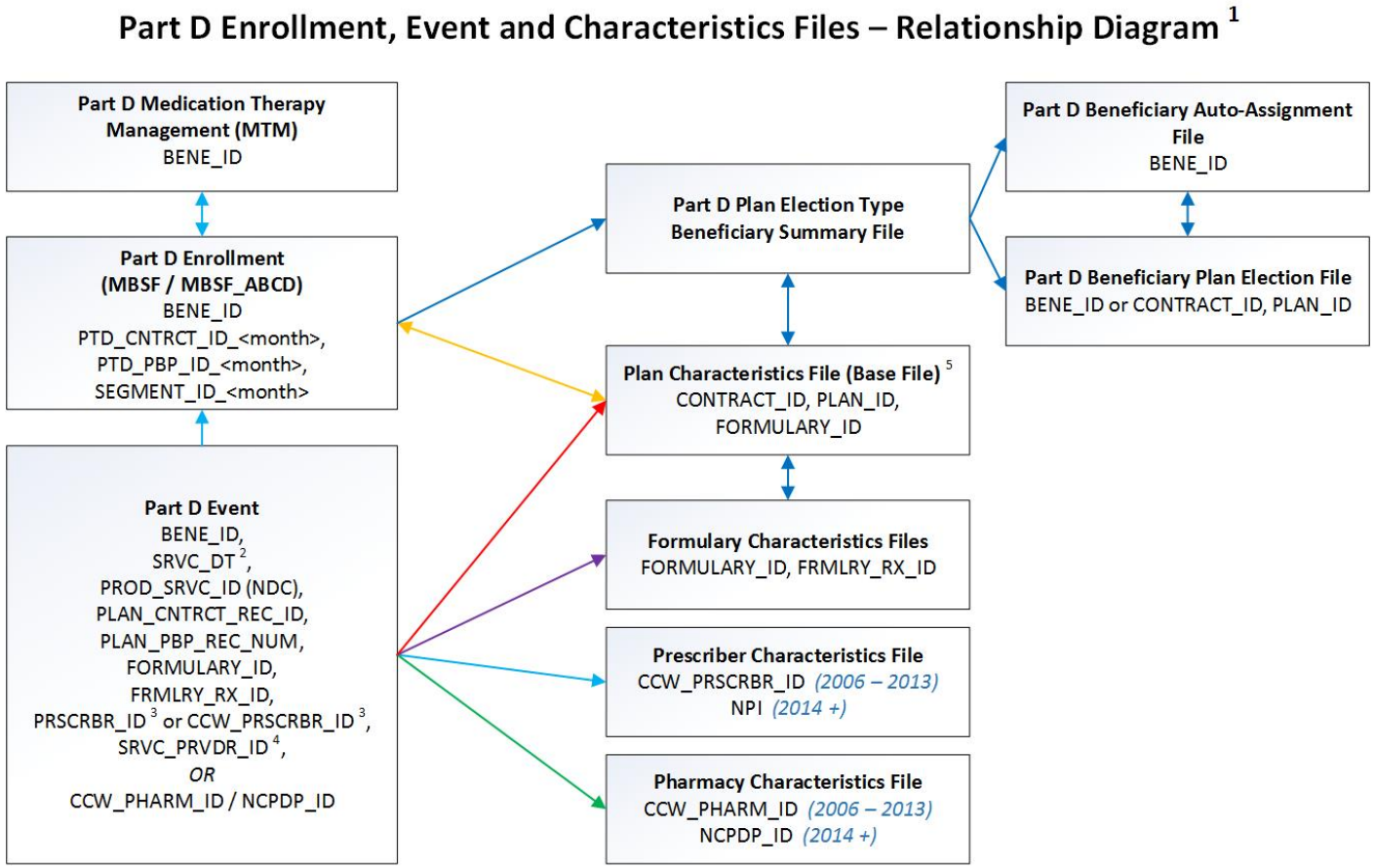
Identifiers appearing in the PDE data or in the Part D Characteristics data files include the contract ID, plan ID, segment ID, and formulary ID – which were always encrypted prior to 2013 in accordance with CMS privacy regulations. The CCW formulary drug identifier (FRMLRY_RX_ID) is a CCW-created identifier that describes the particular drug that was dispensed using information under a special license with FDB. As a CCW-specific variable, this is not applicable or linkable to any other data file.

Additional identifiers are the pharmacy identifier (variable called SRVC_PRVDR_ID) and the prescriber identifier (variable called the PRSCRBR_ID), which could not be released prior to 2013; instead, CCW-created identifiers were used (variable called the CCW_PHARM_ID and the CCW_PRSCRBR_ID), which were not designed to link to any data outside the CCW. For data files 2006 – 2013, investigators must decide whether to obtain the prescriber and pharmacy

identifiers as they appear on the PDE; alternatively, the CCW prescriber identifier (variable called CCW_PRSCRBR_ID), and/or the CCW pharmacy identifier (CCW_PHARM_ID) must be obtained if the corresponding Characteristics Files are requested. Starting in 2014, the CCW-created identifiers were retired, and the actual prescriber identifier on the PDE (PRSCRBR_ID) could be obtained along with the Prescriber Characteristics File. Investigators must decide whether to obtain the actual pharmacy identifier on the PDE (SRVC_PRVDR_ID) or the NCPDP_ID; only the latter will link with the Pharmacy Characteristics File.

Please refer to Figure 4 below, for a schematic illustrating which data elements are key linkage fields for each Part D file.

Figure 4. Part D Files – Relationships and Linkage



[1] Only key variables are listed.

[2] Use SRVC_DT on PDE to identify the applicable monthly plan/contract variables (which appear in the Part D Enrollment Segment).

[3] Beginning in 2014, PRSCRBR_ID will link to NPI in the CCW Prescriber Characteristics Files; prior to 2014, the CCW_PRSCRBR_ID was necessary to link to the CCW Prescriber Characteristics Files.

[4] SRVC_PRVDR_ID will not link to CCW Pharmacy Characteristics Files; the CCW_PHARM_ID or NCPDP_ID must be used.

[5] Starting in 2015 the Plan Characteristics Files include all Part C and D plans.

C. Data Limitations

There are certain expected anomalies in working with large, national, administrative datasets. Minimal data cleansing has occurred during processing of CCW Part D data. However, some of the known limitations of CMS or CCW data are described below. Furthermore, the Part D benefit began in 2006, and standardization of processes and data files has occurred over time (generally speaking, 2011 contain fewer anomalies than 2006 data). The 2006 data may be unreliable for certain research purposes, for example, looking at some of the plan or payment data fields; however the PDE accurately reflect the drugs received through the Medicare Part D benefit.

Although Part D data exist for both managed care and fee-for-service enrollees, Medicare Part A and B claims are not available for beneficiaries enrolled in managed care plans prior to 2015 (note that Managed care encounter data is available for people enrolled in Medicare Advantage [MA] plans in 2015). For researchers wishing to understand the relationship between clinical conditions and treatment utilization and drugs – the subset of beneficiaries with Medicare Parts A/B/D data may be desired. The Medicare coverage information is available in the MBSF_ABCD file.

Some of the CCW data files may contain invalid values, or values not conforming to the valid values provided in the CCW supporting documentation. The CCW data files contain data as received and processed from the original CMS processing source. Invalid values are processed, stored, and delivered as they are received. No modifications or conversions are made to "correct" for invalid variable values.

Chapter 6. Content, Format, and Encryption of CCW Output Files

This section describes the content and format of the CCW Part D output package (the CCW data that are delivered to researchers). The files that are delivered to the researcher are organized in the following format. Descriptions of each of these items are detailed in the tables that follow.

File	File Description
readme_first_req000_20141.txt	This is a text file that describes the files contained in the output package. File Name Example: readme_first_req232_2014.txt
res000011111req000232_2014_PDE.exe (beginning in 2012, this file name ends with *_PDE rather than *_PDES, corresponding with the change in the SAF data source)	This is the executable that must be run to decrypt and uncompress the PDE data file. In this example, 11111 is the Data Use Agreement (DUA) number, 232 is the request number, and 2014 is the year of the data. This executable includes v8 SAS read-in programs, the .dat file, and .fts file which contains the layout and record counts.
res000011111req000232_2014_MBSFABCD.exe	This is the executable that must be run to decrypt and uncompress the Part ABCD Segment of the MBSF. In this example, 11111 is the Data Use

File	File Description
	Agreement (DUA) number, 232 is the request number, and 2014 is the year of the data. This executable includes v6 and v8 SAS read-in programs, the .dat file, and .fts file which contains the layout and record counts.
Plan Characteristics Files*†	
plan_char_2014.dat plan_char_2014.fts plan_char_2014_ readin.sas plan_char_formats_2014.sas	This set of files includes the plan benefit base characteristic .dat (data) file, .fts (layout and record counts) file, and version 8 SAS read-in programs.
premium_2014.dat premium_2014.fts premium_2014_readin.sas	This set of files includes the plan premium .dat (data) file, .fts (layout and record counts) file, and version 8 SAS read-in programs.
tier_2014_.dat tier_2014.fts tier_2014_readin.sas	This set of files includes the plan cost share tier .dat (data) file, .fts (layout and record counts) file, and version 8 SAS read-in programs.
service_area_2014.dat service_area_2014.fts service_area_2014_readin.sas	This set of files includes the plan service area .dat (data) file, .fts (layout and record counts) file, and version 8 SAS read-in programs.
plan_crosswalk_2014.dat plan_crosswalk_2014.fts plan_crosswalk2014_readin.sas	This set of files includes the plan crosswalk .dat (data) file, .fts (layout and record counts) file, and version 8 SAS read-in programs.
Formulary Characteristics Files	
formulary_2014.dat formulary_2014.fts formulary_2014_readin.sas	This set of files includes the formulary base .dat (data) file, .fts (layout and record counts) file, and version 8 SAS read-in programs.
Excl_drugs_2014.dat Excl_drugs_2014.fts Excl_drugs_2014_readin.sas	This set of files includes the excluded drug.dat (data) file, .fts (layout and record counts) file, and version 8 SAS read-in programs.
OTC_drugs_2014.dat OTC_drugs _2014.fts OTC_drugs _2014_readin.sas	This set of files includes the OTC drug.dat (data) file, .fts (layout and record counts) file, and version 8 SAS read-in programs.
Pharmacy Characteristics Files*	
pharm_char_2014.dat pharm_char_2014.fts Pharm_char_2014_readin.sas	This set of files includes the pharmacy characteristic .dat (data) file, .fts (layout and record counts) file, and version 8 SAS read-in programs.
Prescriber Characteristics Files*	
prscrbr _char_2014.dat prscrbr_char_2014.fts prscrbr_char_2014_readin_v8.sas	This set of files includes the prescriber characteristic .dat (data) file, .fts (layout and record counts) file, and version 8 SAS read-in programs.
Medication Therapy Management (MTM) Files	
part_d_mtm_2014.dat part_d_mtm_2014.fts part_d_mtm_2014_readin_v8.sas	This set of files includes the MTM .dat (data) file, .fts (layout and record counts) file, and version 8 SAS read-in programs.

File	File Description
Part D Beneficiary Plan Election and Part D Beneficiary Auto-Assignment Files	
ptd_bene_plan_elctns_000011111_req000232_2014.fts ptd_bene_plan_elctns_000011111_req000232_2014.dat ptd_bene_plan_elctns_read_v8.sas lis_reassign_chooser_000011111_req000232_2014.fts lis_reassign_chooser_000011111_req000232_2014.dat lis_reassign_chooser_read_v8.sas	This set of files includes the Part D Beneficiary Plan Election File and the Part D Beneficiary Auto-Assignment File .dat (data) file, .fts (layout and record counts) file, and version 8 SAS read-in programs.

* Beginning with 2010 "Characteristics Files", only the SAS v8 read-in statements are provided. Previously, the file extension would specify"_readin_v6.sas" or "_readin_v8.sas".
† Starting with 2015, Plan Characteristics Files include all Part C and D Plans and a SNP file is included (i.e., six files comprise Plan Characteristics rather than 5 files). Plan Files are no longer considered Part D files (since they apply more broadly to all Part C/D plans). Requests for the revised Plan Characteristics files will require and updated code on your Data Use Agreement.

In addition to the specific data files the researcher requested, CCW includes a variety of resource files in the deliverable package. These files are described below.

File	Description
Code Reference Sets.xls	Code lists for ICD-9/ICD-10 diagnosis and procedure codes, HCPCS codes, Revenue Center and other codes contained in the extracted files.
Decryption Instructions.pdf	This document contains instructions for decrypting/uncompressing the data files.
Tips on Getting Started with Data.pdf	This document contains tips on getting started with CCW data.

The encryption technique for files extracted from the CCW uses Pretty Good Privacy (PGP) Command Line 9.0 with the Self-Decrypting Archive (SDA) method. This method builds a compressed, encrypted, password protected file using a FIPS 140-1/140-2 approved AES256 cipher algorithm. The SDA is built on the CCW production server, downloaded to a desktop PC, and burned to a CD, DVD, or USB hard drive depending on the size of the files.

After the data media is shipped to the researcher, the password to decrypt the archive is sent to the researcher by electronic mail. Each researcher request will have a unique encryption. The password and the data media will never be packaged together. To decrypt the data files, the researcher will need to access the e-mail containing the decryption password. Detailed instructions for using this password are included with the data.

The CCW beneficiary identifier field (BENE_ID) is specific to the CCW (not applicable to any other identification system or data source). All requested data are linked using this field. It is encrypted using a Buccaneer-developed cipher prior to delivery of data files to researchers. The PDE_ID is also be encrypted using the same cipher since these identifiers are also unique to a beneficiary. (These fields will not be decrypted upon receipt by the researcher. Rather it is intended that the encrypted BENE_ID will be used by the researcher to link the data and the encrypted PDE_ID will be used to identify records from the same claim).

The cipher used is unique for each DUA and is determined at the time the data are requested. This key is then kept on file for future use if requested by a researcher and approved by CMS. A researcher may decide to stipulate in a new DUA that the data obtained must be linked to that obtained from a previous DUA. CMS will then evaluate and approve or disapprove the request. If approved, the data obtained from the CCW will be encrypted using the same cipher as the previous DUA allowing data from both requests to be linked. CCW-assigned Prescriber, Pharmacy, and formulary drug IDs are not encrypted; however they are specific to the CCW and cannot be linked to any other data source.

Chapter 7. Further Assistance with CCW Data

Researchers interested in working with CCW data should contact the Research Data Assistance Center (ResDAC). They offer free assistance to researchers using Medicare data for research. The ResDAC web site 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 web site at http://www.resdac.org for additional information.

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

In the event that a ResDAC technical advisor is not able to answer the question, the technical advisor will direct the researcher to the appropriate person. If additional CMS data (data not available from the CCW) is required to meet research objectives, or the researcher has any questions about other data sources, the researcher should first visit the ResDAC website.

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Appendix A. Acronyms and Abbreviations

BIC	Beneficiary Identity Code; part of the Medicare HIC identifier
CAN	Claim Account Number; part of the Medicare HIC identifier
CME	CMS Common Medicare Environment
CMS	Centers for Medicare & Medicaid Services; part of the U.S. Department of Health and Human Services which administers the Medicare program
CCW	Chronic Condition Data Warehouse; only source for researchers to obtain Medicare Part D data
DEA	Drug Enforcement Agency; collects information regarding prescribers as part of the Controlled Substances Act
DUA	Data Use Agreement delineates the confidentiality requirements of CMS regarding the Privacy Act and data release policies
EDB	Enrollment Database; master file at CMS which indicates Medicare eligibility and enrollment
ESRD	End Stage Renal Disease
FDB	First Databank; proprietary database which may contains a wide variety of drug information; a subset of prescription drug descriptors are available along with the PDE file, through a special licensing agreement
FEHB	Federal Employee Health Benefits Program
HCIdea®	A prescriber database from NCPDP which contains a variety of prescriber information; CCW uses this vendor's file as a primary source to describe the prescriber characteristics
HIC	Health Insurance Claim number; unique Medicare beneficiary identification number
HPMS	Health Plan Management System; CMS-owned database application which Part D plans are required to use to submit contract information, plan benefit package data, and formulary files for CMS approval for each benefit year
ICL	Initial Coverage Limit for the Part D benefit; also referred to as the coverage gap

LEP	Late Enrollment Penalty; premium adjustment added by Medicare for beneficiaries who enroll in the Part D benefit after a period of Part D eligibility with no other form of credible coverage
LINET	Limited Income Newly Eligible Transition; point-of-sale facilitated enrollment Part D plan for LIS beneficiaries
LIPS	Low-Income Premium Subsidy
LIS	Low-Income Subsidy; provides assistance to certain low-income individuals to supplement the premium and cost-sharing (including deductibles and cost-sharing during the coverage gap) associated with the Part D benefit
MA-PD	Medicare Advantage Prescription Drug plan; managed care health and Part D drug coverage
MBSF	Master Beneficiary Summary File; Medicare enrollment data file which contains "segments" or clusters of variables related to Medicare A, B, C & D
MMA	Medicare Modernization Act of 2003
MMP	Medicare-Medicaid Plan; CMS Medicare-Medicaid Coordination Office demonstration program that allows states to begin enrolling participants in 2015
MTM	Medication Therapy Management; CMS requires Part D plans to offer MTM to beneficiaries using multiple prescriptions or high cost prescriptions.
NCPDP	National Council for Prescription Drug Programs; CCW uses the dataQ™ file product from this vendor to describe pharmacy characteristics; in addition, the HCIdea® prescriber database, used as a source for CCW prescriber characteristics, is an NCPDP product
NDC	National Drug Code; in the PDE record layout the variable is called the product service ID
NPI	National Provider Identifier; CMS-required identification number
NPPES	National Plan and Provider Enumeration System; CMS system whereby providers apply for and maintain information regarding their NPI
OTC	Over-The-Counter drugs; medications which do not require a prescription; may appear in the PDE file if covered on the plan's formulary (2011 forward)
PACE	Programs of All-inclusive Care for the Elderly
PDE	Prescription Drug Event

PDP	Prescription Drug Plan; stand-alone prescription drug plan (e.g., not offered as part of a managed care plan MA-PD)
PPO	Preferred Provider Organization
QDWI	Qualified Disabled and Working Individual (eligibility category for state-reported dual eligible status)
QI	Qualifying Individual under a State's Medicaid plan (eligibility category for state- reported dual eligible status)
QMB	Qualified Medicare Beneficiary (eligibility category for state- reported dual eligible status)
RDS	Retiree Drug Subsidy
ResDAC	Research Data Assistance Center
RXCUI	National Library of Medicine RxNorm Concept Unique Identifiers
RxNorm	A normalized naming system for generic and branded drugs produced by the National Library of Medicine (NLM)
SAF	Standard Analytic File; term used to describe a CMS data product which meets certain standardized specifications, which vary by type of data file (e.g., Medicare Part D SAF versus Medicare inpatient SAF)
SLMB	Specified Low Income Medicare Beneficiary (eligibility category for state-reported dual eligible status variable)
SNP	Special-Needs Plans
SPAP	State Pharmaceutical Assistance Programs
SSI	Supplemental Security Income beneficiaries, as reported by states, indicates entitlement to Medicare and concurrent eligibility for a Title XIX benefit (i.e., Medicaid or a Medicare Savings Program)
TRICARE	Health insurance benefit offered through Department of Defense, formerly known as the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)
UM	Utilization Management
UPIN	Unique Physician Identification Number; legacy CMS provider ID system – used prior to July 2007
VA	Veteran's Administration