Chronic Conditions Warehouse

Your source for national CMS Medicare and Medicaid research data

Chronic Conditions Warehouse Virtual Research Data Center

Medicare Part D Data User Guide

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Revision Log

Date	Changed by	Revisions	Version
March 2025	D. Happe	Edits made to comply with Executive Order 14168	6.4
October 2024	K. Schneider	Added explanation for new fields in plan SNP contracts file; added "Beginning with 2023 data" to the "Changes in PDE data over time" section of the document	
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Overview

The Medicare Prescription Drug, Improvement, and Modernization Act MMA of 2003 (MMA, Section 101) authorized the Medicare Part D prescription drug benefit. The Medicare prescription drug benefit, a voluntary benefit offered through 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 Conditions Warehouse (CCW) contains all Part D events, regardless of whether the beneficiary selected a managed care plan that includes coverage for prescription drugs or a standalone prescription drug plan. Beneficiaries who qualify for both Medicare and Medicaid (full-benefit dual eligibles) will automatically receive the Medicare drug benefit. The MMA also provides 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 the beneficiary-related 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. 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 is a research database that 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 CCW data does not limit itself to those with a chronic condition. The CCW system contains data for Medicare enrollment/eligibility, fee-for-service (FFS) institutional and non-institutional claims for 1999 forward, and, starting with 2015, managed care encounter data is available for beneficiaries enrolled in Medicare Advantage (MA) plans. The Data Dictionaries tab on the CCW website contains information for this file. The CCW also contains nursing home assessment data (i.e., Minimum Data Set [MDS], Outcome and Assessment Information Set [OASIS], swing bed assessments, and Inpatient Rehabilitation Facility Patient Assessment Instrument [IRF-PAI]) from January 1, 1999, forward. The CCW team disseminates Medicaid eligibility and claims data from 1999 through 2013, which are available to researchers as the Medicaid Analytic eXtract (MAX) data files, and starting in 2014, delivers the Medicaid data as Transformed Medicaid Statistical Information System (T-MSIS) Analytic Files (TAF).

Academic researchers and certain government agencies with approval under a Data Use Agreement (DUA) may request Research Identifiable Files or RIFs. The CCW Medicare data contain

identifiable information and are subject to the Privacy Act and other federal government rules and regulations; reference the Research Data Assistance Center (ResDAC) website for information on requesting Medicare data.

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

¹US Department of Health and Human Services. CMS. 42 CFR Parts 417, 422, 423, et al., Reference the <u>Federal Register CMS</u> <u>Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Final Rule</u> (Accessed 10/25/2024)

² CMS has phased out MAX. The last calendar year that uses the MAX data format for all states is 2013. States have converted to Transformed Medicaid Statistical Information System (T-MSIS).

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 reference the <u>condition algorithm documentation</u> on the CCW website for more information. Researchers or analysts may also request data 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 https://www.resdac.org/.

This manual provides users with information that may be helpful in understanding and analyzing the CCW Part D data. A list of abbreviations found in this document appears in Appendix A — Acronyms and Abbreviations.

Chapter 1 — Medicare Part D Enrollment Data

Private plans (a.k.a. plan sponsors) provide all Medicare Part D prescription drug benefits. Part D plans are either stand-alone prescription drug plans (PDPs) or Medicare Advantage Prescription Drug Plans (MA-PD). The MA-PD integrates the prescription drug coverage with the healthcare coverage they provide to Medicare beneficiaries under Part C.

The Master Beneficiary Summary File (MBSF) contains the Medicare Part D enrollment data and delivers it 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 and those enrolling in standalone prescription drug plans). Information is also available for Medicare beneficiaries who did not obtain Part D coverage. The <u>Data Dictionaries</u> tab of the CCW website describes the variables contained within each CCW data file.

Note that through 2015, the original MBSF-Part D segment used the CMS Enrollment Database (EDB) as the source. For this legacy MBSF, there were sometimes timing differences when CMS updated its data sources with Part A and B coverage versus Part D enrollment information. As a result, there was 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 has used the CMS Common Medicare Environment (CME) as its source and this issue no longer exists in the current MBSF.

Part D plan sponsors have the 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. MMA, Section 101 also provides 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.

The CMS website at https://www.cms.gov/Medicare/Prescription-Drug-

Coverage/PrescriptionDrugCovContra/PartDManuals.html contains additional information regarding Part D coverage options. Beneficiaries enroll in a plan for a calendar year, with open enrollment occurring annually from October 15—December 7. There is a late enrollment penalty for those eligible for Part D who choose not to enroll for any given year and who 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: employer-based prescription drug coverage, such as the Federal Employees Health Benefits Program (FEHB); qualified State Pharmaceutical Assistance Programs (SPAPs); military-related coverage (e.g., Veterans Administration [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.

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 they had some form of creditable coverage. <u>Table 1</u> lists the key Part D enrollment and coverage variables contained in the MBSF_ABCD.

Table 1. Part D enrollment and coverage variables

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 preferred provider organization (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 Medicare deems the beneficiary 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 if Medicare should subsidize the plan for the beneficiary (12 monthly occurrences).
DUAL_STUS_CD_{MM}	State reported dual eligible status code (01–12)	Monthly indicator of dual eligibility status; where the beneficiary enrolls 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 plan entitles the retiree drug subsidy for a 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 MBSF-A/B/C/D codebook, available on the CCW website.

Part D contract ID — this field is the contract number for the Part D plan selected by the beneficiary (if any). 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 that indicates the type of plan:

- E = Employer direct plan (starting January 2007)
- H = Managed care organizations other than a regional PPO (i.e., local MA-Prescription Drug (MA-PD) plans, 1876 cost plans, Program of All-Inclusive Care for the Elderly (PACE) plans, private fee-for-service plans, or demonstration organization plans)
- R = Regional PPO
- S = Standalone PDP
- X = Limited Income Newly Eligible Transition plan (LINET)
- N = Not Part D enrolled
- 0 = Not Medicare enrolled for the month
- Null/Missing = Enrolled in Medicare A or B, but the beneficiary has no Part D enrollment data

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, CMS began designating employer/union-only direct contract plans with a plan type of "E." Researchers may identify the employer direct plans through the 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 PBP offered (e.g., silver and platinum-level benefits). There are 12 monthly occurrences of this field. Researchers can link this information to the Part D plan characteristics data to better understand the nuances of the benefit available through the plan (reference 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. Researchers can link this information to the Part D Plan characteristics data (reference <u>Chapter 3</u>).

Part D low-income cost-share group — the Part D benefit includes cost-sharing provisions. The low-income subsidy (LIS) program allows State Medicaid and other government-sponsored subsidized premiums and copayments/coinsurance for low-income individuals. Additionally, the Part D benefit allows for means-testing. The LIS assists 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. Medicaid may also provide subsidies to employers to cover eligible beneficiaries. Researchers will find all of these cost-sharing provisions indicated within this variable. There are 12 monthly occurrences of this field. Researchers can find additional details regarding the LIS provisions within the Part D benefit on the CMS website at: http://www.cms.gov/MedicarePresCov/.

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. Researchers may use a monthly indicators document to determine whether the beneficiary received retiree drug subsidies. 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). If Medicare entitles an individual, the plan deems them eligible for a full subsidy:

- 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, 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 in Medicare and Medicaid are available in the <u>CCW Technical Guidance Getting Started with CMS Medicare</u>
<u>Administrative Research Files</u> document on the CCW website.

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.

- Retiree drug subsidy (RDS) months for beneficiaries with an 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 original MBSF that used EDB as the source, included the variable indicating that the Part D plan did not enroll the beneficiary, but they had other creditable coverage for any month of the year, e.g., FEHB, TRICARE, VA, SPAP, or active workers (i.e., ESRD, disabled, aged) in 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

Pharmacies submit claims for prescription drugs to the Part D health plans for beneficiaries enrolled in Medicare Part D. CMS receives this information and creates administrative data files called PDE data files. CMS creates the PDE data from point-of-service transactional data at the time the beneficiary fills a prescription. This database does not contain data for prescriptions ordered but not filled (i.e., data are not prescribing data, but rather filled prescriptions).

The CCW database contains all of the Medicare Part D PDE data beginning with the inception of the Part D benefit in 2006. For 2006–2011, the CCW extracted the PDE file from an annual standard analytic file (SAF) with Part D data from CMS. Starting with 2012 data, the CCW created our version of the SAF³ from weekly CMS PDE data files where we applied a SAF final-action process. The shift to a CCW-produced annual PDE file allows CCW to release the Part D event data several months earlier.

The CCW considers all the PDE data disseminated as "final action," meaning the data represents the final status of a drug event record after 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 CMS locks down the PDE file 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 occurred during the benefit year. Researchers should not consider this PDE data final until CMS has completed all of these types of adjustments.

Not all Medicare-enrolled beneficiaries elect to purchase Part D coverage. Plans that receive RDS or are considered to be Part D creditable coverage (e.g., VA, TRICARE, FEHBP) do not submit PDE data.

The CCW obtains the complete PDE record. This includes information such as the specific drug, cost, pharmacy, provider, and benefits information. To obtain a CMS DUA to use the PDE data, CMS requires researchers to select variables based on minimum data necessary and justify the need for each variable.

NOTE: Before the 2013 data release, CMS required the CCW to encrypt or use CCW-assigned ID values to protect the sensitive data fields. These sensitive fields where those researchers could use to identify the beneficiary, the prescriber, the pharmacy, the plan, or the plan's formulary. CMS no longer requires the CCW to encrypt the prescriber, pharmacy, plan, or formulary identifiers. As a result, starting with the 2014 PDE files, researchers should use the National Council for Prescription Drug Programs (NCPDP) identifier (variable called NCPDP ID) in place of the CCW_PHARM_ID as the linkage variable between the PDE and the pharmacy characteristics file. Similarly, the data uses the actual prescriber identifier on the PDE (the PRSCRBR ID) in place of the CCW_PRSCRBR ID.

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

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

⁴ The <u>CCW Medicare Data White Paper</u> *Medicare Claims Maturity* provides additional details regarding final action for PDEs (Accessed 10/25/2024)

A. PDE Variables

Researchers can find a description of the variables in the PDE file on the <u>Data Dictionaries</u> tab on the CCW website. 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 must provide a variable-by-variable justification as part of the data request packet obtained through ResDAC. CMS bases the pricing for the data file on the size of cohort (e.g., 250,000 beneficiaries, 1 million beneficiaries, etc.). There is an additional cost for obtaining the First Databank (FDB) variables which describe the drug; these drug characteristics variables are appended to the PDE.

1. Identifier and Linkage Variables

Some fields contain CCW-assigned unique IDs in lieu of the actual identifiers, some of which CCW encrypts uniquely for each DUA. Refer to <u>Table 2</u>.

Table 2. CCW identifier variables

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

^{*} The CCW uniquely encrypts this field for each DUA.

Historically, CMS considered the plan, prescriber, and pharmacy identifiers sensitive, and the CCW team could not release them before 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 when the pharmacy identifiers on the PDE data before 2014 use the CCW_PHARM_ID, and the data uses the actual NCPDP ID 2014 and later. Table 4 summarizes the changes in Part D data due to this loosening of the regulation.

2. Commonly Used PDE Variables

Product service ID (PROD_SRVC_ID) — this field is the National Drug Code (NDC). Researchers may also select some optional data fields to append to the PDE:

Drug characteristics — through a special licensing agreement with First Databank, CCW can 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. The PDE price does not include these variables; there is an additional fee.

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

Quantity dispensed (QTY_DSPNSD_NUM) — this is the quantity of the drug that the pharmacy dispensed. This field indicates the number of units, grams, milliliters, or other quantities 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 pharmacy dispensed the prescription 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' supply (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.

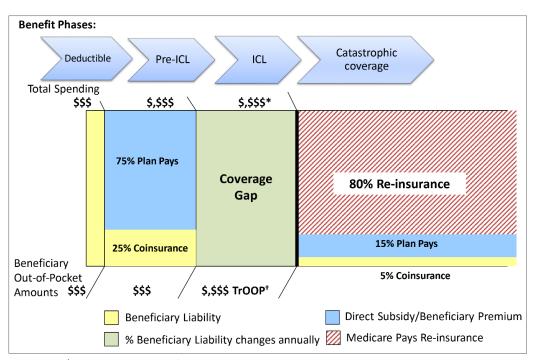
Service date (SRVC_DT) — this is the date on which the pharmacist filled the prescription.

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 that researchers may elect to purchase. Please refer to Figure 1 for an illustration of the standard benefit phases, and Figure 2 for how Medicare altered the ICL phase for 2011 forward. If a Part D plan does not enroll a beneficiary with a defined standard benefit, but rather has an alternative benefit type (e.g., basic alternative or enhanced alternative plan), the benefit parameters used for benefit phase determination may differ from what we illustrate below. For example, alternative plans may have no deductibles or a modified ICL amount that effectively eliminates the coverage gap.

The CCW team identifies the benefit phase determination for every covered PDE 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 Table 3 below Figure 1 or the dollar amounts of these parameters.





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

[†] TrOOP amount; includes beneficiary payments (or payments made on behalf of a beneficiary from a third party) for covered Part D drugs.

Table 3. Part D benefit parameters, through 2023, 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
2006	TrOOP**	\$250	\$750	\$3,600
2007	Total Drug Costs	\$265	\$2,400	\$5,451.25
2007	TrOOP	\$265	\$808.75	\$3,850
2008	Total Drug Costs	\$275	\$2,510	\$5,726.25
2008	TrOOP	\$275	\$833.75	\$4,050
2009	Total Drug Costs	\$295	\$2,700	\$6,153.75
2009	TrOOP	\$295	\$896.25	\$4,350
2010	Total Drug Costs	\$310	\$2,830	\$6,440
2010	TrOOP	\$310	\$940	\$4,550
2011	Total Drug Costs	\$310	\$2,840	\$6,483.72
2011	TrOOP	\$310	n/a	\$4,550
2012	Total Drug Costs	\$320	\$2,930	\$6,730.39
2012	TrOOP	\$320	n/a	\$4,700
2013	Total Drug Costs	\$325	\$2,970	\$6,954.52
2013	TrOOP	\$325	n/a	\$4,750
2014	Total Drug Costs	\$310	\$2,850	\$6,690.77
2014	TrOOP	\$310	n/a	\$4,550
2015	Total Drug Costs	\$320	\$2,960	\$7,061.76
2015	TrOOP	\$320	n/a	\$4,700
2016	Total Drug Costs	\$360	\$3,310	\$7,515.22
2016	TrOOP	\$360	n/a	\$4,850
2017	Total Drug Costs	\$400	\$3,700	\$8,071.16
2017	TrOOP	\$400	n/a	\$4,950
2018	Total Drug Costs	\$405	\$3,750	\$8,417.60
2018	TrOOP	\$405	n/a	\$5,000
2019	Total Drug Costs	\$415	\$3,820	\$8,139.54
2019	TrOOP	\$415	n/a	\$5,100
2020	Total Drug Costs	\$435	\$4,020	\$9,719.38
2020	TrOOP	\$435	n/a	\$6,350
2021	Total Drug Costs	\$445	\$4,130	\$10,048.39
2021	TrOOP	\$445	n/a	\$6,550
2022	Total Drug Costs	\$480	\$4,430	\$10,690.20
2022	TrOOP	\$480	n/a	\$7,050
2023	Total Drug Costs	\$505	\$4,660	\$11,206.28
2023	TrOOP	\$505	n/a	\$7,400

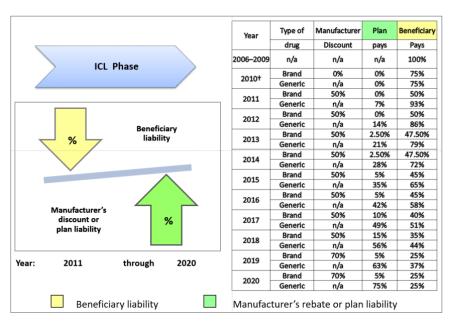
^{*} CMS publishes an annual Medicare Advantage rate announcement that includes updated Part D benefit parameters. Reference https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents

- ** TrOOP costs are beneficiary payments for covered Part D drugs made by the beneficiary, by a third party on behalf of the beneficiary, or by the Part D low-income subsidy.
- † The figures shown for total drug costs are for a beneficiary with no other form of third-party coverage. Starting in 2011, the beneficiary's TrOOP costs include the value of any discounts that beneficiaries receive on brand-name drugs under the Medicare Coverage Gap Discount Program. 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; refer to the CMS website for additional details regarding this program). Beginning in 2011, manufacturers provided a 50% discount on brand-name drugs which the plan applies at the point-of-sale, with those discounts contributing to the beneficiary's TrOOP accumulation. Additional legislation made provisions for Part D sponsors to reduce coinsurance on generic drugs beginning in 2011 and on brand name drugs in 2013.

By 2020, CMS closed the coverage gap, and those beneficiaries enrolled in standard benefit plans had a 25% coinsurance once they met the deductible until their TrOOP reached the catastrophic threshold. A combination of manufactures' discounts (50% for applicable drugs through 2018, and 70% starting with 2019⁵) and increasing plan liability results in these beneficiary coinsurance reductions for brand-name drugs. By 2020, plans 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



^{*} Illustration represents cost-sharing for "applicable beneficiaries."

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

⁵ The Balanced Budget Act of 2018 increased the manufacturer gap discount from 50% to 70%, and reduced beneficiary coinsurance in 2019 to 25%. Refer to "CMS Rate Announcement, 2019" (April 2, 2018). https://www.cms.gov/MEDICARE/HEALTH-PLANS/MEDICAREADVTGSPECRATESTATS/DOWNLOADS/ANNOUNCEMENT2019.PDF (Accessed 10/25/2024)

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 2.

The BENEFIT_PHASE field differs somewhat from the information in the catastrophic coverage code field on the PDE (CTSTRPHC_CVRG_CD). 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., TrOOP balance transfer issues). Beginning in 2011, CMS did not require plans to populate the catastrophic coverage code field.

The two-digit benefit phase variable uses intelligence for both digits. The first digit = benefit phase at the start of prescription fill, second digit = phase once the pharmacy dispenses the drug (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 the date of service. 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 represent 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 how the pharmacist receives the prescription — as an electronic prescription, phone, fax, or written paper copy.

CMS added two additional linkage variables to the PDE: the formulary ID (FORMULARY_ID) and the formulary drug ID (FRMLRY_RX_ID). Using the two variables in combination, researchers can link the PDE data 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 was 96.5% in 2010. The UM variables are present in the 2006–2009 PDE data since CMS had not yet developed the formulary characteristics file. 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). The data includes this amount 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 CMS's final plan-to-plan reconciliation processing for approximately 0.01% of 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

CMS no longer requires the CCW team to encrypt most of the previously encrypted variables. The CCW team delivers Part D plan, contract, segment, and formulary IDs without encryption. The BENE_ID and PDE_ID remain encrypted specifically for each DUA (no change).

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). This last PDE variable explains why nursing homes provided less than a half-month supply of drugs.

Beginning with 2014 data

For the 2006–2013 data years, researchers who are interested in the prescriber identifiers would obtain the CCW_PRSCRBR_ID. Starting with 2014, researchers uses the PRSCRBR_ID variable. Those interested in pharmacy identifiers would obtain the CCW_PHARM_ID from 2006–2013, and the NCPDP_ID for 2014+.

Beginning with 2023 data

CMS added the Other True Out-of-Pocket (TrOOP) Indicator (variable called OTHR_TROOP_AMOUNT_IND) to identify whether the Other TrOOP Amount (variable called OTHR_TROOP_AMOUNT) includes Inflation Reduction Act Subsidy Amount (IRASA) dollars. Effective January 1, 2023, the Inflation Reduction Act (IRA) eliminates the deductible and imposes a statutory maximum beneficiary cost sharing of \$35 per month's supply for Part D covered insulins. In addition, effective January 1, 2023, the IRA eliminates the deductible and imposes a statutory maximum beneficiary cost sharing of \$0 for adult vaccines as recommended by the Advisory Committee on Immunization Practices (ACIP).

CMS defines IRASA as the difference between the beneficiary cost sharing for the covered insulin, or ACIP-recommended vaccine, under the plan's 2023 benefit design, and the applicable statutory maximum cost sharing (\$35 for insulins and \$0 for vaccines). The IRASA is available only for 2023. Additional details are available from CMS (reference: https://www.cms.gov/files/document/irasapdeguidance508g.pdf).

5. Historical PDE Linkage Variables and Encryption

Historically, CMS required several fields encrypted before the 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, the CCW team no longer encrypts these.

Starting with the 2014 data release, the CCW team completed the transition to use unencrypted variables on the PDE. The CCW team re-specified some linkage variables to enable releasing an additional source PDE field. A summary of current and historical linkage variables appears in <u>Table 4</u>. Beginning with 2014 data files, CMS allowed investigators to obtain the prescriber's unique identification number (the PRSCRBR_ID) from the PDE and obtain the CCW prescriber characteristics file. In general, the CMS-assigned National Provider Identifier (NPI) populates 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 proprietary crosswalk. Additional details are available later in this document (refer to Chapter 3). Researchers who receive the PRSCRBR_ID may also select the prescriber identifier

qualifier code (a variable called PRSCRBR_ID_QLFYR_CD), directly from the source PDE. This variable indicates which type of prescriber submitted the identification number on the PDE. However, the CCW analysts have found that this variable is not always accurate, particularly for the early years of the Medicare Part D benefit. For 2006–2013 PDE, researchers should use the CCW_PRSCRBR_ID.

For 2006–2013, the CCW team derived the pharmacy identifier (variable called the CCW_PHARM_ID). Starting with the 2014 data release, researchers should use the NCPDP_ID as a linkage variable between the PDE and the CCW pharmacy characteristics file. Through a special licensing arrangement with the NCPDP for the use of their dataQ[™] product, the CCW can provide researchers with the information in the pharmacy characteristics data file; the NCPDP_ID was the basis for the legacy CCW_PHARM_ID.

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

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

Table 4. Linkage variable changes between PDE and characteristics files with three different identifiers:

Prescriber identifiers

2006–2013 variable name	Description	2014+ variable name	Description	Linkage
CCW_PRSCRBR_ID	CCW-assigned prescriber identifier	PRSCRBR_ID	Prescriber identifier on source PDE (NPI populated)	Links PDE to Part D prescriber characteristic file; may obtain the prescriber bridge file* to crosswalk NPI to CCW_PRSCRBR_ID

Pharmacy identifiers

2006–2013 variable name	Description	2014+ variable name	Description	Linkage
CCW_PHARM_ID	CCW-assigned pharmacy identifier	NCPDP_ID	NCPDP identifier	Links PDE to Part D pharmacy characteristic file; may obtain crosswalk between NCPDP_ID and CCW_PHARM_IDs (available in the pharmacy bridge file†)

Plan and formulary identifiers

2006–2013 variable name	Description	2014+ variable name	Description	Linkage
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	no change	no change‡	Actual identifiers on source Health Plan Management System (HPMS) and PDE data [‡]
FORMULARY_ID	Formulary ID	no change	no change‡	Actual identifiers on source HPMS and PDE data [‡]

- * The CCW team developed the prescriber bridge file to provide information regarding the CCW_PRSCRBR_IDs used from 2006—2013. Additional details regarding this file are available in the (<u>Prescriber Characteristics File</u> section of this document).
- † The CCW team developed the pharmacy bridge file to provide information regarding the CCW_PHARM_IDs used from 2006—2013. The CCW team populates the associated NCPDP_ID. Additional details regarding this file are available in the Pharmacy Characteristics File section of this document.
- ‡ For data files that CCW disseminated before the 2013 data release, the CCW team encrypted these fields 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. PDE data does not include pharmacy claims the sponsor rejected. For example, if a pharmacy submits an original claim to a plan sponsor which the plan sponsor rejects due to a prior authorization requirement and later when the pharmacy meets the authorization criteria, resubmits the sponsor-accepted claim, the sponsor then submits 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 does not submit a PDE record to CMS. Additionally, since the PDE data in the CCW represent "final action," the data includes all PDE adjustments received by CMS through the PDE submission deadline for payment reconciliation, including PDE adjustments, resubmissions, and deletions.

The PDE files do not include all drugs used by Part D enrolled beneficiaries. 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 claims the plan sponsor did not submit (e.g., if a beneficiary pays cash out-of-pocket) are not available. Similarly, the PDE files do not contain free prescription fills offered by pharmacies or manufacturers' samples. In addition, since Part D excludes over-the-counter (OTC) drugs, the PDE files do not typically contain them, 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, CMS does not require some organizations 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 CCW team cannot link the plan information on the PDE to the HPMS plan information (i.e., the CCW Part D plan characteristics file), the CCW team applies the value of "XX" to the benefit phase

1. 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 a pharmacy may have 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 researchers can assume the difference in these amounts 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

The <u>Data Dictionaries</u> tab on the CCW website contains data file layouts and descriptions for each file.

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, CMS had delivered these variables (tier, step therapy, quantity limits, and prior authorization) 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 to the Formulary Characteristics Files section and Figure 3, a linkage diagram.

<u>Chapter 5</u> contains additional information regarding the linkage of data files.

A. Plan Characteristics Files

CMS requires Medicare Part C (i.e., Medicare Advantage [MA] managed care plans) and Part D plan sponsors to submit via the HPMS particular information regarding the structure of the benefit (i.e., PBP) offered to Medicare consumers. CMS can then use this information to help review plan benefits for compliance requirements. Information covers the plan benefit for a calendar year (e.g., plan sponsors must submit so CMS can approve by the October before the start of the new benefit year).

Starting with the 2015 benefit year, the CCW team prepares a Plan Characteristics set of six files per year with detailed information on those plan characteristics. Researchers can join to the MBSF to better understand the benefits available to enrollees. Note that these plan characteristics files enhance 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. Researchers will notice that the CCW team removed a small number of duplicative variables in the Part D plan characteristics "base" file, and other minor changes — which we describe below.

NOTE: To filter the 2015+ plan characteristics file to include only the Part D plans, use the Part C and 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 MA-PDs or PDPs offer this level of coverage, they may also offer supplemental

benefits under enhanced alternative coverage for a supplemental premium. Organizations offering drug plans have flexibility in designing 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 benefits 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 in six files per year (note that for the Part D plan characteristics files 2007–2014, there were five files per year), which researchers can easily join together, or join 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, researchers can use a variable within each of the files (except for the cost-sharing tier file and SNP file — which only include Part D Plans) 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. We describe each of these files 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 how the benefit operated during the last month of the calendar year (as minor adjustments in the benefit might have occurred during the year). CMS and the CCW team name the variables that are the same from year-to-year the same. Also, CCW has made every attempt to standardize the values of common variables. However, this was not always possible. The CCW team includes the variables in each annual set of plan characteristics files in the data dictionary. 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 CONTRACT_ID and PLAN_ID uniquely determine a Part C or Part D plan. 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 a separate row of data for each segment ID [SEGMENT_ID] within the plan premium file). The cost-sharing tier file has multiple tiers for each Part D plan, while the premium and service area files have 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). 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. The data are complete files 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:

- Type of plan (e.g., HMO or PPO [MA-PD], PDP; special needs, PACE 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 CME does not require some Part D organizations to submit PBP information (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) is not available. The CCW team also does not include tier-level information for MMP and other CMS demonstrations.

NOTE: Those who use the Part D plan characteristics files (2006–2014) should note that the CCW team removes variables related to the Part D tier, which redundantly appeared on the tier file, from the plan benefit base file (e.g., GAP_TIER_01–06 is in the tier file as GAP_TIER_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 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 and D contract, plan, and segment (i.e., CONTRACT_ID, PLAN_ID, and SEGMENT_ID). Therefore, unless the researcher is interested in 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 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
- Whether the Part D subsidy level is 25, 50, 75, or 100%

3. Plan Cost-Sharing Tier File

This file describes the 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 concerning their benefit offerings in terms of the number of tiers included in their formulary, what types of drugs they cover on each tier, whether they classify the tier as a specialty tier, and payment structure for the 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 the comparison of plans on several key dimensions of the benefit, which

may vary by tier. The file contains highly specific cost-sharing information (copayment amounts and coinsurance rates) for each tier along the dimensions of:

- Benefit phase (i.e., pre-ICL, coverage gap [aka ICL], and catastrophic [post out-of-pocket threshold])
- Day supply amounts (i.e., one month supply, three-month supply, and other)
- 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. CMS does not require LINET, PACE, and employer plans to submit a plan benefit package for approval; therefore, these types of plans will generally not have data within this file. The data fields may vary somewhat from year-to-year, under HPMS reporting requirements. The CCW team notes these changes 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 is more TIER_ID values in this cost-sharing tier file than researchers will find 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 they submitted on the final formulary file to the CMS HPMS. Researchers can ignore any extra tiers in the tier file since no pharmacy will dispense drugs on such a formulary tier.

Researchers may purchase the formulary characteristics file, described in the next section of this document, which they may join 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 or D benefit. This file contains the region, state, or county included in a plan benefit package service area. Additional information regarding <u>Medicare Part D service areas</u> is available on the CMS website.

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 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 the plan premiums may vary by segment.

CMS lists the data for local MA-PDs, 1876 Cost plans, private fee-for-service plans, and demonstration organization plans (i.e., "H" and "E" contracts) by state and county. CMS lists regional MA-PD plans (i.e., "R" contracts) by MA-PD region and state, and lists PDP (i.e., "S" contracts) by PDP region and state. For MA-PD or PDP regions containing multiple states, the data lists a row for each 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 a new plan altogether, or simply a pre-existing plan split into one or more plan/contract IDs. The CCW team creates the plan crosswalk data files to allow researchers to examine consistency in plan offerings and enrollment over time. The plan crosswalk data files include all plans which appear in the plan characteristics files for the year (i.e., all approved plans in HPMS), and all plans for the prior year. Starting with the 2015 data file, the plan crosswalk file includes all Part C and D plans.

Variable names include either the reference year (i.e., the year of the data file) or the previous year. CMS calls the variables for the current year (aka reference year) the PLAN_ID_{YY} (YY=current year) and CONTRACT_ID_{YY}; calls the variables for the prior year the PLAN_ID_{YY-1} (YY-1=year before reference year) and CONTRACT_ID_{YY-1}. For example, if you receive 2019 Part D data and the Part D plan crosswalk file, then CMS names the variable for the contract ID for the prior year CONTRACT_ID_18 and calls the variable for the current year contract ID CONTRACT_ID_19. The CCW team maps these plans 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., the 2007 file includes 2006 plans — and indicates status $vis-\dot{a}-vis$ 2006). The plan benefit base file includes details regarding the plan offerings.

6. SNP Contracts File

In 2015, the SNP contracts file contains indicators to show which condition categories (e.g., heart failure, diabetes) the SNP covers. SNPs are always MA-PD plans.

The Bipartisan Budget Act (BBA) of 2018 permanently authorized Medicare Advantage Dual Eligible Special Needs Plans (D-SNPs) and strengthened Medicare-Medicaid integration requirements. All D-SNPs must have executed contracts with state Medicaid agencies, referred to as the "State Medicaid Agency Contract" (SMAC) or MIPPA contract, that meet a number of requirements, including Medicare-Medicaid integration requirements. The SNP Contracts file added three new fields, starting with the 2023 file, to account for D-SNP plan updates.

Additional details regarding D-SNPS is available on the CMS website, for example: https://www.cms.gov/medicare/medicaid-coordination/about/dsnps

B. Formulary Characteristics Files

Starting in 2010, the CCW team created the formulary characteristics files 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 the Part D benefit plan generally excludes, or as OTC drugs for each plan's Part D PBP. Beginning in 2020, CMS added an optional indication-based formulary for plans that restrict coverage of the drug for certain FDA-approved conditions or diseases. Beginning in 2021, CMS added a file for the insulins offered by participating plans through the Part D senior savings (PDSS) model.

A contract may use the same formulary with more than one PBP. Formulary information is available for every Part D plan (note that CCW imputes an "open" formulary for PACE and other organization types that CMS does not require 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 PBPs may include additional supplemental drugs, typically non-covered drugs. These drugs that CMS normally excludes 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. These two types of formulary characteristics files do not have records for every formulary or every Part D plan, only for those plans or formularies that include that type of coverage.

The CCW team makes the formulary base file available with 2010 data. From 2011 to 2019, three files were available, for 2020, there were four files, and for 2021 forward there are five files that the formulary characteristics files include. The 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 would contain drug characteristics variables if the drug appeared in First Databank.
- 4. **Indication-based formulary file** identifies the disease/indication for which the formulary includes the drug. The file contains drug characteristics variables (available 2020+).
- 5. **Part D senior savings (PDSS) model file** identifies the insulin drugs the plans include in the Part D Senior Savings model. The file contains drug characteristics variables and the associated monthly copay amount (available 2021+).

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 CCW team builds the formulary characteristics files from the CMS approved formulary data found in the CMS's HPMS, where CMS assigns a proxy NDC to each RXCUI. CMS maps the proxy NDC for each drug product to a unique FDB brand name and proprietary clinical formulation identifier, which they then assign a CCW formulary drug identifier (FRMLRY_RX_ID). 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 three formulary files (i.e., the base, excluded drug or OTC file); 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, a 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).

Researchers can identify plans offering OTC or excluded drug coverage 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 — a formulary ID (FORMULARY_ID) and a CCW-assigned formulary drug ID (FRMLRY_RX_ID) are the unique keys for the CCW formulary base file and OTC drug file. These identifiers also key the excluded drug file and indication-based formulary file. 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 can provide the brand name, generic name, strength, and dosage form for the CCW-assigned formulary drug ID (FRMLRY_RX_ID). Historically, the CCW team delivers the FDB variables describing the drug (the NDC) 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 with the same ingredients and the drug manufacturers brand 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. If researchers would like to have the drug characteristics information for more of the PDEs, they should request the CCW team append the FDB variables to the PDE. If researchers don't, they will miss this information for approximately 2.75% of the PDEs.

The formulary characteristics files are the same for all researchers. That is, the data are complete files — 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 Part D covered drugs on the formulary for each plan, and the UM variables associated with each drug. Before 2010 data, the CCW provided this information 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.

UM variables — the formulary base file includes four UM variables that CMS requires plan sponsors 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., the pharmacy does not collect any data at the time of the transaction to indicate the actual beneficiary experience).

The four UM variables are:

- **Tier (TIER_ID)** on which tier of the formulary the drug (FRMLRY_RX_ID) appeared according to the plan's benefit design
- Step (STEP) whether the drug (FRMLRY_RX_ID) was subject to step therapy according to the plan's benefit structure
- Quantity limits (QUANTITY_LIMIT_YN) whether the drug (FRMLRY_RX_ID) was subject to quantity limits according to the plan's benefit structure
- **Prior authorization (PRIOR_AUTHORIZATION_YN)** whether the plan required prior authorization for the drug (FRMLRY_RX_ID)

The formulary base file does not duplicate drug products within a formulary. However, the source formulary data has duplicates in rare instances 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 are 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. Investigators can assume in these cases that the Part D plan submitted more cost-sharing tiers for approval than it used.

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

A supplemental benefit under Enhanced Alternative Part D coverage may include Part D non-covered (or excluded) drugs. 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 plans covered (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).

We caution investigators 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 researchers identify on the Excluded Drug file (the FORMULARY_ID) 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 plan covers the excluded drugs that appear in the excluded drug file.

The excluded drug file did not include step therapy, quantity limit, and prior authorization UM variables in 2011, but the CCW team added these 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 drug 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. The CCW team limits the OTC drug file to OTC drugs where the NDC appears in the PDE and links 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).

The CCW team cautions investigators 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 (the FORMULARY_ID) includes these OTC 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 plan allows the over-the-counter drugs that appear in the OTC drug file.

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).

Researchers may use the formulary base file, or either of the excluded drug or OTC drug files, in conjunction with the PDE file. Linkage of 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 formulary tier of the plan handled the dispensing event, in terms of UM variables (note that UM variables do not apply and are not available in the OTC File). Researchers may use the formulary characteristics file and the excluded drug file 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 the pharmacy did not dispense drugs.

4. Indication-based Formulary File (available beginning with 2020 data)

Starting in 2020, Part D sponsors may utilize step therapy-like requirements within their prior authorization (PA) to promote cost-effective drug therapy by requiring the use of one formulary drug for a certain indication before authorizing coverage of a second drug for that indication. If a Part D sponsor intends to limit the formulary inclusion of a Part D drug to only certain FDA-approved indications, CMS requires plans to submit indication information to HPMS.

The CMS fact sheet <u>Indication-Based Formulary Design Beginning in Contract Year (CY) 2020</u> details this optional formulary feature. Before 2020, and when not specified in this file, the plan formulary lists drugs for all FDA-approved indications.

A unique record for the indication-based formulary file consists of the formulary (FORMULARY_ID), the drug (FRMLRY_RX_ID), and the DISEASE. There may be more than one row of data for each formulary. Plans use the variable called DISEASE to specify the various FDA-approved indications/diseases for which they consider the drug onformulary. This file will link to the PDE file using formulary ID and formulary drug ID (variables called FORMULARY_ID and FRMLRY_RX_ID).

5. Part D Senior Savings (PDSS) Model Formulary File (available beginning with 2021 data)

CMS is testing the impact of offering beneficiaries an increased choice of enhanced alternative Part D plan options that offer lower out-of-pocket costs for insulin. The voluntary model began on January 1, 2021, and will continue for five years, through December 31, 2025. Additional details regarding this CMS Innovation Center Model are available on the CMS website.

The PDSS model file includes a record for each formulary drug ID (FRMLRY_RX_ID) for the applicable insulin drug product that the plan's PDSS model covers. Plans use the variable called COPAY to indicate the beneficiary cost sharing for a one-month supply of insulin (note that the copay is specific to one-month supply of insulin which ranges from 28–34 days). This file allows data users to correctly identify the beneficiary copay amount for the model-covered insulins. The Part D plan may choose to extend the benefit to other non-model insulins. With this flexibility, one will have to use this file to correctly identify the copay instead of the usual benefit design (i.e., from the tier file).

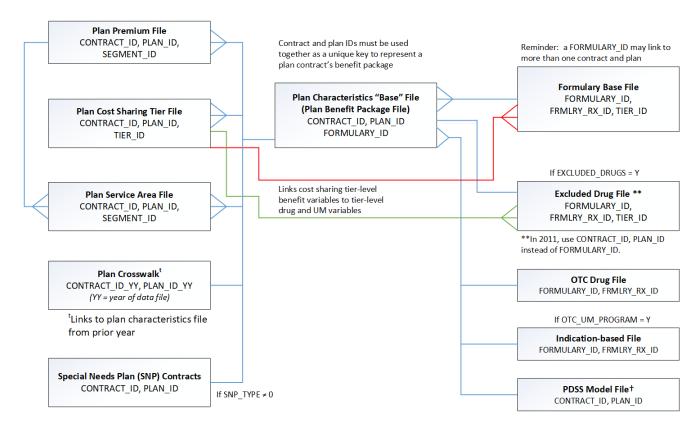


Figure 3. Part D plan characteristics files — entity relationship diagram

C. Pharmacy Characteristics File

The objective of this file is to allow researchers to understand better 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 NCPDP to use their data Q^{TM} product, the CCW team can provide researchers with this information.

Pharmacies participate with NCPDP to receive an industry-recognized pharmacy identifier they can use 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 NCPDP updates monthly. It only includes the information about the pharmacy in the historical NCPDP database at the end of the year. The file does not include changes throughout the year.

The pharmacy ID (CCW_PHARM_ID for 2006–2013) or NCPDP_ID (for files 2014+) uniquely keys the CCW pharmacy characteristics file, which links with the pharmacy identifiers in the PDE file. Occasionally, a PDE record has a null CCW_PHARM_ID/NCPDP_ID. 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

^{*} The figure lists only key variables; starting in 2015, the plan characteristics files include all Part C and D plans.

[†] Beware that it is possible not all segments of CONTRACT_ID/PLAN_ID participate in PDSS.

business. Researchers can use the CCW-assigned CCW_PHARM_ID/NCPDP_ID to link to the pharmacy characteristics file. This enables researchers to obtain descriptive information about the pharmacy.

For 2006–2013, the CCW team created the CCW_PHARM_ID variable to link the PDE and the CCW pharmacy characteristics file; for 2014+ years, the CCW team retired the CCW_PHARM_ID variable and uses NCPDP_ID as the linkage variable.

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 PDE data. For all seven years of data, the CCW pharmacy ID bridge file lists NCPDP_ID associated with each CCW_PHARM_ID.

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 understand better the type of provider who prescribed the medication (e.g., type of provider and specialty). The HCldea® Prescriber Database is the source of information for the CCW prescriber characteristics file. Through a special licensing arrangement with NCPDP, the CCW team can provide researchers with this information.

HCldea obtains prescriber information from a variety of data sources, including the CMS National Plan and Provider Enumeration System (NPPES); assigns a unique NPI to each provider), Drug Enforcement Agency (DEA, 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, or UPIN number. Note that there are few instances where it was not possible to confidently identify a unique provider — however, this occurred for less than 1% of the prescribers in the HCldea database.

The CCW team collects a range of variables, and different information may exist for providers at different points in time. The CCW obtains monthly files from HCIdea and creates a CCW provider history database. The CCW team then extracts an annual CCW prescriber characteristics file from the provider history database. The annual CCW prescriber characteristics file includes information for all Part D prescribers from the yearly PDE file found in the HCIdea files. It is possible, although rare, for a provider to have more than five different values for taxonomy, credentials, or state during a year. When this occurs, the CCW team uses the most frequently occurring information for the timeframe. Providers self-select their taxonomy codes in NPPES and designate a primary taxonomy code.

HCIdea limits their data files to those providers who are likely prescribers (i.e., they do not include all NPIs from NPPES, rather the NPIs where taxonomy codes indicate a type of provider likely to have prescribing privileges). The HCIdea generally does not include organizational NPIs.

Not all prescribers will have all of the data fields populated in the prescriber characteristics file (e.g., taxonomy code was not present for about 10% of providers). The CCW team provides a description of the primary taxonomy code in the data file. If researchers would like to append the descriptions for other taxonomy codes, refer to the National Uniform Claims Committee (NUCC) taxonomy descriptions.

For 2006–2013 data, the CCW prescriber ID (CCW_PRSCRBR_ID) uniquely keys the CCW prescriber characteristics file, which links with the CCW prescriber ID written to the PDE data. Starting in 2014, the NPI uniquely keys the prescriber characteristics file, 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 HCldea files. For 2006–2013, an event record might have a negative CCW prescriber ID value when CCW could not find a conclusive link between the prescriber identification number in the source PDE data, and the prescriber identification numbers in the HCldea 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, the CCW prescriber characteristics file may link to the PDE with the CCW prescriber ID (CCW_PRSCRBR_ID). For 2014+, the PRSCRBR_ID in the prescriber characteristics file (which is the NPI) may link to the PDE file. This linkage makes it 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 PDE data (i.e., the PRSCRBR_ID). For all seven years of data, the CCW team lists the HCIdea proprietary prescriber identification number (variable called HCID) associated with each CCW_PRSCRBR_ID, 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). The CCW team created this variable to identify the type of prescriber identifier found on the original PDE. The CCW team populates this field 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 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 a 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) pharmacists or other qualified providers furnish.

Eligibility criteria — CMS targets 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 for the MTM programs, as described in§423.153(d)(1). CMS establishes eligibility targeting requirements 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). CMS encourages sponsors (but does not require them) 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, 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 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, 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 developing a Medicare Part D sponsor's bid. 2) annually, sponsors must submit an MTM program description to CMS for review and approval in the 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, refer to: 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. CMS uses reporting sections for monitoring only and excludes them from DV. CMS only releases data for contracts receiving at least the minimal DV score to pass. Find more information about the data validation standards 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 copayments for low-income beneficiaries. Beneficiaries who qualify for the Extra Help program include Medicaid dual eligibles, Supplemental Security Income (SSI) recipients, and other low-income beneficiaries.^{6, 7}

The LIS program also established a strategy of auto and facilitated enrollment. Under auto enrollment, if CMS deems a Medicare dual-eligible eligible for the full LIS subsidy does not select a plan, CMS randomly assigns them to a plan that qualifies for the full subsidy the Part D premium. The facilitated enrollment process is similar, but applies to all other beneficiaries who CMS finds eligible for LIS.⁸

Full premium subsidies are available in plans whose bid for standard Part D coverage was at or below the average in that PDP region. CMS calls the average premium associated with such bids 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 standalone PDPs and MA-PD plans and switch plans if they choose. Beneficiaries eligible for the full LIS and enrolled in an at or below the benchmark plan will pay zero premiums. If they enroll in above the benchmark plans, they are responsible for paying the premium amount above the benchmark. Because CMS recalculates benchmarks annually, 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 or facilitated enrolled into one of these plans, CMS reassigns 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.⁹

Passive enrollment is a process when CMS informs a beneficiary that CMS considers them requesting enrollment in a new Part D plan by taking no action. CMS permits passive enrollment 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.¹⁰

In some parts of the United States, CMS may enroll beneficiaries voluntarily or through passive enrollment into the CMS' Financial Alignment (FA) Demonstration for Medicare-Medicaid enrollees. ¹¹ In passive enrollments, the state or

⁶ Medicare.gov "Help with drug costs." https://www.medicare.gov/basics/costs/help/drug-costs (Accessed 10/25/2024)

⁷ 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 10/25/2024)

⁸ CMS.gov https://www.cms.gov/Medicare/Prescription-Drug-Coverage/LimitedIncomeandResources/downloads/11186.pdf (Accessed 10/25/2024)

⁹ CMS.gov Medicare. Low-Income Subsidy for Medicare Prescription Drug Coverage. "Reassignment." https://www.cms.gov/Medicare/Eligibility-and-Enrollment/LowIncSubMedicarePresCov/Reassignment.html (Accessed 10/25/2024)

¹⁰ CMs.gov "Medicare Prescription Drug Benefit Manual. Chapter 3. Eligibility, Enrollment, and Disenrollment." (updated August 2011) https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicarePresDrugEligEnrol/Downloads/CY-2015-PDP-Enrollment-and-Disenrollment-Guidance.pdf (Accessed 10/25/2024)

¹¹ CMS.gov "Medicare-Medicaid Plan Enrollment and Disenrollment Guidance. Released on: June 14, 2013."
https://www.cms.gov/Medicare-Medicaid-Coordination/Medi

CMS notifies the Medicare-Medicaid dually eligible individual that CMS considers them requesting to enroll in a Medicare-Medicaid Plans (MMP) by taking no 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.¹²

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

The CCW team has created two research identifiable files, the "Part D beneficiary plan election file" and the "Part D beneficiary auto assignment file," using the 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 CCW team gets the key information in this data file 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 = FA Demonstration Beneficiary Election
- N = Rollover by Plan Transaction

The CCW team partitions files into two annual files, starting with the onset of the Part D benefit in 2007. The <u>Data</u> <u>Dictionaries</u> tab on the CCW website has additional information.

¹² CMS.gov "Medicare Limited Income NET Program." <u>Medicare Limited Income NET Program — Centers for Medicare & Medicaid</u> <u>Services</u> (Accessed 10/25/2024)

1. Part D Beneficiary Plan Election File

This section provides detailed information on Part D plan enrollment transactions, including why beneficiaries enroll in specific plans (as indicated by the Part D enrollment type codes). There are nine variables in the Part D beneficiary plan election data file.

The source data contain separate records for each beneficiary enrolled plan — even if the beneficiary made multiple selections before the benefit year (i.e., even if they were never the valid/active plan, the source data records these choices).

At least one record for each beneficiary enrolled in Part D during the reference year (aka Part D benefit year) appears in the data file. There are additional rows of data when more than one plan election occurred during the reference year. There may be circumstances when a beneficiary has a record in the file, yet the Part D plan never actively enrolled the beneficiary for the benefit year (i.e., a beneficiary made Part D plan selection, 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 reassignment or whether the beneficiary chose their plan. There are seven variables in the data file.

Researchers may use these files 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 MBSF includes the Part D plan and contract ID. In addition, researchers can join the Part D plan and contract IDs 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 CMS waives the plan sponsor from providing plan benefit information (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 the CCW is the end-of-the-year snapshot. CMS terminates a few Part D contracts during the year, and this annual source data file may not capture the plan characteristics 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., the plan doesn't cover OTC or excluded drugs), drugs removed or added to formularies through the year but the end-of-year file doesn't contain them, and branded generics where the brand listed in the formulary doesn't correspond with what beneficiaries 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 the CCW database contains 100% of Medicare enrollment and PDEs.

The standard CCW PDE file includes events for a random 10% or 20% of Medicare Part D beneficiaries, and the standard 5% Medicare sample. Not all Medicare beneficiaries have Part D coverage, as it is an optional benefit (refer to CCW data regarding the proportion of Medicare enrollees who obtain Part D coverage: <u>Table F.1</u> on the CCW website). However, all dually enrolled Medicare and Medicaid beneficiaries have Part D coverage. The health status and prescription drug needs of beneficiaries enrolled in Part D may not represent all Medicare beneficiaries.

Researchers may define their study cohort or population of interest for the CCW team to extract 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 two digits of the CAN are: 05, 20, 45, 70, 95, 10, 35, 60, 85, or 00.

The CCW team removes the Medicare beneficiary HICs from the data files delivered to researchers (unless otherwise specified/approved in the DUA). The CCW team includes a unique CCW beneficiary identifier in each data file delivered, allowing linkage of an individual's data across CCW data files.

<u>Chapter 5</u> lists additional details regarding the CCW beneficiary identifier. If a researcher needs to obtain the HIC 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. In that case, the CCW team will include the HIC to the CCW beneficiary identifier crosswalk as a separate file.

Researchers should include requests for control populations or comparison groups in the initial data request. The researcher should also specify the inclusion or exclusion criteria for the control population on the data request form. The CCW team can apply the standard, modified standard, or custom definitions explained above for research populations 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, dates, 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 (BENE_ID) is specific to the CCW and not applicable to any other identification system or data source) CCW encrypts the identifier and all data files before delivering to researchers (refer to <u>Chapter 6</u> 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 not include any patient identifying information beyond the CCW beneficiary ID. Regardless of whether the data includes patient identifying information, 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 CCW team creates the unique CCW BENE_ID from the CMS CME database, using the CME Link Number, MBI¹³ or HIC number, and other beneficiary identifiers (i.e., sex, Social Security number [SSN], date of birth). The CCW team performs an analysis to ensure that the beneficiary does not appear multiple times in the CCW BENE_ID history table. This unique CCW identifier follows an enrollee across years and the other CCW research data sources. For example, the CCW also contains Medicaid enrollment and claims data, and assessment data (e.g., MDS and OASIS). The BENE_ID facilitates analysis across all CMS data sources in the CCW.

B. Part D Identifiers

Identifiers appearing in the PDE data or the Part D characteristics data files include the contract ID, plan ID, segment ID, and formulary ID — always encrypted before 2013 under CMS privacy regulations. The CCW formulary drug identifier (FRMLRY_RX_ID) is a CCW-created identifier that describes the particular drug that the pharmacy 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 (NCPDP_ID) and the prescriber identifier (PRSCRBR_ID), which are available in 2014+. For data files 2006–2013, investigators use the CCW_created identifiers (CCW_PHARM_ID and the CCW_PRSCRBR_ID). The CCW_PHARM_ID and CCW_PRRSCRBR_ID were retired in 2014.

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

¹³ CMS began using a new Medicare beneficiary identifier (MBI) in place of the HIC, starting in 2018.

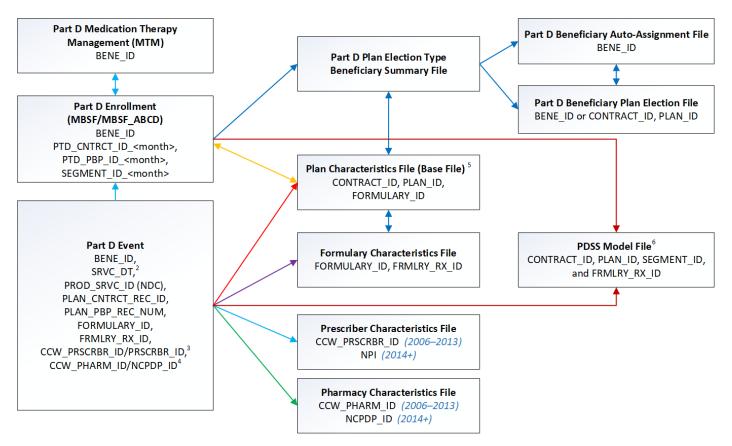


Figure 4. Part D files — relationships and linkage diagram¹

¹ Lists only key variables.

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, the CCW team uses PRSCRBR_ID to identify the prescriber and link to NPI in the CCW prescriber characteristics files; before 2014, the team used CCW_PRSCRBR_ID to link to the CCW prescriber characteristics files.

⁴ Beginning in 2014, the CCW team uses the NCPDP_ID to identify the pharmacy and link to the CCW pharmacy characteristics files; before 2014, the team used the CCW PHARM ID.

⁵ Starting in 2015, the plan characteristics files include all Part C and D plans.

⁶ The linkage for the PDSS model file is different than for the other formulary characteristics files. The key link variables to Part D enrollment are CONTRACT_ID, PLAN_ID, and SEGMENT_ID. The key linking variables to the PDE is FRMLRY_RX_ID. This file is available 2021+.

C. Data Limitations

Researchers should expect anomalies in working with large, national, administrative datasets. Minimal data cleansing has occurred during the processing of CCW Part D data. However, we describe some of the known limitations of the CMS or CCW data below. Furthermore, the Part D benefit began in 2006, and both the CMS process and data files standardized 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 reflects the drugs received through the Medicare Part D benefit.

Although Part D data exist for managed care and fee-for-service enrollees, Medicare Part A and B claims are not available for beneficiaries enrolled in managed care plans before 2015 (note that managed care encounter data is available for people enrolled in MA plans starting in 2015). For researchers wishing to understand the relationship between clinical conditions and treatment utilization and drugs — they may want the subset of beneficiaries with Medicare Parts A/B/D data. 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. The CCW receives data — processes it, stores, and delivers is the data as received. The CCW team does not modify data to "correct" invalid variable values.

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

This section describes the content and format of the CCW Part D output package (the CCW data physically delivered to researchers). The CCW team delivers files to the researcher in the following format. <u>Table 5</u> lists descriptions of each of these contents.

Table 5. Format and naming convention for the CCW files

File	File description
readme_first_req000_20191.txt	This is a text file that describes the files contained in the output package. Filename example: readme_first_req232_2019.txt
res000011111req000232_2019_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 researchers must run to decrypt and uncompress the PDE data file. In this example, 000011111 is the DUA number, 232 is the request number, and 2019 is the year of the data. This executable includes v8 SAS read-in programs, the .dat file, and .fts file containing the layout and record counts.
res000011111req000232_2019_MBSFABCD.exe	This is the executable that researchers must run to decrypt and uncompress the Part ABCD segment of the MBSF. In this example, 000011111 is the DUA number, 232 is the request number, and 2019 is the year of the data. This executable includes v6 and v8 SAS read-in programs, the .dat file, and .fts file containing the layout and record counts.

Plan characteristics files*†

File	File description
plan_char_2019.dat	This set of files includes the plan benefit base characteristic .dat
plan_char_2019.fts	(data) file, .fts (layout and record counts) file, and version 8 SAS
plan_char_2019_ readin.sas	read-in programs.
plan_char_formats_2019.sas	
premium_2019.dat	This set of files includes the plan premium .dat (data) file, .fts
premium_2019.fts	(layout and record counts) file, and version 8 SAS read-in
premium_2019_readin.sas	programs.
tier_2019dat	This set of files includes the plan cost share tier .dat (data) file,
tier_2019.fts	.fts (layout and record counts) file, and version 8 SAS read-in
tier_2019_readin.sas	programs.
service_area_2019.dat	This set of files includes the plan service area .dat (data) file, .fts
service_area_2019.fts	(layout and record counts) file, and version 8 SAS read-in
service_area_2019_readin.sas	programs.
plan_crosswalk_2019.dat	This set of files includes the plan crosswalk .dat (data) file, .fts
plan_crosswalk_2019.fts	(layout and record counts) file, and version 8 SAS read-in
plan_crosswalk2019_readin.sas	programs.
snp_contract_info_2019.dat	This set of files includes the snp contract .dat (data) file, .fts
snp_contract_info_2019.fts	(layout and record counts) file, and version 8 SAS read-in
snp_contract_info_2019_readin.sas	programs.

Formulary characteristics files*‡

File	File description
formulary_2019.dat	This set of files includes the formulary base .dat (data) file, .fts
formulary_2019.fts	(layout and record counts) file, and version 8 SAS read-in
formulary_2019_readin.sas	programs.
Excl_drugs_2019.dat	This set of files includes the excluded drug .dat (data) file, .fts
Excl_drugs_2019.fts	(layout and record counts) file, and version 8 SAS read-in
Excl_drugs_2019_readin.sas	programs.
OTC_drugs_2019.dat	This set of files includes the OTC drug .dat (data) file, .fts (layout
OTC_drugs _2019.fts	and record counts) file, and version 8 SAS read-in programs.
OTC_drugs _2019_readin.sas	
IBC_2020.dat	This set of files includes the Indication-based formulary drug .dat
IBC _2020.fts	(data) file, .fts (layout and record counts) file, and version 8 SAS
IBC _2020_readin.sas	read-in programs.
PDSS_2021.dat	This set of files includes the Part D senior savings model (PDSS)
PDSS _2021.fts	.dat (data) file, .fts (layout and record counts) file, and version 8
PDSS _2021_readin.sas	SAS read-in programs.

Pharmacy characteristics files*

File	File description
pharm_char_2019.dat	This set of files includes the pharmacy characteristic .dat
pharm_char_2019.fts	(data) file, .fts (layout and record counts) file, and version
Pharm_char_2019_readin.sas	8 SAS read-in programs.

Prescriber characteristics files*

File	File description
prscrbr _char_2019.dat	This set of files includes the prescriber characteristic .dat
prscrbr_char_2019.fts	(data) file, .fts (layout and record counts) file, and version
prscrbr_char_2019_readin_v8.sas	8 SAS read-in programs.

Medication Therapy Management (MTM) files*

File	File description
part_d_mtm_2019.dat	This set of files includes the MTM .dat (data) file, .fts
part_d_mtm_2019.fts	(layout and record counts) file, and version 8 SAS read-
part_d_mtm_2019_readin_v8.sas	in programs.

Part D beneficiary plan election and Part D beneficiary auto-assignment files*

File	File description
ptd_bene_plan_elctns_000011111_req000232_2019.fts ptd_bene_plan_elctns_000011111_req000232_2019.dat	This set of files includes the Part D beneficiary plan Election file and the Part D beneficiary auto-
ptd_bene_plan_elctns_read_v8.sas	assignment file .dat (data) file, .fts (layout and
lis_reassign_chooser_000011111_req000232_2019.fts lis_reassign_chooser_000011111_req000232_2019.dat lis_reassign_chooser_read_v8.sas	record counts) file, and version 8 SAS read-in programs. In this example, 000011111 is the DUA number, 232 is the request number, and 2019 is the year of the data.

^{*} Beginning with 2010 "characteristics files," the CCW team provides only the SAS v8 read-in statements. Previously, the file extension would specify" readin v6.sas" or " readin v8.sas"

In addition to the specific data files the researcher requested, CCW includes a variety of resource files in the deliverable package. <u>Table 6</u> shows these files.

Table 6. CCW resources accompanying data files

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.
Z Decryption instructions.pdf	This document contains instructions for decrypting/uncompressing the data files.
Tips on getting started with data.pdf	This document contains tips for using the 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 CCW team builds the SDA on the CCW production server, downloads it to a desktop PC, and burns it to a CD, DVD, or USB hard drive depending on the size of the files.

After the CCW team ships the data to the researcher, they send the password to decrypt the archive to the researcher via email. Each researcher request has a unique encryption. The CCW team never packages the password and the data media together. To decrypt the data files, the researcher accesses the email containing the decryption password. The data package contains detailed instructions for using this password.

[†] Starting with 2015, the CCW team includes plan characteristics files, with all Part C and D plans, and includes a SNP file (i.e., six files comprise plan characteristics rather than five files). CMS no longer considers plan files Part D files (since they apply more broadly to all Part C and D plans). Requests for the revised plan characteristics files will require an updated code on your DUA.

[‡] The IBC is not available until 2020; the PDSS is not available until 2021. We include these file in the table for illustrative purposes.

Chapter 7 — Further Assistance with CCW Data

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

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

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

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

Appendix A — Acronyms and Abbreviations

CAN Claim Account Number; part of CME CMS Common Medicare Environment CMS Centers for Medicare & Medicare Which administers the Medicare CCW Chronic Conditions Warehouse DEA Drug Enforcement Agency; consubstances Act DUA Data Use Agreement; delinear data release policies EDB Enrollment database; master ESRD End-stage renal disease FDB First Databank; proprietary data prescription drug descriptors FEHB Federal Employee Health Ben HCIdea® A prescriber database from Novendor's file as a primary south HIC Health Insurance claim number to submit Part D plan contract approval for each benefit years.	t of the Medicare HIC identifier	
CAN Claim Account Number; part of CME CMS Common Medicare Environment CMS Centers for Medicare & Me		
CME CMS Common Medicare Envir CMS Centers for Medicare & Medica which administers the Medica CCW Chronic Conditions Warehous DEA Drug Enforcement Agency; co Substances Act DUA Data Use Agreement; delinea data release policies EDB Enrollment database; master ESRD End-stage renal disease FDB First Databank; proprietary da prescription drug descriptors FEHB Federal Employee Health Ben HCIdea® A prescriber database from N vendor's file as a primary sour HIC Health insurance claim number Health Plan Management Syst to submit Part D plan contract approval for each benefit yea ICL Initial Coverage Limit for the Re	of the Medicare HIC identifier	
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vendor's file as a primary sour HIC Health insurance claim number HPMS Health Plan Management System to submit Part D plan contract approval for each benefit year ICL Initial Coverage Limit for the Recognition of the Recog	efits Program	
HIC Health insurance claim number HPMS Health Plan Management Syst to submit Part D plan contract approval for each benefit yea ICL Initial Coverage Limit for the R	CPDP which contains a variety of prescriber information; CCW uses this rce to describe the prescriber characteristics	
to submit Part D plan contract approval for each benefit yea ICL Initial Coverage Limit for the R	er; unique Medicare beneficiary identification number	
ICL Initial Coverage Limit for the I	tem; CMS-owned database application which CMS requires sponsors to use t information, plan benefit package data, and formulary files for CMS r	
	Part D benefit; also referred to as the coverage gap	
	nium adjustment added by Medicare for beneficiaries who enroll in the	
	of Part D eligibility with no other form of credible coverage	
LINET Limited Income Newly Eligible beneficiaries	e Transition; point-of-sale facilitated enrollment Part D plan for LIS	
LIPS Low-Income Premium Subsidy	/	
	s assistance to certain low-income individuals to supplement the premium eductibles and cost-sharing during the coverage gap) associated with the	
MA-PD Medicare Advantage Prescrip	tion Drug plan; managed care health and Part D drug coverage	
MBSF Master Beneficiary Summary of variables related to Medica	File; Medicare enrollment data file which contains "segments" or clusters are A, B, C, and D	
MMA Medicare Modernization Act		
	S Medicare-Medicaid Coordination Office demonstration program that generation program that	
	ment; CMS requires Part D plans to offer MTM to beneficiaries using	
NCPDP National Council for Prescript	ion Drug Programs; CCW uses the dataQ [™] file product from this vendor to	
NDC National Drug Code; in the PD	stics; in addition, the HCldea prescriber database, used as a source for	

Acronym	Description		
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; standalone prescription drug plan (e.g., not offered as part of a managed care plan MA-PD)		
PDSS	Part D Senior Savings		
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 the 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 before July 2007		
VA	Veteran's Administration		