# CMS Payment Standardization Methodology for Part D v.2

# For Services Provided During 2015 - 2021 (Updated October 2021)

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# INTRODUCTION

Payment standardization is the process of producing standardized claim payment amounts that 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 provider resource use for services covered by Medicare Part A, Part B, and Part D programs[1].

Part D payment standardization, in particular, is meant to facilitate analysis of provider resource use for prescription drugs covered under the Medicare Part D program. 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. To illustrate, Part D standardization will allow resource use comparisons for providers who prescribe the same drug, even if the drug products are covered under varying Part D plans, produced by different manufacturers, or dispensed by separate pharmacies. As is outlined in the following sections of this document, Part D standardized amounts are calculated using standard prices for each Part D drug, thereby removing much of this non-clinical cost variation. This allows standardized amounts to reflect meaningful differences in provider resource use, facilitating the incorporation of prescription drug costs into performance programs and enabling the development of more robust cost measures that more accurately represent episodes of care.

As with Parts A and B payment standardization, the current Part D standardization methodology outlined in this document is subject to periodic updates from CMS. Crucially, this allows CMS to update the standardization algorithm to account for changes in Part D program

[1] For basic and detailed versions of the Parts A and B payment standardization methodologies, please see the CMS Price (Payment) Standardization Overview **article** on ResDAC.

policies, relevant data sources, as well as evolving needs of CMS performance programs and stakeholders. As a result, CMS will continue to reevaluate and implement cyclical updates to the Part D payment standardization methodology and documentation in accordance with these changes.

The remainder of this document provides a comprehensive overview of the Part D standardization methods, in two 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 Prescription Drug Event (PDE) claims. For additional questions about the Part D payment standardization methodology, please email **cm-payment-standardization-support@acumenllc.com**.

# I. OVERVIEW OF PART D PAYMENT STANDARDIZATION

The Part D standardization methodology is designed to produce standardized amounts that can facilitate meaningful comparisons of provider resource use despite the high variation in drug prices observed within the market-based Medicare Part D program. The methodology implements a monthly price index with a standard price per unit for each drug, calculated from observed drug costs. The following section contains an overview of how this price index is constructed and used in the standardization of Part D claims.

As the basis for the drug price index, clinically substitutable drug products (identified by national drug code [NDC]) are grouped into drugs based on active ingredient, strength, route of administration, dosage form, and brand/generic designation. 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. Based on these groupings, two drug products that are clinically substitutable (e.g., both are 500mg oral tablets of the same active ingredient) will have the same standard price according to the price index even if one drug comes in a blister pack and another comes in a bottle. This methodological design allows standardized 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 three products of 2MG 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.

To determine a standard price for each drug, the median per-unit cost is calculated for each drug on a monthly basis, using three months of Part D claims with service dates in the standardization month (i.e., the month for which claims are being standardized) and two prior months. Claims with relevant service dates are pulled one month after the end of the standardization month, resulting in a one-month runout period to allow time for claims with

relevant service dates to be submitted and processed. As an example, standardized prices for January are calculated using claims with November, December, and January service dates, with process dates up to the end of February. These data procedures are meant to ensure that median prices are calculated with enough claims to be representative of true median per-unit drug costs and that standard drug prices are generally stable over time, even if Part D prices fluctuate significantly from one month to another due to sudden pricing changes. These data procedures and the calculation of median per-unit costs result in a price index for the standardization month, where each drug is assigned a standard price, referred to as the Median Unit Price.

After constructing the price index, a standardized amount is assigned to each Part D claim by multiplying the Quantity Dispensed (the number of drug units noted on the claim) by the Median Unit Price for the relevant drug:

$$\text{Standardized Cost} = \text{Median Unit Price} \bullet \text{Quantity Dispensed}$$

where the Quantity Dispensed variable is used as an indicator of resource use to calculate standardized amounts that exclude drug price variation captured in Actual Claim Cost. This approach is intended to produce standardized costs that can represent resource use within performance programs.

After standardized amounts are calculated across claims, outliers are identified for winsorization. Claims are determined to be outliers if the Quantity Dispensed value is extremely low or extremely high compared to Actual Claim Cost and Days Supply, and are identified based on extreme Unit Price values (calculated as Actual Claim Cost / Quantity Dispensed) and extreme Daily Quantity Dispensed (calculated as Quantity Dispensed / Days Supply) within each drug distribution. Given that standardized amounts are calculated as the product of Median Unit Price and Quantity Dispensed, claims with extreme Quantity Dispensed values would likely be assigned extreme standardized values. To prevent extreme standardized amounts, the 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 Price values, claim Quantity Dispensed values are adjusted and then used to recalculate standardized cost. Further details of this winsorization methodology can be found in Step 3.2 in Section II below.

$$\text{Standardized Cost for Outlier Claims} = \text{Median Unit Price} \bullet \text{Adjusted Quantity Dispensed}$$

To summarize the Part D standardization methodology described in the paragraphs above, Acumen calculates and assigns standardized amounts to each Part D claim using the following three steps:

1. Classify drug products (NDCs) into clinically substitutable drugs with the same strength, route of administration, dosage form, active ingredient, and brand/generic status
2. For each drug, set a standard price, calculated as the median cost per unit (*Median Unit Price*) of claims with service dates in the standardization month and prior two months, with a one-month claim runout from the end of the standardization month
3. Calculate and assign Part D claim standardized amounts using the following formula:

   Standardized Cost = Median Unit Price • Quantity Dispensed

   applying winsorization for outlier claims

These steps are repeated on a monthly basis, for each monthly production run of standardized Part D claims. The next section includes technical details for implementing these three methodological steps.

# II. DETAILED PAYMENT STANDARDIZATION METHODOLOGY

The following sections describe the three steps of Part D payment standardization in more detail. Given the data procedures outlined in Section I, standardization for any given month will require PDE records queried based on service date, where claim service dates fall within the standardization month, as well as the two months prior to the standardization month. Claims should be pulled using a one-month claim run-out, allowing claim process dates up to the end of the month after the standardization month. Using this data, the following sections describe the three-step process to construct a drug price index (Steps 1 and 2) and calculate standardized amounts for Part D claims (Step 3) on a monthly basis.

## 1. Classification of NDCs into Drugs

As a first step to constructing the drug price index, drugs in the price index are defined based on groupings of clinically substitutable NDCs. To form these groupings, 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 groupings based on clinical characteristics. Detailed steps are as follows:

(i) ***Map NDC to RxNorm description*** - Obtain 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, route of administration, and dosage form

(iii) ***Assign Drug IDs based on the cleaned descriptions*** - 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 drug databases, obtain brand/generic classifications for all NDCs found in the queried data

(v) ***Create final drug classifications*** - Stratify Drug IDs based on brand/generic status to create final drug classifications

## 2. Calculation of Median Unit Price for Each Drug

To set a standard price for each drug in the price index, calculate the Median Unit Price for each drug (as defined in Step 1) using queried claims:

(i) ***Calculate claim unit prices*** - For each queried Part D claim, calculate the Unit Price for the claim using the following formula:

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

(ii) ***Calculate the Median Unit Price for each drug*** - For each drug defined in Step 1, identify relevant Part D claims (i.e., claims with NDCs that map to the given drug) from the queried data and calculate the Median Unit Price based on identified claims.

Step 2 results in a price index for the standardization month containing a list of drugs (identified in the queried data), each with a standard price (Median Unit Price).

## 3. Standardization of Part D Claims

Using the price index constructed in Steps 1 and 2, Step 3 calculates Part D standardized amounts. For the majority of medium-to-high cost drug claims, Step 3.1, which calculates and assigns a standardized amount for each Part D claim, will result in final standardized values. Step 3.2 then identifies a minority of claims with outlier Unit Price values, replacing extreme standardized amounts (calculated in Step 3.1) with recalculated amounts based on winsorized claim values.

### 3.1 Calculation of Standardized Amounts

Calculate a standardized amount for each Part D claim based on the following formula:

$$\text{Standardized Cost} = \text{Median Unit Price} \bullet \text{Quantity Dispensed}$$

where the Median Unit Price is the standard price for the relevant drug (identified by the NDC listed on the claim) in the price index for the standardization month, and the Quantity Dispensed value is taken from the claim.

## 3.2 Winsorization of Outlier Claims

Once standardized amounts are calculated for all Part D claims, claims with outlier Unit Price values and Daily Quantity values are identified for winsorization to prevent extreme standardized amounts caused by extreme Quantity Dispensed values. To implement the winsorization methodology, outlier thresholds are first determined for each drug to limit the variation between the standardized cost of a claim and its actual cost, based on analysis of historical drug price variation. Specifically, drug price distributions are used to establish lower and upper bounds for the following ratio:

$$\text{Standardized to Actual Cost Ratio} = \frac{\text{Standardized Cost}}{\text{Actual Claim Cost}}$$

Ratio limits are set for each drug according to Table 1 based on each drug's median claim cost in combination with the median unit price.[2]

**Table 1. Schedule for Standardized to Actual Cost Ratio Limits**

| Median Claim Cost | Median Unit Price | Standardized to Actual Ratio | |
|---|---|---|---|
| | | Maximum | Minimum |
| $0-$20 | $0-$2 | 1.0 | 1.0 |
| $0-$20 | $2+ | 5.0 | 0.25 |
| $20-$40 | N/A | 5.0 | 0.25 |
| $40-$60 | N/A | 4.0 | 0.30 |
| $60-$80 | N/A | 3.0 | 0.35 |
| $80-$100 | N/A | 2.5 | 0.40 |
| $100-$200 | N/A | 2.0 | 0.50 |
| $200-$500 | N/A | 1.7 | 0.60 |
| $500-$1,000 | N/A | 1.5 | 0.65 |
| $1,000-$2,000 | N/A | 1.4 | 0.70 |
| $2,000+ | N/A | 1.3 | 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 standardized to actual cost ratio limits, respectively. For example, a drug with median claim cost of $45, would have 4.0 and 0.3 as the maximum and minimum ratio of standardized to actual limits. Based on these limits, an example claim for that drug with an extreme Daily Quantity and a standardized to actual cost ratio of 10 would be identified as requiring winsorization for this drug. To ensure that these limits are precise to the unique cost variation of drugs and reflect changes in drug costs over time, thresholds will be calculated using the most recent drug pricing data at the time of update.

Once claims are identified as outliers using this method, the Unit Price values for these outlier claims are winsorized. Winsorized Unit Price values are then used to adjust Quantity Dispensed

[2] Compounded drugs also have a Standardized to Actual ratio of 1. Drug compounding involves the combining of two or more drugs. Since the NDC field on Part D claims does not allow for multiple NDCs, Median Unit Price cannot be calculated reliably.

values for recalculation of standardized amounts. Steps to implement this winsorization methodology are outlined below:

(i) ***Determine outlier thresholds for each drug*** – Determine the Standardized to Actual Cost Ratio thresholds for each drug in the price index, setting upper and lower thresholds based on historical drug price distributions.

(ii) ***Identify outlier claims*** - Identity outlier claims as claims that fall outside the $25^{th}$-$75^{th}$ Daily Quantity range and outside the Standardized to Actual Cost Ratio thresholds for each drug using the following steps:

(a) Calculate the Standardized to Actual Cost Ratio for each claim using the formula:

$$\text{Standardized to Actual Cost Ratio} = \frac{\text{Standardized Cost}}{\text{Actual Claim Cost}}$$

(b) For each claim, compare the claim Standardized to Actual Cost Ratio with the upper and lower ratio thresholds for the relevant drug. If the claim ratio falls outside of the thresholds, identify claim as an outlier.

(iii) ***Re-standardize outlier claims*** - For all outlier claims, winsorize Unit Price values and recalculate standardized amounts based on the winsorized values, using the following steps:

(a) Winsorize Unit Price values

i. For claims above the maximum Standardized to Actual Cost Ratio, set Unit Price equal to the Unit Price of the lowest percentile claim in the Unit Price distribution that falls below the Standardized to Actual Cost Ratio threshold

ii. Conversely, for claims that fall below the minimum Standardized to Actual Cost Ratio threshold, set the Unit Price equal to the Unit Price of the highest percentile claim in the Unit Price distribution that falls within the threshold

(b) Adjust Quantity Dispensed values using winsorized Unit Price values according to the following formula:

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

(c) Recalculate standardized costs using Adjusted Quantity Dispensed values:
Standardized Cost for Outlier Claims =
Median Unit Price • Adjusted Quantity Dispensed

# APPENDIX A: METHODOLOGY CHANGE LOG

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

## A.1 Changes in v.2

- Section 3.2: Added table with thresholds.

Non-methodological changes were also made for presentation and clarity.