

**CMS Payment Standardization Methodology  
for Part D v.4**

**For Services Provided During 2015 – 2024  
(Updated November 2024)**

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## INTRODUCTION

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Payment standardization is the process of calculating estimated payment amounts that are nationally representative of payments for services, drugs, and conditions under specific payment policies for Medicare fee-for-service. These standardized claim payment amounts allow for the measurement and analysis of provider resource use by the Centers for Medicare & Medicaid Services (CMS). Specifically, standardized amounts are intended for use in a variety of CMS performance programs to evaluate and compare resources needed to furnish services and drugs covered by Medicare Part A, Part B, and Part D programs.<sup>1</sup> Development of standardized payment amounts for Medicare Parts A and B is based on payment rates established by CMS for services and conditions under Medicare fee-for-service through annual notice and comment rulemaking. Part D standardized payments, in contrast, are based on payments by Part D plans for drug products.

Part D data differ from Parts A and B claims data in both their procedural role and the information contained within them. Part D data include claims under the Medicare prescription drug plan for both Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs). Every time a beneficiary fills a prescription covered under Part D, plans must submit a summary record called the prescription drug event (PDE) record to CMS. The PDE record contains prescription drug cost and payment data that will enable CMS to reconcile payments to plans and otherwise administer the Part D benefit. Part D plan sponsors pay

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<sup>1</sup> For basic and detailed versions of the Parts A and B payment standardization methodologies, please see the CMS Price (Payment) Standardization documents available on the CMS Research Data Assistance Center (ResDAC), available here: <https://resdac.org/articles/cms-price-payment-standardization-overview>.

pharmacies for the drugs dispensed to enrollees, and Medicare provides reimbursement via prospective subsidy payments and retrospective reconciliation processes. This is different from Parts A and B claims, where the provider submits the claim to the Medicare Administrative Contractors (MACs), who then pay it and request reimbursement from Medicare. PDE data, therefore, represent transactions between insurers and drug manufacturers/pharmacies. As such, the price of a drug is the cost of the drug to the insurer. Standardization of these claims, i.e., of payments, minimizes geographic and other types of variation that affect drug payments, including beneficiary cost sharing.

Part D payment standardization has one methodology that applies to all drugs purchased and paid for under the benefit. Generic and brand-name drugs, prescription and non-prescription drugs, and small- and large-molecule drugs (biologics and biosimilars) are all included in standardization, though branded-generic cost variation is preserved in the standardized amounts. Payments for drugs that do not have a National Drug Code (NDC) mapped in RxNorm are also standardized so long as they are covered under Part D. In these cases, rather than grouping NDCs of the same drugs in RxNorm, an NDC not in RxNorm counts as its own drug group.

As indicated above, Part D payment standardization is intended to facilitate analysis of prescription drug spending for beneficiaries receiving the same or similar prescription drugs across different geographic areas. This is particularly important given the substantial variation in Part D drug prices both between and within Part D plans, due largely to the fact that Part D plan sponsors negotiate drug prices directly with pharmaceutical companies and pharmacies. For example, Part D standardized amounts are used along with Parts A and B standardized claims to assess cost of care for a number of episode-based cost measures, such as for end-stage renal disease and heart failure. The standardized Part D costs of treatment attributed to a provider for one of these episode-based cost measures will be the same even if the drug products are covered under varying Part D plans, produced by different manufacturers, or dispensed by separate pharmacies. Part D standardization therefore allows prescription drugs to be incorporated into performance programs and enables the development of cost measures that more accurately represent comprehensive episodes of care. In short, Part D standardized amounts facilitate comparisons based on resource use by removing variation in drug prices due to non-clinical factors such as price differences associated with geography or Part D plans.

As with Parts A and B payment standardization, CMS updates the Part D standardization algorithms regularly to account for changes in Part D program policies, such as Medicare allowed coverage determinations or pricing requirements. Occasionally, CMS modifies the Part D methodology to address evolving needs of CMS performance programs and stakeholders. While routine and ongoing updates to the standardization algorithms and processes are not typically reflected in this methodology document, changes to the overall methodology and approach are documented in the annual update.

The remainder of this document provides a comprehensive overview of the Part D standardization methods in 2 parts. Section I presents a conceptual overview of the Part D standardization methodology, along with rationale for key methodological steps. Section II includes detailed technical steps for implementation of Part D standardization using PDE record data. For additional questions about the Part D payment standardization methodology, please email [CMS-PaymentStandardizationSupport@cms.hhs.gov](mailto:CMS-PaymentStandardizationSupport@cms.hhs.gov).

## **I. OVERVIEW OF PART D PAYMENT STANDARDIZATION**

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The Part D standardization methodology is designed to produce Standardized Claim Amounts that can facilitate meaningful comparisons of payments by Part D plans for prescription drugs, despite the high variation in drug prices observed within the market-based Medicare Part D program. Standardization is applied the same way to all PDE records, including both stand-alone PDPs and MA-PDs. The methodology implements a monthly Drug Price Index with a Standard Unit Price for each drug, calculated from observed drug costs. The following section contains an overview of how this Drug Price Index is constructed and used in the standardization of PDE records.

As the basis for the Drug Price Index, clinically substitutable drug products (identified by national drug code [NDC]) are grouped into drug groups based on active ingredient, strength, dosage form, route of administration, and brand/generic classification. Non-clinical drug characteristics such as drug packager, labeler, and manufacturer are not considered so that products with identical clinical characteristics, but with different packaging, are classified under the same drug group. Based on these groupings, 2 drug products that are clinically substitutable and have the same brand/generic classification (e.g., both are branded 500 mg oral tablets of the same active ingredient) will have the same Standard Unit Price according to the Drug Price Index even if one drug comes in a blister pack and the other comes in a bottle. This methodological design allows Standardized Claim Amounts to capture variation in Part D cost due to clinical or treatment factors, while excluding cost variation unrelated to care (e.g., due to packaging or labeling of drug products). As an illustrative example, standardization would exclude cost variation based on packaging differences among the following 3 products of generic 2 mg warfarin oral tablets: regular tablets at \$2.17 per tablet, 50-tablet blister packs at \$2.05 per tablet, and 28-tablet blister packs at \$2.30 per tablet.<sup>2</sup>

To determine a Standard Unit Price for each drug group, the distribution of Actual Unit Price (Actual Ingredient Cost / Quantity Dispensed) is calculated for each drug group on a monthly basis, using 3 months of PDE records with service dates in the standardization month (i.e., the month for which claims are being standardized) and two prior months. Claims with

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<sup>2</sup> Prices listed do not reflect actual costs; they are for illustrative use only.

relevant service dates are pulled at least one month after the end of the standardization month, resulting in a runout period to allow claims with relevant service dates to be submitted and processed. As an example, Standard Unit Prices for January 2024 are calculated for the first time in March 2024 using claims with November 2023 – January 2024 service dates and process dates through the end of February 2024. Calculating the Actual Unit Price distributions across 3 months of data helps ensure a sufficient sample size to accurately calculate the distributions, and it helps stabilize Standard Unit Prices over time even if Part D prices fluctuate from one month to another. These procedures result in a Drug Price Index for the standardization month where each drug group is assigned a Standard Unit Price equal to its median Actual Unit Price. The distributions of Actual Ingredient Cost are also calculated using the same 3 months of data and included in the Drug Price Index.

The detection of outlier claims, discussed in more detail below, requires information about the distribution of Daily Quantity (Quantity Dispensed / Days Supply). The distributions of both Daily Quantity and Quantity Dispensed are also calculated and included in the Drug Price Index. These distributions are determined using 12 months of data, unlike the Actual Unit Price and Actual Ingredient Cost distribution calculations which use 3 months of data. For example, these values are first calculated for the January 2024 Drug Price Index in March 2024 using February 2023 – January 2024 claims.

The steps to construct the Drug Price Index are repeated monthly and for each month within a year until the Drug Price Index for that year is finalized in July of the following year. For example, the Drug Price Index for January 2024 is created in March 2024, the first time in 2024 that a full month of claims (January claims) are available with a month-long runout period. Likewise, the Drug Price Index for February 2024 is created in April using claims with a month-long runout period; however, February 2023 – January 2024 claims are queried again and the January 2024 Drug Price Index is updated. Table 1 displays the approximate dates the procedures are performed (run dates), the service date ranges queried during each month, and the months of the Drug Price Index that are updated using the query results for every run date that affects the Drug Price Index for months in 2023.

**Table 1. Date Ranges for the Drug Price Index Updates**

Run Date	Last Service Date	First Service Date	Months to Update
3/15/2023	1/31/2023	2/1/2021	January 2022 – January 2023
4/15/2023	2/28/2023	2/1/2021	January 2022 – February 2023
5/15/2023	3/31/2023	2/1/2021	January 2022 – March 2023
6/15/2023	4/30/2023	2/1/2021	January 2022 – April 2023
7/15/2023	5/31/2023	2/1/2021	January 2022 – May 2023
8/15/2023	6/30/2023	2/1/2022	January 2023 – June 2023
9/15/2023	7/31/2023	2/1/2022	January 2023 – July 2023
10/15/2023	8/31/2023	2/1/2022	January 2023 – August 2023
11/15/2023	9/30/2023	2/1/2022	January 2023 – September 2023
12/15/2023	10/31/2023	2/1/2022	January 2023 – October 2023

Run Date	Last Service Date	First Service Date	Months to Update
1/15/2024	11/30/2023	2/1/2022	January 2023 – November 2023
2/15/2024	12/31/2023	2/1/2022	January 2023 – December 2023
3/15/2024	1/31/2024	2/1/2022	January 2023 – January 2024
4/15/2024	2/29/2024	2/1/2022	January 2023 – February 2024
5/15/2024	3/31/2024	2/1/2022	January 2023 – March 2024
6/15/2024	4/30/2024	2/1/2022	January 2023 – April 2024
7/15/2024	5/31/2024	2/1/2022	January 2023 – May 2024

After constructing the Drug Price Index, an Initial Standardized Ingredient Cost is assigned to each PDE record with a processing date in the standardization month, regardless of the service date. The Initial Standardized Ingredient Cost is calculated by multiplying the Quantity Dispensed (the number of drug units noted on the claim) by the Standard Unit Price for the relevant drug group. The Quantity Dispensed variable is used as an indicator of resource use to calculate Standardized Claim Amounts that exclude non-clinical drug price variation captured in Actual Claim Amounts. This approach is intended to produce Standardized Claim Amounts that can represent resource use within performance programs.

After Initial Standardized Ingredient Costs are calculated across claims, outliers are identified for winsorization, a statistical method used to replace extreme values with values that are more consistent with other, similar claims. Claims are determined to be outliers if the Quantity Dispensed value is extremely low or extremely high compared to both Actual Ingredient Cost and Days Supply. Outlier claims are identified based on having both extreme Actual Unit Prices (Actual Ingredient Cost / Quantity Dispensed) and extreme Daily Quantities (Quantity Dispensed / Days Supply) within each drug group distribution. Given that Initial Standardized Ingredient Costs are calculated as the product of Standard Unit Price and Quantity Dispensed, claims with extreme Quantity Dispensed values would likely be assigned extreme Standardized Claim Amounts. To prevent extreme Standardized Claim Amounts, the Standardized Ingredient Costs on outlier claims are winsorized to ensure that the ratios of Standard to Actual Unit Prices do not exceed pre-defined upper and lower bounds, set for each drug. Further details of this winsorization methodology can be found in Step 4.b in Section II below.

Following winsorization, the Standardized Claim Amount is calculated by adding other costs associated with a claim, provided that those costs do not vary in a non-clinically relevant manner. Specifically, the additional costs added to the winsorized or Initial Standardized Ingredient Costs include any applicable Dispensing Fee and Vaccine Administration Fee, while any Sales Tax is excluded due to its geographic variation.

Similar to creation of the Drug Price Index, claim standardization and winsorization is repeated on a monthly basis. All claims with service dates after January 2019 that are processed within the standardization month are standardized using the standardization month in the Drug Price Index that applies to the claim service date. For example, during March 2024 all claims

with processing dates in January 2024 are standardized, but this query is likely to also return claims with service dates in November and December 2023, which must be standardized using the Drug Price Index values from the respective rolling 3 month queries for those months.

To summarize, the Part D standardization methodology describes the process of calculating and assigning a Standardized Claim Amount to each PDE record using the following steps:

1. Classify drug products (i.e., NDCs) into clinically substitutable drug groups with the same active ingredient, strength, dosage form, route of administration, and brand/generic classification
2. For each drug group, set a Standard Unit Price, calculated as the Median Actual Unit Price of claims with service dates in the standardization month and the prior 2 months
3. Calculate and assign Initial Standardized Ingredient Costs to claims with processing dates in the standardization month
4. Identify and winsorize outlier Initial Standardized Ingredient Costs
5. Calculate Standardized Claim Amounts

The next section includes technical details for implementing these methodological steps.

## **II. DETAILED PAYMENT STANDARDIZATION METHODOLOGY**

The following sections describe the five steps of Part D payment standardization in more detail. To prepare for the calculation of standardized Part D amounts, a preliminary step is to extract prescription drug event (PDE) records based on the service dates and process dates.<sup>3</sup> Claims are pulled based on the date of service using at least a one-month claim runout, allowing claim process dates up to the end of the month after the standardization month. In addition, PDE records are obtained for service dates occurring up to 11 months prior to the standardization month. Combining multiple months of data allows for increased sample size and stability of the Standardized Claim Amounts. Once the claims have been extracted as described above, the initial two steps are to construct a Drug Price Index by first creating drug groups and then calculating the Standard Unit Price and other necessary metrics. After this, standardization is performed followed by identifying and winsorizing outliers and then calculation of Standardized Claim Amounts.

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<sup>3</sup> The fields from PDE records used in calculating Standardized Claim Amounts are available in Appendix C.

## 1. Creation of Drug Groups (Part 1 of Drug Price Index)

As noted above, the methodology for developing monthly standardized payments for Part D drugs requires construction of a monthly Drug Price Index with a Standard Unit Price for each drug group. Drugs are grouped according to mappings from the National Library of Medicine's (NLM) **RxNorm database**. The Standard Unit Price in the Drug Price Index is based on the median Actual Unit Price of all drugs in the same drug group (separately for brand and generic) over a 3-month time period. This process is described in detail below.

As a first step to constructing the Drug Price Index, Drug IDs are assigned to drug products based on groupings of clinically substitutable NDCs. These drug groups are formed using RxNorm, a classification system produced and maintained by the NLM, which is updated continuously. To form the drug groups for the Drug Price Index, NDCs in the queried data are mapped to their **RxNorm database** descriptions, which contain clinical information on each drug product. After cleaning and processing steps, RxNorm descriptions, along with brand/generic drug classifications from the FDA drug database, can be used to aggregate NDCs into drug groups based on clinical characteristics.<sup>4</sup>

The process of classifying NDCs and creating drug groups involves the following steps:

- (i) ***Map NDC to RxNorm description*** – Each month, download RxNorm database descriptions for all NDCs found in the queried data
- (ii) ***Clean/Process NDC descriptions*** – Create a clinical description for each NDC by removing non-clinical details (e.g., brand-name, drug packager, labeler, manufacturer) from the original RxNorm descriptions, while retaining clinical information for active ingredient, strength, dosage form and route of administration
- (iii) ***Assign Drug IDs based on the clinical information*** – All NDCs that share the same clinical description are assigned the same Drug ID
- (iv) ***Obtain brand/generic drug classifications*** – Using the RxNorm and FDA/SPL drug databases, obtain brand/generic classifications for all NDCs found in the queried data<sup>5</sup>
- (v) ***Create final drug groups*** – Stratify Drug IDs based on brand/generic classification and create final drug groups by appending the Drug IDs with a B or G

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<sup>4</sup> The FDA's drug database uses Structured Product Labeling (SPL) as a standard for exchanging product and facility information. For additional information about the use of SPL by the FDA, please see: <https://www.fda.gov/industry/fda-data-standards-advisory-board/structured-product-labeling-resources>. FDA data are the main upstream source for NDCs, which feed into both RxNorm and Medi-Span GPI. FDA data are used here to assign brand/generic labels to the NDCs in RxNorm.

<sup>5</sup> RxNorm data are continuously updated by the NLM, as NDCs are being added and/or removed. For standardization, the latest RxNorm data are downloaded as required for standardizing a month of PDE records. FDA data are also downloaded as needed for each run, such that the data run at least through the end of the month for the service dates for which PDE records are being standardized.

## 2. Calculation of Relevant Data Distributions for Each Drug Group (Part 2 of Drug Price Index)

To set a Standard Unit Price for each drug group in the Drug Price Index, calculate the Median Actual Unit Price for each drug group using queried claims:

- (i) **Calculate Actual Unit Prices** – For each queried PDE record, calculate the Actual Unit Price for the claim using the following formula:

$$\text{Actual Unit Price} = \frac{\text{Actual Ingredient Cost}}{\text{Quantity Dispensed}}$$

- (ii) **Calculate Daily Quantities** – For each queried PDE record, calculate the Daily Quantity for the claim using the following formula:

$$\text{Daily Quantity} = \frac{\text{Quantity Dispensed}}{\text{Days Supply}}$$

- (iii) **Calculate the data distributions for each drug group** – For each drug group, identify relevant PDE records (i.e., claims with NDCs that map to the same Drug ID) from the queried data for the 3 month period and calculate the distributions of Actual Unit Prices and Actual Ingredient Costs at each percentile based on identified claims. Calculate the distributions of Daily Quantities and Quantities Dispensed using the 12-month period.<sup>6</sup>

This step results in a Drug Price Index for the standardization month containing a list of drug groups (identified in the queried data), each with a Standard Unit Price (median Actual Unit Price), and the other metrics necessary to perform the standardization.

## 3. Initial Standardization of Ingredient Costs

The next step in the process is to assign Initial Standardized Ingredient Costs to each PDE record based on the Standard Unit Price from the Drug Price Index. For the majority of medium-to-high cost drug claims, this step will result in the Standardized Ingredient Cost used to calculate the Standardized Claim Amount. However, as described in Section 4 below, a minority of claims with outlier Actual Unit Prices and outlier Daily Quantities are re-standardized using a winsorization methodology. For these claims, winsorization is considered as part of their standardization methodology, and the Winsorized Standardized Ingredient Cost is what is used to calculate the Standardized Claim Amount.

Initial Standardized Ingredient Costs are calculated for each PDE record based on the following general formula:

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<sup>6</sup> The standardization methodology requires only the full distribution of Unit Prices, the median Actual Ingredient Cost, and the 25<sup>th</sup> and 75<sup>th</sup> percentiles for Daily Quantity.

$$\text{Initial Standardized Ingredient Cost} = \text{Standard Unit Price} \times \text{Quantity Dispensed}$$

where the Standard Unit Price is taken from the Drug Price Index for the relevant Drug ID and standardization month, or NDC and standardization month if the drug product is not contained in the RxNorm data. The Quantity Dispensed value is taken from the claim.

#### 4. Identification of Outliers and Winsorization

Once Initial Standardized Ingredient Costs are calculated for all PDE records, claims with outlier Actual Unit Prices and Actual Daily Quantities are identified for winsorization to prevent extreme Standardized Claim Amounts caused by extreme Quantity Dispensed values.<sup>7</sup>

##### a. Identifying Outliers

To implement the winsorization methodology, outlier thresholds are first determined for each drug group to limit the variation between Standard Unit Prices and Actual Unit Prices, based on analysis of historical drug price variation.<sup>8</sup> Specifically, historical drug price distributions are used to establish lower and upper bounds for the following ratio:

$$\text{Standard to Actual Unit Price Ratio} = \frac{\text{Standard Unit Price}}{\text{Actual Unit Price}}$$

Ratio limits are set for each drug group according to Table 2 based on each drug's median Actual Ingredient Cost, and for low-cost drugs, the median Actual Unit Price.<sup>9</sup>

**Table 2. Schedule for Standard to Actual Unit Price Ratio Limits**

Median Actual Ingredient Cost	Median Actual Unit Price	Standard to Actual Unit Price Ratio	
		Maximum	Minimum
\$0-\$20	\$0-\$2	1.00	1.00
\$0-\$20	\$2+	5.00	0.25
\$20-\$40	N/A	5.00	0.25
\$40-\$60	N/A	4.00	0.30
\$60-\$80	N/A	3.00	0.35
\$80-\$100	N/A	2.50	0.40
\$100-\$200	N/A	2.00	0.50
\$200-\$500	N/A	1.70	0.60
\$500-\$1,000	N/A	1.50	0.65
\$1,000-\$2,000	N/A	1.40	0.70
\$2,000+	N/A	1.30	0.75

These upper and lower bounds serve as thresholds for winsorizing outlier claims, where outlier claims are those falling above or below the maximum and minimum Standard to Actual

<sup>7</sup> Winsorization is a statistical method of adjusting a dataset to account for extreme values, or outliers, which may be skewing the data. This is done by replacing extreme values with less extreme values, typically by replacing values beyond a certain threshold with that of a pre-determined value that is less extreme.

<sup>8</sup> Periodic analyses of historical pricing data are used to empirically assign cost bins/upper and lower thresholds for each drug in the price index.

<sup>9</sup> Compounded drugs also have a Standard to Actual ratio of 1. Drug compounding may involve the combining of 2 or more drugs. Since the NDC field on PDE records does not allow for multiple NDCs, median Unit Price cannot be calculated reliably.

Unit Price Ratio limits, respectively. For example, a drug group with a median Actual Ingredient Cost of \$45, would have 4.00 and 0.30 as the maximum and minimum limits for the Standard to Actual Unit Price Ratio. Based on these limits, an example claim for that drug group with both a Standard to Actual Price Ratio of 10.00 and an extreme Daily Quantity would be identified as requiring winsorization.

Outlier claims requiring winsorization must have an extreme Daily Quantity in addition to a Standard to Actual Unit Price Ratio outside of limits. Extreme Daily Quantities are defined as those that fall outside the 25<sup>th</sup> – 75<sup>th</sup> percentile range of Daily Quantities for the relevant drug group and standardization month, or NDC and standardization month for drug products not assigned to a drug group because they are not contained in the RxNorm data.

### **b. Winsorization**

For all outlier claims, winsorize the Initial Standardized Ingredient Cost according to the following formula:<sup>10</sup>

$$\begin{aligned} & \textit{Winsorized Standardized Ingredient Cost} \\ &= \textit{Initial Standardized Ingredient Cost} \times \frac{\textit{Actual Unit Price}}{\textit{Threshold Unit Price}} \end{aligned}$$

Where the Threshold Unit Price is the Actual Unit Price at the percentile where the ratio of Standard Unit Price to Actual Unit Price is within the Standard to Actual Unit Price Ratio limits.

- i. For claims above the maximum Standard to Actual Unit Price Ratio, set Threshold Unit Price equal to the Actual Unit Price of the lowest percentile claim in the distribution that falls below the maximum Standard to Actual Unit Price Ratio limit.
- ii. Conversely, for claims below the minimum Standard to Actual Unit Price Ratio, set the Threshold Unit Price equal to the Actual Unit Price of the highest percentile claim in the distribution that falls above the minimum Standard to Actual Unit Price Ratio limit.

Example – Standard to Actual Unit Price Ratio Range: [0.50-4.00]

Metric/Percentile	1 <sup>st</sup> Percentile	2 <sup>nd</sup> Percentile	50 <sup>th</sup> Percentile	98 <sup>th</sup> Percentile	99 <sup>th</sup> Percentile
Actual Unit Price	\$0.25	\$1.00	\$2.00	\$3.00	\$3.00
Standard to Actual Unit Price Ratio	8.00	2.00	1.00	0.66	0.66

- Note there is an inverse relationship between Actual Unit Price percentile and Standard to Actual Unit Price Ratio.

<sup>10</sup> The winsorization is expressed in the simplest terms possible in this section, refer to Appendix D for an alternative explanation motivated by adjusting Daily Quantities.

- In this example, a claim at the 1<sup>st</sup> percentile has an outlier Actual Unit Price, such that the Standard to Actual Unit Price Ratio is above the established threshold of 4.00.
- The 2<sup>nd</sup> percentile is the lowest percentile claim with a Standard to Actual Unit Price Ratio below the threshold of 4.00.
- Thus, for winsorization, set the Threshold Unit Price of the outlier claim to that of the 2<sup>nd</sup> percentile, i.e., \$1.00.

## 5. Calculation of Standardized Claim Amounts

Following winsorization the Standardized Claim Amounts are calculated by summation with the Dispensing Fee and Vaccine Administration Fee, when applicable:

$$\begin{aligned}
 & \textit{Standardized Claim Amount} \\
 & = \textit{Standardized Ingredient Cost} + \textit{Dispensing Fee} \\
 & + \textit{Vaccine Administration Fee}
 \end{aligned}$$

Where the Standardized Ingredient Cost is the Winsorized Standardized Ingredient Cost for outlier claims and the Initial Standardized Ingredient Cost for non-outlier claims.

## **APPENDIX A: METHODOLOGY CHANGE LOG**

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The appendix notes the differences between the current Part D payment standardization methodology presented in this document and previous versions.

### **A.1 Changes in v.2**

- Section 3(a)(i): Added table with thresholds.

Non-methodological changes were made for presentation and clarity.

### **A.2 Changes in v.3**

- Added Appendix B to provide examples of standardization for various scenarios.
- Added Appendix C to share information on the variables and fields from PDE data used in standardization.

Non-methodological changes were made for presentation and clarity.

### **A.3 Changes in v.4**

- Added Appendix D to retain the description of winsorization motivated by adjusting Daily Quantities.

Non-methodological changes were made for presentation and clarity.

## APPENDIX B: EXAMPLES (COVERING ALL SCENARIOS)

This appendix provides examples of the standardization steps and their outputs. Aggregated values used in this example, e.g., Standard Unit Price, are actual values used for the August 2024 standardization. Individual claim values are fictitious.

### B.1 Creation of Drug Groups (Part 1 of Drug Price Index)

Creating the Drug Groups produces a crosswalk table between NDCs, which are reported on the claims, and Drug IDs, which are used to identify Drug Groups (Table B1). A Drug Group is defined by a combination of active ingredient, strength, dosage form, and route of administration. Brand and generic drugs are standardized separately; therefore, the Drug IDs are appended with a B or G to indicate the brand/generic classification. *Any NDC not contained in the RxNorm is not assigned a Drug ID but is standardized based on claims for that NDC.*

**Table B1. NDC to Drug ID Crosswalk**

NDC	RxNorm Description	Drug Group Description	Brand or Generic	Drug ID
00173063302	Lamotrigine 25 MG Oral Tablet [Brand Name]	lamotrigine 25 MG Oral Tablet	B	BDFE2FA010C5A9D1C21F7DCAAF51C4FE <b>B</b>
00173063310	{35 (Lamotrigine 25 MG Oral Tablet [Brand Name]) } Pack [Brand Name Blue (For Patients Taking Valproate)]	lamotrigine 25 MG Oral Tablet	B	BDFE2FA010C5A9D1C21F7DCAAF51C4FE <b>B</b>
00093003901	Lamotrigine 25 MG Oral Tablet	lamotrigine 25 MG Oral Tablet	G	BDFE2FA010C5A9D1C21F7DCAAF51C4FE <b>G</b>
00378425101	Lamotrigine 25 MG Oral Tablet	lamotrigine 25 MG Oral Tablet	G	BDFE2FA010C5A9D1C21F7DCAAF51C4FE <b>G</b>
00615796439	{35 (Lamotrigine 25 MG Oral Tablet) } Pack	lamotrigine 25 MG Oral Tablet	G	BDFE2FA010C5A9D1C21F7DCAAF51C4FE <b>G</b>

### B.2 Calculation of Data Distributions for Each Drug Group (Part 2 of Drug Price Index)

Calculating the rolling 3-month and 12-month data distributions allows for inclusion of the necessary metrics in the Drug Price Index (Table B2). These metrics include the entire percentile distribution of Actual Unit Prices (ellipses in the table below indicates columns omitted from the example presentation), the median Actual Ingredient Cost, and the 25<sup>th</sup> and 75<sup>th</sup> percentiles for Daily Quantity. A similar table is constructed using NDCs instead of Drug IDs for the purpose of standardizing claims for an NDC not contained in the RxNorm data.

**Table B2. Drug Price Index for Lamotrigine 25 MG Oral Tablets**

Drug ID	Year	Rolling Month	1st % Actual Unit Price	...	Standard Unit Price (Median Actual Unit Price)	...	99th % Actual Unit Price	Median Actual Ingredient Cost	25th % Daily Quantity	75th % Daily Quantity
BDFE2FA010C5A9D1C21F7DCAAF51C4FE <b>B</b>	2024	8	0.1312	...	10.2582	...	11.886	1185.93	2	4

Drug ID	Year	Rolling Month	1st % Actual Unit Price	...	Standard Unit Price (Median Actual Unit Price)	...	99th % Actual Unit Price	Median Actual Ingredient Cost	25th % Daily Quantity	75th % Daily Quantity
BDFE2FA010C5A9D1 C21F7FDCAF51C4FE G	2024	8	0	...	0.0697	...	0.9386	5.36	2	3

### B.3 Initial Standardization of Ingredient Costs

The Drug Price Index is then applied to claims from the current month to standardize them. An Initial Standardized Ingredient Cost is calculated for each claim by multiplying the Quantity Dispensed on the claim with the Standard Unit Price in the Drug Price Index.

**Table B3. Initial Standardization and Outlier Check for Branded Lamotrigine 25 MG Oral Tablets**

Drug ID	Actual Ingredient Cost (\$)	Quantity Dispensed	Days Supply	Actual Unit Price (\$)	Daily Quantity	Initial Standardized Ingredient Cost (\$)	Standard to Actual Unit Price Ratio
BDFE2FA010C5A9D1 C21F7FDCAF51C4FE B	800	90	30	8.8888889	3	923.238	0.86651546
BDFE2FA010C5A9D1 C21F7FDCAF51C4FE B	800	90	90	8.8888889	1	923.238	0.86651546
BDFE2FA010C5A9D1 C21F7FDCAF51C4FE B	1200	180	90	6.6666667	2	1846.476	0.649886595
BDFE2FA010C5A9D1 C21F7FDCAF51C4FE B	3000	450	90	6.6666667	5	4616.19	0.649886595
BDFE2FA010C5A9D1 C21F7FDCAF51C4FE B	450	30	30	15	1	307.746	1.462244838

### B.4 Identification of Outliers and Winsorization

#### a. Identifying Outliers

Outlier identification is a two-step process. First, the Daily Quantity from the claim is compared to the Drug Price Index to determine if it is outside the 25<sup>th</sup> – 75<sup>th</sup> percentile range. Second, the Standard to Actual Unit Price Ratio is compared to the Schedule for Standard to Actual Unit Price Ratio Limits (Table 1) to determine if it is outside the specified range. Claims are winsorized only if both criteria are outside of range.

For our fictitious examples in Table B3, the median Actual Ingredient Cost of \$1185.93 specifies a Standard to Actual Unit Price Ratio range of 0.7 – 1.4. The first example claim meets neither criterion for winsorization, the second meets only the Daily Quantity criterion, and the third meets only the Standard to Actual Unit Price Ratio criterion. Thus, none of the first three claims are winsorized. The fourth and fifth claims are both outside the Daily Quantity 25<sup>th</sup> – 75<sup>th</sup> percentile range and outside the 0.7 – 1.4 Standard to Actual Unit Price Ratio range. Thus, the last two claims are winsorized.

**b. Winsorization**

The Threshold Unit Price needs to be determined to winsorize claims 4 and 5 (Table B3). Claim 4 has a Standard to Actual Unit Price Ratio below the required range; thus, we need to determine the Actual Unit Price of the highest percentile in the distribution that falls above the minimum Standard to Actual Unit Price Ratio limit. The Drug Price Index indicates the 99<sup>th</sup> percentile for Actual Unit Price is \$11.886 (Table B2); thus, the ratio at this percentile falls within range ( $\$10.2582 / \$11.886 = 0.863$ ) and the Threshold Unit Amount is \$11.886.

Claim 5 has a Standard to Actual Unit Price Ratio above the required range; thus, we need to determine the Actual Unit Price of the lowest percentile in the distribution that falls below the maximum Standard to Actual Unit Price Ratio limit. Although the column is not displayed in Table B2, the Drug Price Index indicates the 2<sup>nd</sup> percentile for Actual Unit Price is \$8.6954; thus, the ratio at this percentile falls within range ( $\$10.2582 / \$8.6954 = 1.180$ ) while the ratio at the 1<sup>st</sup> percentile does not ( $\$10.2582 / \$0.1312 = 78.188$ ). Thus, the Threshold Unit Amount for this claim is \$8.6954.

After determining Threshold Unit Prices, the Winsorized Standardized Ingredient Cost is calculated by multiplying the Initial Standardized Ingredient Cost and the ratio of Actual Unit Price / Threshold Unit Price (Table B4).

**Table B4. Winsorization of Branded Lamotrigine 25 MG Oral Tablet Outlier Claims**

Drug ID	Actual Ingredient Cost	Actual Unit Price	Initial Standardized Ingredient Cost	Standard to Actual Unit Price Ratio	Winsorized Standardized Ingredient Cost
BDFE2FA010C5A9D1C21F7DCAF51C4FEB	3000	6.6666667	4616.19	0.6498866	2589.1469
BDFE2FA010C5A9D1C21F7DCAF51C4FEB	450	15	307.746	1.4622448	530.87725

**B.5 Calculation of Standardized Claim Amounts**

The final step is to calculate the Standardized Claim Amounts by adding any applicable Dispensing or Vaccine Administration Fees to the Winsorized Standardized Ingredient Cost or Initial Standardized Ingredient Cost, for outlier and non-outlier claims, respectively.

## APPENDIX C: VARIABLES AND FIELDS FROM PDE DATA USED IN STANDARDIZATION

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### C.1 Calculating Standardized Amounts

Variable	Description	PDE Field Name
PROD_SERVICE_ID	National Drug Code	PRODUCT_SERVICE_ID
INGRDNT_COST_PD	Ingredient cost	INGREDIENT_COST_PAID
DSPNSNG_FEE_PD	Dispensing fee	DISPENSING_FEE_PAID
VAC_ADMIN_FEE	Vaccine administration fee	VACCINE_ADMINISTRATION_FEE
QUANTITY_DISPENSED	Quantity dispensed	QUANTITY_DISPENSED
DAYS_SUPPLY	Days supply	DAYS_SUPPLY
RX_DOS_DT	Date prescription is filled	DATE_OF_SERVICE (DOS)

### C.2 Variables that Uniquely Identify a PDE Record

Variable	Description
FILL_NUM	Fill number, defaults to zero.
RX_SERV_REF_NUM	The pharmacy's internal invoice number on pharmaceutical claims.
RX_DOS_DT	The first day on the billing statement covering services rendered to the beneficiary (also known as 'Statement Covers From Date'). (NCH)
SRVC_PROVIDER_ID_QUAL	The type of number used to identify a service provider. For example: 01 = NPI 06 = UPIN 07 = NCPDP Number 08 = State License Number 11 = Federal Tax Number 99 = Other mandatory for Standard Data Format Values of '06', '08', '11', or '99' only acceptable if non-Standard Format = 'B', 'X', or 'P'
SRVC_PROVIDER_ID	A number used to identify a service provider.
PKG_AUDT_KEY_ID	An IDR assigned surrogate key for a package identifier.

## APPENDIX D: DESCRIPTION OF WINSORIZATION MOTIVATED BY ADJUSTING DAILY QUANTITIES

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Section 4.b. presents the winsORIZATION in the simplest terms possible, mathematically speaking. However, expressing the winsORIZATION in this way can make it difficult to understand in concrete terms. Here we preserve the winsORIZATION in terms that convey the original motivation.

Claims are determined to be outliers if the Quantity Dispensed is extremely low or extremely high compared to the Actual Ingredient Cost and Days Supply. Outlier claims are identified based on extreme Actual Unit Prices (Actual Ingredient Cost / Quantity Dispensed) and extreme Actual Daily Quantities (Quantity Dispensed / Days Supply) within each drug distribution. Given that standardized amounts are calculated as the product of Standard Unit Price and Quantity Dispensed, claims with extreme Actual Quantity Dispensed values would likely be assigned extreme Standardized Claim Amounts. To prevent extreme Standardized Claim Amounts, the Actual Unit Price values on outlier claims are winsORIZED to ensure that the Unit Price of a claim does not exceed pre-defined upper and lower bounds of Unit Price, set for each drug. Based on the WinsORIZED Unit Prices, the Quantities Dispensed are adjusted and then used to recalculate Standardized Ingredient Cost.

For all outlier claims, winsORIZE Actual Unit Price values and recalculate standardized amounts based on the winsORIZED values, using the following steps:

- i. For claims above the maximum Standard to Actual Unit Price Ratio, set WinsORIZED Unit Price equal to the Actual Unit Price of the lowest percentile in the distribution that falls below the maximum Standard to Actual Unit Price Ratio limit.
- ii. Conversely, for claims below the minimum Standard to Actual Unit Price Ratio, set the WinsORIZED Unit Price equal to the Actual Unit Price of the highest percentile in the distribution that falls above the minimum Standard to Actual Unit Price Ratio limit.

Example – Standard to Actual Unit Price Ratio Range: [0.50-4.00]

Metric/Percentile	1 <sup>st</sup> Percentile	2 <sup>nd</sup> Percentile	50 <sup>th</sup> Percentile	98 <sup>th</sup> Percentile	99 <sup>th</sup> Percentile
Actual Unit Price	\$0.25	\$1.00	\$2.00	\$3.00	\$3.00
Standard to Actual Unit Price Ratio	8.00	2.00	1.00	0.66	0.66

- Note there is an inverse relationship between Actual Unit Price percentile and Standard to Actual Unit Price Ratio.
- In this example, a claim at the 1<sup>st</sup> percentile has an outlier Actual Unit Price, such that the Standard to Actual Unit Price Ratio is above the established threshold of 4.00.

- The 2<sup>nd</sup> percentile is the lowest percentile claim with a Standard to Actual Unit Price Ratio below the threshold of 4.00.
- Thus, for winsorization, set Winsorized Unit Price of the outlier claim to that of the 2<sup>nd</sup> percentile, i.e., \$1.00.

Once claims are identified as outliers using this method, the Actual Unit Price values for these outlier claims are winsorized. Winsorized Unit Prices are then used to adjust Actual Quantity Dispensed values for recalculation of Standardized Ingredient Costs. Steps to implement this winsorization methodology are outlined below:

- (a) Adjust Actual Quantity Dispensed using Winsorized Unit Price according to the following formula:

$$\text{Adjusted Quantity Dispensed} = \frac{\text{Actual Ingredient Cost}}{\text{Winsorized Unit Price}}$$

- (b) Recalculate Standardized Ingredient Costs using Adjusted Quantity Dispensed:

$$\begin{aligned} \text{Winsorized Standardized Ingredient Cost} \\ = \text{Standard Unit Price} \times \text{Adjusted Quantity Dispensed} \end{aligned}$$

Below we prove the method presented in Section 2.b is mathematically equivalent to the method presented in Appendix D by deriving the former from the latter. Note that Winsorized Unit Price in Appendix D is referred to as Threshold Unit Price in Section 2.b and Appendix B. Likewise, Actual Quantity Dispensed in Appendix D is referred to as Quantity Dispensed in Section 2.b and Appendix B.

1. 
$$\begin{aligned} \text{Winsorized Standardized Ingredient Cost} \\ = \text{Standard Unit Price} \times \text{Adjusted Quantity Dispensed} \end{aligned}$$
2. 
$$\begin{aligned} \text{Winsorized Standardized Ingredient Cost} \\ = \text{Standard Unit Price} \times \frac{\text{Actual Ingredient Cost}}{\text{Winsorized Unit Price}} \end{aligned}$$
3. 
$$\begin{aligned} \text{Winsorized Standardized Ingredient Cost} \\ = \frac{\text{Standard Unit Price} \times \text{Actual Ingredient Cost}}{\text{Winsorized Unit Price}} \end{aligned}$$
4. 
$$\begin{aligned} \text{Winsorized Standardized Ingredient Cost} \\ = \frac{\text{Standard Unit Price} \times \text{Actual Quantity Dispensed} \times \text{Actual Unit Price}}{\text{Winsorized Unit Price}} \end{aligned}$$

5. *Winsorized Standardized Ingredient Cost*  
$$= \frac{\text{Initial Standardized Ingredient Cost} \times \text{Actual Unit Price}}{\text{Winsorized Unit Price}}$$

6. *Winsorized Standardized Ingredient Cost*  
$$= \text{Initial Standardized Ingredient Cost} \times \frac{\text{Actual Unit Price}}{\text{Winsorized Unit Price}}$$