Technical Report:

2026 Outpatient Prospective Payment System (OPPS)
Drug Acquisition Cost Survey (ODACS)

United States Department of Health and Human Services
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1 Background And Purpose

Section 1833(t)(14)(A)(iii) of the Social Security Act requires the Secretary of the Department of Health and Human Services to set payment rates for specific covered outpatient drugs (SCODs), beginning in 2006, at the amount the Secretary determines to be the average acquisition cost for the drug in that year, when survey data on hospital acquisition costs is available. Pursuant to Section 1833(t)(14)(D)(i)(I), the Government Accountability Office (GAO) conducted such surveys in 2004 and 2005 to inform 2006 rates.

Section 1833(t)(14)(D)(ii) then directs the Secretary to periodically conduct surveys on hospital acquisition costs to inform payment rates for SCODs in later years. On April 18, 2025, President Trump signed Executive Order (EO) 14273,[1] directing the Secretary to publish in the *Federal Register* a plan to conduct a survey of SCODs and drugs that CMS has historically treated as SCODs. In response, as announced in the Calendar Year (CY) 2026 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Final Rule,[2] the Centers for Medicare & Medicaid Services (CMS) conducted the OPPS Drug Acquisition Cost Survey (ODACS) to collect the acquisition costs of certain outpatient drugs and biological products purchased by hospitals paid under the OPPS between July 1, 2024 and June 30, 2025.

CMS has comprehensively analyzed the ODACS data received from hospitals to inform its policymaking related to payment rates for drugs and biological products in the CY 2027 OPPS/ASC Proposed Rule. As the EO stipulates, CMS has used the results of the ODACS analysis to consider and propose appropriate adjustments that align Medicare payment with hospitals' acquisition costs, consistent with the budget neutrality requirement in Section 1833(t)(9)(B) of the Act and other legal requirements.

This technical report details the methodology and primary results of the ODACS data analysis conducted by CMS in conjunction with its contractor Acumen. Section 2 provides a brief overview of the ODACS structure and data elements. Section 3 details the methodological specifications used to analyze the survey data, including steps to ensure its statistical validity and representativeness. Section 4 summarizes key insights from the analysis and implications for CMS's proposed policy changes.

2 ODACS Survey Design and Data Collection

Hospitals were to submit their ODACS data on the Fee-For-Service (FFS) Data Collection System (FFSDCS) between January 1, 2026 and April 7, 2026. CMS did not use a sampling method; all received survey responses deemed valid and reliable were used in the analyses described in this document.

Section 2.1 discusses the hospitals included for participation in the survey. Section 2.2 describes the drugs and biological products for which hospitals reported data. Section 2.3 outlines the required data fields.

2.1 Study Population

CMS identified 4,494 entities[3] for inclusion in the ODACS study population due to their submission of at least one qualifying FFS claim paid under the OPPS during the ODACS study period, hereinafter referred to as "survey-eligible hospitals."

Qualifying claims met all of the following criteria:

- Claim date of service of July 1, 2024 to June 30, 2025
- Claim type of Part B outpatient (code 40)
- Facility type code of 12 (hospital inpatient/home health), 13 (hospital outpatient), 14 (hospital other), and 76 (community mental health center)
- Payment greater than zero
- Status indicator denoting separately payable drugs or other relevant Part B outpatient services (G, H, J1, J2, K, Q1, Q2, Q3, Q4, R, S, T, U, or V)

Claims billed by hospital types not paid under the OPPS were removed.[4] After this initial claims-based identification, CMS ensured that each entity had valid Medicare enrollment during the ODACS study period using the Provider Enrollment, Chain, and Ownership System (PECOS).

These criteria were intended to be maximally inclusive to identify all entities paid under the OPPS that could have purchased survey-relevant outpatient drugs during the ODACS study period. Entities were identified by their unique CMS Certification Number (CCN) and could submit only one survey response. There was no sampling as the study population was intended to be the entire universe of OPPS entities.

2.2 Drugs and Biological Products

CMS identified 1,843 outpatient drugs and biological products[5] for inclusion, using their 11-digit National Drug Code (NDC), as those products that were separately payable under the OPPS during at least part of the ODACS study period and for which a payment was made under the OPPS during that period. These 1,843 NDCs corresponded to 519 HCPCS codes, hereinafter referred to as "survey-relevant HCPCS codes."[6]

Hospitals were to report data for all of those NDCs that they purchased between July 1, 2024 and June 30, 2025 and either leave the data fields blank or write zero for any NDCs that they did not purchase during that time period.

2.3 Data Elements

For each NDC, hospitals were to report (i) the total number of units purchased (Section 2.3.1) and (ii) the total net acquisition cost for those units, inclusive of all discounts and rebates able to be applied to specific NDCs (Section 2.3.2), between July 1, 2024 and June 30, 2025.

Hospitals reported these values separately for acquisitions made through the 340B Drug Discount Program and acquisitions made outside the 340B Program, as applicable. Since certain discounts and pricing reductions are specific to drugs acquired through the 340B Program, this survey design ensured that all discounts were accurately captured and represented as part of each hospital's acquisition costs.

2.3.1 Total Units

"Total units" is the number of units purchased by the hospital as defined by the NDC package amount.[7] Hospitals were to report total units as a positive number with up to two decimal places. Total units for purchases that were intended for inpatient use only and/or returned were to be excluded.

2.3.2 Total Net Acquisition Cost

"Total net acquisition cost" is the amount that the hospital paid to acquire all units of specified 340B and non-340B drugs and biological products, including all rebates and discounts tied to that individual NDC.

Hospitals were instructed to *include* the following discount types in the net acquisition cost:

1. Group Purchasing Organization (GPO) or buying group savings, rebates, or discounts that are (i) tied to specific NDCs or (ii) not tied to a specific NDC but that hospitals can reasonably incorporate into their NDC acquisition costs (e.g., discounts applied at the invoice level)
2. Any other wholesaler or distributor rebates or credits applicable to a specific NDC
3. *For 340B drugs only:* 340B discounts or any other federally mandated pricing reductions

Hospitals were not to include financial concessions that *could not* reasonably be linked to a specific NDC's acquisition cost. Instead, if a hospital received additional discounts or rebates from being part of a GPO or other buying group, it was to separately report that dollar amount in the *Price Concessions* field of the ODACS module on the FFSDCS.

3. Methodological Specifications

In analyzing the received ODACS data, CMS's primary objective was to validate whether hospitals' acquisition costs appropriately and accurately align with Medicare payment rates. To ensure that these analyses provided a representative picture of acquisition costs for all hospitals paid under the OPPS, CMS also conducted extensive analyses of the respondent hospital population composition and sensitivity analyses to assess the statistical robustness and validity of the received ODACS responses.

Section 3.1 describes analyses to characterize the respondent population and compare it with the overall survey-eligible population. Section 3.2 outlines the calculation used to compare acquisition costs with Medicare payment rates. Section 3.3 summarizes five data refinements to exclude anomalous and implausible survey data. Section 3.4 discusses the methodology to identify and remove survey responses with outlier acquisition costs. Finally, Section 3.5 describes the statistical approaches used to analyze the representativeness of the received data and assess the sufficiency of the sample size.

3.1 Assessment of Hospital Populations

To understand which entities responded to ODACS, CMS determined (i) the share of survey-eligible hospitals that submitted any survey response and (ii) the share of hospitals that submitted a response in which they reported acquiring at least one surveyed NDC (i.e., did not submit a blank response). These response rates were stratified by geography (Census region) and whether the hospital was participating in the 340B Program. To assess the representativeness of the received sample, CMS compared the

composition of the respondent population, nonrespondent population, and overall survey-eligible population along observable hospital characteristics: OPPS drug claims volume, hospital size, rurality, and teaching status (refer to Appendix *Table A1* for definitions and data sources for each characteristic).

As part of these analyses, CMS applied two refinements to more precisely identify and characterize the ODACS population. Section 3.1.1 summarizes how CMS identified each entity as a parent unit or subunit and created parent–subunit pairs. Section 3.1.2 describes the creation and application of a refined hospital population to focus on survey-eligible hospitals with meaningful outpatient drug acquisitions.

3.1.1 Identification of Parent and Subunit Pairs

The ODACS study population of 4,494 CCNs includes both parent units and subunits. Parent units were identified as entities where all six digits of its CCN are numeric. Subunits have S (denoting psychiatric units) or T (denoting inpatient rehabilitation units) in the third position of CCN. To identify the parent unit for each subunit, the S or T in the subunit's CCN was replaced with "0"; the resulting six-digit string matched the CCN of the parent unit.[8] CMS also conducted manual review using facility name and ZIP Code to ensure the accuracy of each parent–subunit pair.

3.1.2 Creation of Refined Study Population

As described in Section 2.1, the population of 4,494 CCNs initially identified for inclusion in ODACS was intended to be maximally inclusive of all entities paid under the OPPS that could have purchased relevant outpatient drugs during the ODACS study period. However, further claims analysis revealed that a subset of the 4,494 eligible entities did not submit any OPPS claims for survey-relevant HCPCS codes during the study period. Many of these entities, which were largely subunits or non–acute care hospitals, also did not
submit an ODACS response or submitted a response reporting zero drug acquisitions. These observations are not unexpected given that many subunits likely acquire their outpatient drugs in conjunction with their parent unit and some non–acute care entities do not acquire or administer the specific outpatient drugs included in the survey at all.

Taking these results into consideration, CMS applied two refinements to the ODACS study population before analyzing hospitals' acquisition costs:

1. Collapse subunits with their parent unit[9]
2. Remove parent units where neither the parent nor any of its subunits reported acquisition data nor submitted OPPS claims for survey-relevant HCPCS codes during the ODACS study period

The resulting refined population is composed exclusively of 3,147 parent units that billed a survey-relevant HCPCS code or submitted the survey; in other words, entities that, either via their ODACS response or claims data, reported OPPS utilization of survey-relevant drugs. Consequently, this population more precisely reflects the universe of hospitals with meaningful and relevant outpatient acquisition volume for drugs included in the survey.

Table 1 compares the composition of the initial ODACS population with the refined population. While subunits account for 16.5% of the initial population, they no longer appear in the refined population as distinct entities. This refinement also markedly reduced the number of psychiatric hospitals, long-term care hospitals, and rehabilitation hospitals because the majority of these hospitals neither reported ODACS acquisition costs nor billed any OPPS claims for drugs included in the survey. As a result, 94.6% of the refined population are short-term/acute care hospitals as compared to 67.2% of the initial population.

Table 1. Number and Percentage of ODACS Entities by Hospital Type (Initial and Refined Population)

Hospital Type	Initial Population		Refined Population	
	Number	Percentage	Number	Percentage
Total ODACS Population	***4,494***	***100.0%***	***3,147***	***100.0%***
Children's Hospital	67	1.5%	61	1.9%
Inpatient Rehabilitation Unit	334	7.4%	0	0.0%
IPPS-Exempt Freestanding Cancer Hospital	11	0.2%	11	0.3%
Long-Term Care Hospital	202	4.5%	29	0.9%
Psychiatric Hospital	296	6.6%	42	1.3%
Psychiatric Unit	408	9.1%	0	0.0%
Rehabilitation Hospital	158	3.5%	27	0.9%
Short-Term/Acute Care Hospital	3,018	67.2%	2,977	94.6%

To target analyses on the hospitals that used survey-relevant drugs during the ODACS study period, CMS elected to assess survey validity and representativeness by comparing ODACS respondents (i.e., entities that reported acquiring survey-relevant drugs) to the refined population (i.e., entities that reported administering survey-relevant drugs to Medicare FFS beneficiaries) rather than to the initial population. This is described in more detail in Section 3.5.

3.2 Calculation of Acquisition Cost Margins

After implementing the population refinements to focus on hospitals that reported acquisition costs, CMS compared hospitals' survey-reported acquisition costs for all survey-eligible drugs to the equivalent ASP-based Medicare payment amount for those drugs under the OPPS. This comparison was constructed as a percent difference between these two values, hereinafter referred to as the "acquisition cost margin."

The aggregate acquisition cost margin was calculated using two key data points:

1. The sum of total acquisition costs reported for all NDCs in the survey by all respondents
2. The volume-weighted sum of the survey-reported NDCs' corresponding ASP-based payment amounts (refer to Section 3.2.1 for details on how this value was obtained)

Formula 1 displays the calculation of the acquisition cost margin using these two data points, which was performed separately for non-340B and 340B acquisitions. Negative values indicate that, in aggregate, hospitals reported acquisition costs below ASP. Positive values indicate that, in aggregate, hospitals reported acquisition costs above ASP.

Formula 1. Calculation of Aggregate Acquisition Cost Margin Weighted by ODACS Acquisition Volume

$$margin = 100 * \left(\frac{(\sum_{NDCs} total\ acquisition\ cost\ ) - (\sum_{NDCs} (adjusted\ ASP * total\ units))}{\sum_{NDCs} (adjusted\ ASP * total\ units)} \right)$$

Given that ASPs can vary by quarter, acquisition costs were compared to both the mean ASP and the median ASP payment rate in effect across the four quarters of the ODACS time period (2024Q3 to 2025Q2). These two ASP benchmarks were used to ensure that any fluctuations in payment rate over time were accounted for while mitigating the influence of any quarters with abnormal payment rates; CMS assessed any differences in the margins that resulted from the two benchmarks. Finally, margins for individual drug classes were calculated to detect any acquisition cost variations along relevant clinical stratifications.

CMS performed the margin calculation at the aggregate level—i.e., comparing total acquisition costs to total equivalent ASP-based amounts, rather than comparing average acquisition cost to ASP—to properly factor in variation in reported acquisition volume between different NDCs. Volume-weighting ensured that ASPs for the NDCs that represented a larger share of total reported purchasing activity contributed more substantially to the estimated acquisition cost margins. This approach produced a representative estimate of aggregate Medicare payments that was fair and comparable to hospitals' aggregate acquisition costs reported for those NDCs, and is consistent with longstanding OPPS principles of basing payment policy on observed utilization and resource use.

3.2.1 Calculation of Volume-Weighted ASP-Based Medicare Reimbursement Amounts

To obtain the volume-weighted sum of the survey NDCs' ASP-based amounts, CMS first identified the Medicare payment rate for each NDC's associated HCPCS code.[10] Since ASPs are reported by HCPCS billing unit, ASPs were adjusted to the NDC package units where necessary using an NDC-HCPCS adjustment factor.[11] CMS then removed any applicable drug-specific payment rate add-ons (+6% for most drugs and biologicals, +8% for qualifying biosimilar products, +3% for select AMP-based products, or +6% and a per-unit furnishing fee for hemophilia clotting factors[12]) to obtain its ASP+0% rate.

Each NDC's adjusted ASP rate was then multiplied by the number of survey-reported units for that NDC to appropriately weight its influence in the aggregate margin calculation by its acquisition volume. In the absence of such weighting, the ASPs for drugs with lower reported volume but atypical acquisition costs could exert a disproportionate influence on the aggregate margin between acquisition costs and ASPs.

3.2.1.1 Alternate Approach Considered to Volume-Weight ASP Amounts

CMS also considered an alternate volume-weighting approach using the number of HCPCS units billed for survey-relevant HCPCS codes by all survey-eligible hospitals.[13] In this approach, instead of adjusting ASPs to the package size of each NDC, the number of units reported in each survey response was multiplied by the number of HCPCS units in one package of that NDC. All survey responses were then aggregated to the HCPCS code level, summing the total acquisition costs and number of HCPCS units acquired by all respondents. The average adjusted acquisition cost for each HCPCS code, calculated as the total cost divided by the total number of billing units purchased, was then compared to its ASP.

Each aggregate acquisition cost margin was calculated using *Formula 2,* with the non-340B margin weighted by the number of non-340B units billed and the 340B margin weighted by 340B units billed.[14]

$$margin = 100 * \left(\frac{(\sum_{HCPCS}(average\ adjusted\ acq.cost * units\ billed)) - (\sum_{HCPCS}(ASP * units\ billed))}{\sum_{HCPCS}(ASP * units\ billed)} \right)$$

Formula 2. Alternate Calculation of Aggregate Acquisition Cost Margin Weighted by OPPS Claims Volume

However, this approach introduced inconsistencies due to discrepancies between claims data and survey responses. For example, CMS observed instances where survey respondents had billed a substantial number of units for a HCPCS code without reporting that they acquired any of its corresponding NDCs in their ODACS response.

Meanwhile, these discrepancies are nonissues when weighting by survey acquisition volume, which ensures that acquisition cost margins are fully grounded in the reported acquisition cost data and better reflects the distribution of hospital drug purchasing activity as captured via the survey. Accordingly, to rely on a consistent survey-based framework for both acquisition costs and Medicare payment amounts, CMS elected to not volume-weight ASP-based payment amounts by OPPS claims volume.

3.3 Exclusion of Anomalous Data

Through manual and programmatic review of the received ODACS responses, CMS identified five scenarios in which reported data displayed anomalous values, likely due to miscalculation, data entry error, or other respondent confusion. Survey records[15] meeting at least one of these scenarios were excluded from all analyses used to assess acquisition cost relationships to ensure that the margin calculations were not unduly influenced by implausible or unreliable data.[16]

Applying these five refinements collectively removed 14,313 survey records, 8.9% of the total 160,430 records received through the survey, while retaining 146,117 survey records in the analysis dataset, 91.1% of the total 160,430 records received. *Table 2* summarizes the impact of each refinement; there are some overlaps where the same record was excluded for meeting more than one exclusion criterion. Sections 3.3.1 through 3.3.5 discuss each scenario in more detail.

Table 2. Number of Records Excluded Through Each Data Refinement

Data Refinement	Number of Records	Percent of Total Records
Total Survey Records Received	***160,430***	***100.0%***
Total Survey Records Retained	***146,117***	***91.1%***
Total Survey Records Excluded	***14,313***	***8.9%***
Submission of 340B Acquisition Data by Non-340B Hospitals	850	0.5%
Submission of 340B Acquisition Data for NDCs Without Ceiling Price	839	0.5%
Submission of 340B Acquisition Data Where Per-Unit Cost Exceeded Ceiling Price	4,667	2.9%
Submission of Duplicative Data by Hospital Subunit	4,799	3.0%
Submission of Acquisition Data in Units Other Than NDC Packages	4,398	2.7%

3.3.1 Submission of 340B Acquisition Data by Non-340B Hospitals

CMS identified instances in which 16 respondents that were not participating in the 340B Program during the ODACS study period reported acquisition cost data for at least one NDC in the 340B data fields of the survey. These survey records likely reflected reporting errors or confusion about the survey reporting period, given that these respondents could not have accessed 340B discounts during the relevant period.

Consequently, these survey records were excluded from all analyses of 340B acquisition costs to maintain consistency with the survey design and statutory framework. This refinement removed 850 survey records, 0.5% of the total 160,430 records received through the survey.

3.3.2 Submission of 340B Acquisition Data for NDCs Without Ceiling Price

CMS identified instances in which respondents reported acquiring drugs through the 340B Program for 58 NDCs that did not have a 340B ceiling price during the ODACS study period. These survey records may reflect reporting errors (e.g., reporting acquisition data for the incorrect NDC within a drug HCPCS code), given that no 340B agreement or associated discount was available for these NDCs. In cases where these NDCs had 340B ceiling prices outside the ODACS study period, these records may be the result of confusion over the survey reporting period or the period when these NDCs had a 340B ceiling price.

Alternatively, these cases may reflect acquisitions of non-340B NDCs through the 340B Prime Vendor Platform (PVP) without receiving a 340B discount price;[17] while respondents may have considered these purchases to be 340B acquisitions for the purposes of their ODACS reporting, evaluating these records as part of 340B margin calculations would provide an inaccurate depiction of the acquisition costs for NDCs with 340B discounts. CMS also elected to not evaluate these records in non-340B calculations given the inability to separate reporting errors from non-340B purchases made through the 340B PVP.

Consequently, these survey records were excluded from all analyses of acquisition costs to maintain consistency with the survey design and statutory framework. This refinement removed 839 survey records, 0.5% of the total 160,430 records received through the survey.

3.3.3 Submission of 340B Acquisition Data Where Per-Unit Cost Exceeded Ceiling Price

CMS identified instances in which respondents reported per-unit costs for drugs acquired through the 340B Program that exceeded the maximum applicable 340B ceiling price during the survey time period. By statute, covered entities cannot be required to pay more than the 340B ceiling price for 340B-acquired drugs. These records cannot be representative of actual 340B acquisition costs and are likely attributable to reporting or data entry errors (e.g., miscalculations or incorrect decimal placement).

Consequently, these survey records were excluded from all analyses of 340B acquisition costs to maintain consistency with statutory requirements. This refinement removed 4,667 survey records, 2.9% of the total 160,430 records received through the survey.

3.3.4 Submission of Duplicative Data by Hospital Subunit

CMS identified instances in which 27 subunits submitted identical data to their parent unit (refer to Section 3.1.1 for discussion of parent/subunit identification). Identical parent–subunit data were identified as survey records with the exact same number of total units and total net acquisition costs reported for the exact same NDCs. Records from these subunits likely reflective duplicative data reported by one submitter who was responsible for submitting ODACS data for multiple entities on the FFSDCS.

Consequently, survey records submitted by these 27 subunits were excluded from all analyses of acquisition costs in favor of only retaining the equivalent responses from their parent unit. This refinement removed 4,799 survey records, 3.0% of the total 160,430 records received through the survey.

3.3.5 Submission of Acquisition Data in Units Other Than NDC Packages

CMS identified instances in which some respondents reported acquisition data for hemophilia clotting factors and select respiratory therapies using international units (IU) or milligrams (MG) rather than NDC package units. This likely occurred because IU is the HCPCS billing unit for these clotting factors and MG is the HCPCS billing unit for these respiratory therapies.[18]

However, because the survey study design required reporting units in NDC packages (refer to Section 2.3.1), survey records reported in IU or MG units displayed substantial distortions in per-unit acquisition costs due to their extremely high reported unit volumes relative to total acquisition costs. Therefore, these survey records are not comparable to records reported in NDC package units. If these survey records had been retained in analyses of acquisition costs, it would have driven down acquisition costs substantially relative to ASP-based payment rates, resulting in inaccurately large negative percent margins.

Consequently, all survey records for these clotting factor and respiratory therapy NDCs were excluded from all analyses of acquisition costs to avoid possible selection bias from specifically excluding survey records with units reported in IU or MG. This refinement removed 4,398 survey records, 2.7% of the total 160,430 records received through the survey.

3.4 Identification and Exclusion of Outliers

In addition to the five exclusion scenarios described in Section 3.3, CMS sought to mitigate the influence of extreme and anomalous ODACS responses that could distort estimates of hospital drug acquisition costs by identifying and excluding outlier responses. These responses may reflect atypical purchasing arrangements, data anomalies, or reporting inconsistencies.

CMS applied a trimming approach that identified and removed as outliers all survey records with a per-unit acquisition cost more than three standard deviations from the geometric mean per-unit cost for each NDC, as outlined in *Formula 3*. This approach was selected to be consistent with CMS's standard methodology for processing extreme outliers to develop policy under the OPPS.[19]

Formula 3. Calculation of Outlier Thresholds Under Geometric Mean Methodology

$$lower\ outlier\ threshold = (geo\ mean\ per\ unit\ cost) - 3(standard\ deviation)$$
$$upper\ outlier\ threshold = (geo\ mean\ per\ unit\ cost) + 3(standard\ deviation)$$

Outlier identification was performed separately for 340B and non-340B drug acquisitions of each NDC, producing tailored outlier thresholds based on the unique data distribution for each drug through each purchasing channel. Application of the geometric mean trimming methodology necessitated removal of NDCs for which fewer than 10 survey respondents reported their purchase because outlier values cannot be detected with nine or fewer survey records using this method.

CMS also evaluated the effectiveness of an alternate approach to identify and trim outliers in comparison to the geometric mean approach, but ultimately chose to not apply the alternate approach, as described in Section 3.4.1.

3.4.1 Alternate Approach Considered to Identify and Trim Outliers

CMS also considered the Tukey interquartile range (IQR) method as an alternate methodology to trim outliers. In this approach, for each NDC (stratified by 340B or non-340B drug acquisition), outlier thresholds were established based on the first (Q1) and third (Q3) quartiles of the distribution of hospitals' survey-reported per-unit acquisition costs, as outlined in *Formula 4*.

Formula 4. Calculation of Outlier Thresholds Under Tukey's IQR Methodology

$$IQR = Q3 - Q1$$
$$lower\ outlier\ threshold = Q1 - 1.5(IQR)$$
$$upper\ outlier\ threshold = Q3 + 1.5(IQR)$$

Survey records with per-unit acquisition costs that fall outside these thresholds were identified and removed as outliers. Application of the IQR-based trimming methodology necessitated removal of NDCs for which fewer than four survey respondents reported their purchase because outlier values cannot be detected with three or fewer survey records using this method.

Table 3 compares the impact of excluding outliers using the geometric mean approach versus the IQR-based approach, after applying the five data exclusions described in Section 3.3. The geometric mean approach to trim outliers removed 2,051 survey records, 1.4% of the total 146,117 records remaining after data cleaning, while the IQR approach removed 15,563 records, 10.7% of the total 146,117 records.

Table 3. Number of Records Excluded Through Each Outlier Trimming Methodology

Outlier Trimming Methodology	Number of Records	Percent of Total Records
Total Survey Records After Applying Data Refinements	***146,117***	***100.0%***
Removed Using Geometric Mean Approach	2,051	1.4%
Removed Using Tukey's IQR Approach	15,563	10.7%

Manual review of the survey records that were trimmed using each approach and the data distribution for each NDC suggested that the IQR approach erroneously identified some records as outliers despite their per-unit acquisition cost being generally in-line with the overall data distribution for that NDC. This is likely due to the distributional characteristics of the ODACS data, including evidence of skew in the distribution of reported acquisition costs for some NDCs. It has been established that the effectiveness of Tukey's IQR lessens when data are skewed and may lead to overidentification of observations as outliers.[20,21,22]

In addition, the large number of records removed by the IQR-based approach is inconsistent with CMS's objective to analyze ODACS-reported drug acquisition costs using the largest amount of reasonable data received from hospitals as possible. Consequently, CMS did not adopt the IQR outlier methodology.

3.5 Evaluation of Survey Representativeness and Statistical Validity

After completing initial analysis of hospitals' survey-reported data as described in Sections 3.1 through 3.4, CMS evaluated whether survey respondents comprised a sample that is sufficiently large to generate statistically significant and representative estimates of all hospitals' acquisition costs. To do so, CMS conducted sensitivity analyses by applying inverse probability weighting (IPW) to the received responses (Section 3.5.1) and calculating confidence intervals (CIs) for each acquisition cost margin (Section 3.5.2).

3.5.1 Application of Inverse Probability Weighting

IPW is a widely used statistical technique in survey research[23,24,25,26,27] to ensure that data received produce estimates that accurately represent the population of interest. IPW was applied to the submitted survey responses to account for potential underrepresentation or overrepresentation of hospitals with particular characteristics among respondents and to evaluate whether acquisition cost margins derived from survey responses sufficiently reflected outpatient drug acquisition costs for all OPPS hospitals.

To focus analyses of survey representativeness on hospitals with evidence of using survey-relevant drugs during the ODACS study period, respondent and nonrespondent populations were constructed to align with the refined hospital population discussed in Section 3.1.2:

- *Respondents:* Survey-eligible hospitals that reported acquisition data for at least one NDC
- *Nonrespondents:* Survey-eligible hospitals that did not submit a survey response but billed at least one OPPS claim for survey-relevant drugs[28]

In other words, respondents that reported acquiring surveyed NDCs via ODACS were compared to nonrespondents that reported administering survey-relevant HCPCS codes to Medicare FFS beneficiaries. Because acquisition cost margins were calculated separately for 340B and non-340B drugs, these groups were further stratified based on whether the hospital had evidence of 340B drug use, as identified using the Health Resource Service Administration's (HRSA) 340B OPAIS enrollment information and OPPS claims submitted with 340B modifiers.[29]

After identifying the respondent and nonrespondent populations, response propensity scores were calculated using logistic regression models based on the observed hospital characteristics described in Section 3.1 and Appendix *Table A1*. These propensity scores were estimated separately for hospitals acquiring drugs outside the 340B Program and for hospitals acquiring drugs through the 340B Program. A higher propensity score indicated that the hospital was more likely to submit a survey response; a lower propensity score indicated that the hospital was less likely to submit a survey response.

Inverse probability weights were then calculated as equal to the inverse of each hospital's estimated probability of responding to the survey, as shown in *Formula 4*.

Formula 4. Calculation of Inverse Probability Weights

$$IPW = \frac{1}{propensity\ score}$$

Hospitals with a higher likelihood of response received smaller weights, while hospitals with a lower likelihood of response received larger weights. Down-weighting hospitals with a higher probability of response while upweighting CCNs with a lower probability of response adjusted for any differential representation of hospital characteristics in the respondent sample as compared to the broader population of survey-eligible hospitals.

To calculate the IPW-adjusted acquisition cost margins, the calculated weights were applied to hospitals' total acquisition costs and corresponding ASP-based payment amounts. The percent difference between acquisition cost and ASP was then calculated in an analogous manner to the margin calculation described in Section 3.2, as displayed in *Formula 5*.

Formula 5. Calculation of IPW-Adjusted Aggregate Acquisition Cost Margin

$$margin = 100 * \left(\frac{(\sum_{CCNs}(IPW * total\ acquisition\ cost)) - (\sum_{CCNs}(IPW * adjusted\ ASP * total\ units))}{\sum_{CCNs}(IPW * adjusted\ ASP * total\ units)} \right)$$

3.5.2 Calculation of Confidence Intervals

To evaluate whether the number of received survey responses was sufficient to produce statistically valid estimates of hospitals' acquisition costs, CMS calculated CIs for both unadjusted[30] and IPW-adjusted acquisition cost margins. The CIs provide measures of whether the response rate adequately captures true population results. When response rate is insufficiently low, CIs are wide due to the high degree of uncertainty regarding where the true result lies. Conversely, when response rate is sufficient, CIs narrow as uncertainty lessens.

CMS calculated the CIs using a bootstrap methodology. First, the full dataset of survey records (after applying data refinements and excluding geometric mean outliers) was repeatedly sampled with replacement using hospitals as the sample unit; acquisition cost margins were recalculated for each repeated sample. This process was repeated 10,000 times to generate distributions of unadjusted and IPW-adjusted acquisition cost margin estimates. Finally, the 95% CIs were identified for each margin estimate using the 2.5th percentile as the lower bound and the 97.5th percentile as the upper bound.

4. Results of ODACS Data Analyses

CMS comprehensively analyzed the ODACS data received from hospitals in accordance with statutory requirements. Section 4.1 describes the survey response rate using both the initial and refined hospital population definitions, stratified by 340B participation status and Census region. Section 4.2 compares the population composition between all survey-eligible hospitals, respondents, and nonrespondents to assess the representativeness of the received sample. Section 4.3 evaluates hospitals' survey-reported acquisition costs relative to ASP-based Medicare payment amounts for both non-340B and 340B drugs, including using alternate methodological specifications and for specific drug classes. Finally, Section 4.4 discusses results of the IPW and CI analyses that confirm the statistical robustness of the received data.

4.1 Survey Response Rate

Out of the 4,494 entities in the initial population, 1,958 CCNs submitted any ODACS response, a 43.6% response rate. When stratifying by 340B participation status, 56.0% of non-340B CCNs and 27.4% of 340B CCNs submitted any ODACS response. Of these initial 4,494 survey candidates, 29.8% of all CCNs, 34.9% of non-340B CCNs, and 23.1% of 340B CCNs reported acquiring at least one drug included in the survey. The difference between the overall response rate and the response rate when restricted to

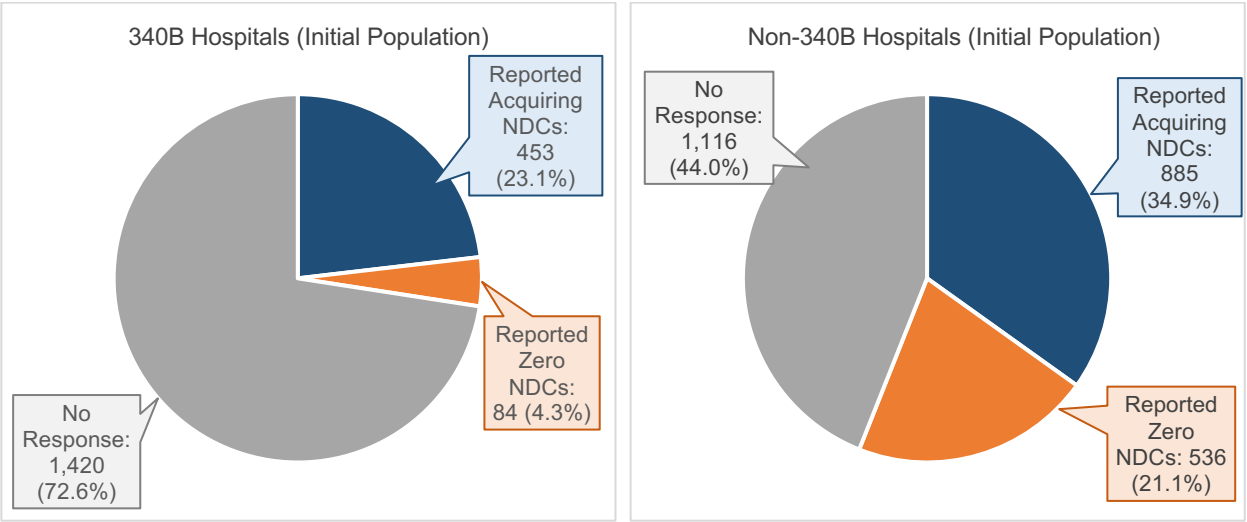
respondents that reported drug acquisitions largely is due to subunits and non–acute care entities that did not bill any claims for survey-relevant HCPCS codes, as described in Section 3.1.2.

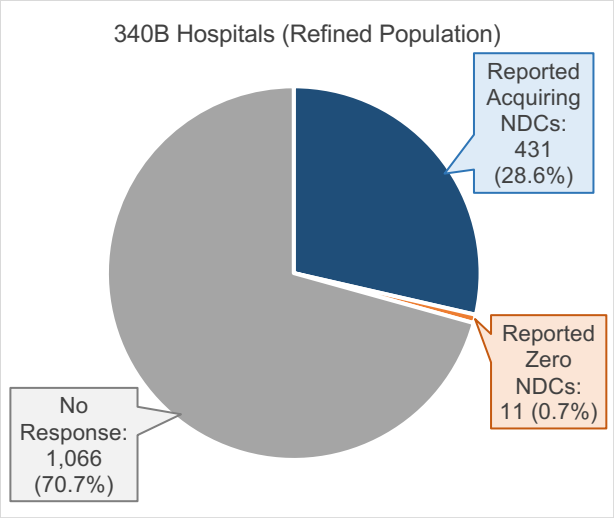
Therefore, after applying the refinements described in Section 3.1.2 to focus the population on the 3,147 hospitals with evidence of acquiring survey-relevant drugs during the ODACS study period, 1,304 CCNs submitted an ODACS response in which they reported acquisition costs, a 41.4% response rate. When stratifying by 340B participation status, 53.3% of non-340B CCNs and 28.6% of 340B CCNs submitted an ODACS response in which they reported acquisition costs (*Table 4*, *Charts 1a–1d*).

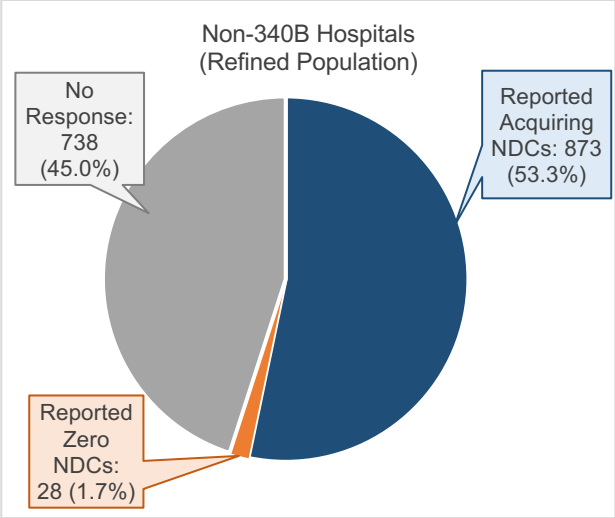
Table 4. ODACS Response Status by 340B Participation Status (Initial and Refined Population)

Response Status		Initial Population			Refined Population		
		All Hospitals	**Non-340B Hospitals**	**340B Hospitals**	**All Hospitals**	**Non-340B Hospitals**	**340B Hospitals**
Number of Survey-Eligible Hospitals		***4,494***	***2,537***	***1,957***	***3,147***	***1,639***	***1,508***
All Survey Respondents	Number	1,958	1,421	537	1,343	901	442
	Percentage	43.6%	56.0%	27.4%	42.7%	55.0%	29.3%
Respondents Reporting Drug Acquisitions	Number	1,338	885	453	1,304	873	431
	Percentage	29.8%	34.9%	23.1%	41.4%	53.3%	28.6%

Charts 1a–1d. ODACS Response Status by 340B Participation Status (Initial and Refined Population)







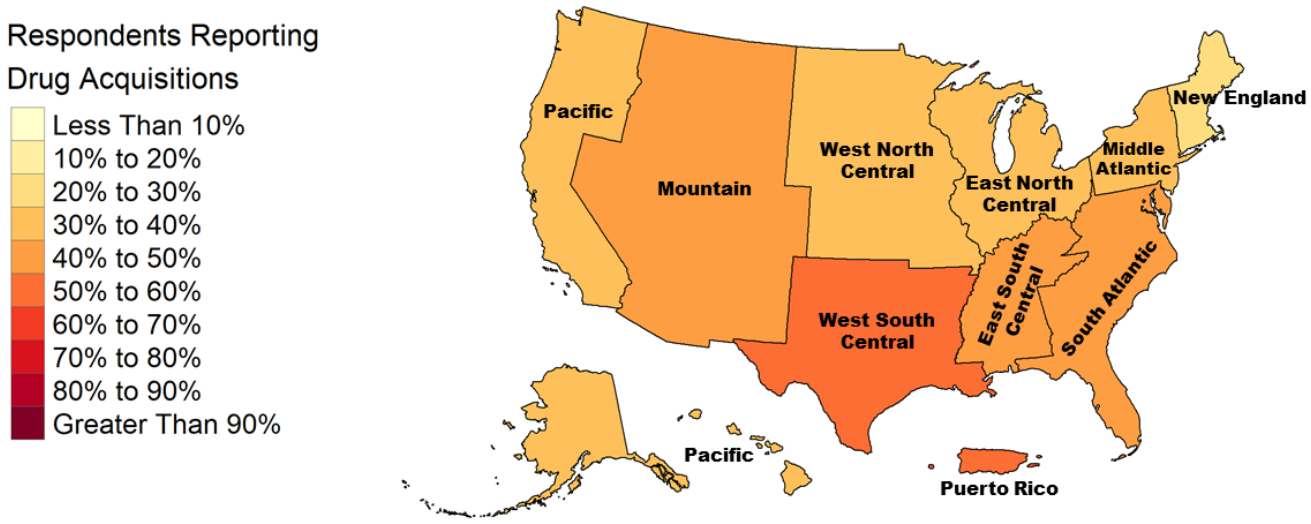
4.1.1 Response Rate by Census Region

There was slight variation in response rates by Census region (*Table 5*, *Map 1*). Out of the nine Census regions, four regions had 30–40% of all survey-eligible hospitals respond and report drug acquisitions while three regions had 40–50% of all eligible hospitals respond and report drug acquisitions. Hospitals in the West South Central region, which is composed of Arkansas, Louisiana, Oklahoma, and Texas, had the highest response rate at 58.5%. Hospitals in New England, which is composed of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont, had the lowest response rate at 24.3%.

Table 5. ODACS Response Rate by Census Region (Refined Population)

Census Region	All Survey-Eligible Hospitals	Respondents Reporting Drug Acquisitions	Response Rate
All Hospitals	***3,147***	***1,304***	***41.4%***
New England	136	33	24.3%
Middle Atlantic	346	129	37.3%
South Atlantic	518	219	42.3%
East North Central	484	166	34.3%
East South Central	266	129	48.5%
West North Central	237	87	36.7%
West South Central	504	295	58.5%
Mountain	226	100	44.2%
Pacific	388	125	32.2%
Puerto Rico	42	21	50.0%

Map 1. ODACS Response Rate by Census Region (Refined Population)



4.2 Comparison of Hospital Characteristics Between Populations

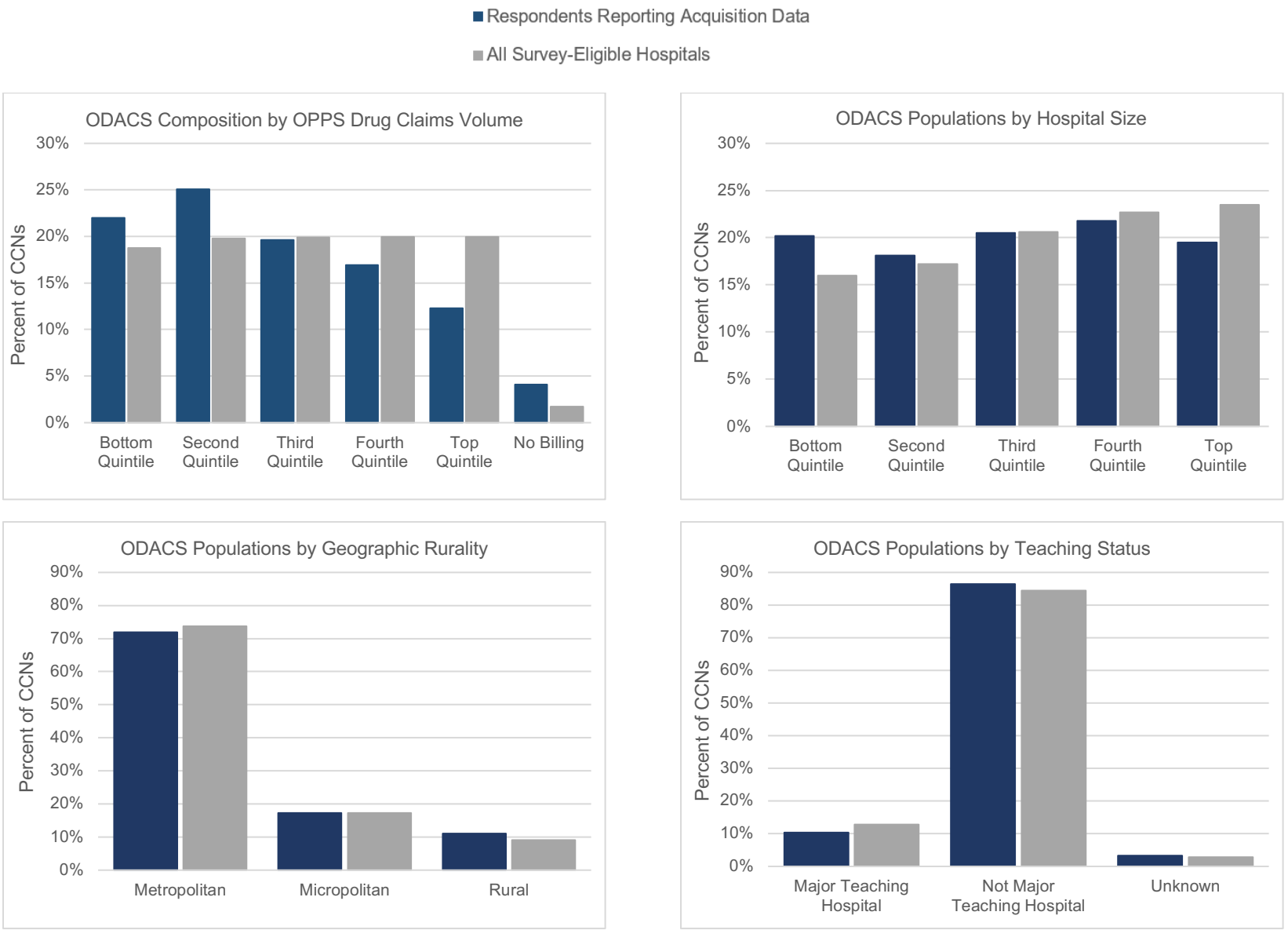
Using the refined population to focus on hospitals with evidence of acquiring survey-relevant drugs during the ODACS study period, the observable characteristics of the 1,304 hospitals that reported drug acquisition costs differ slightly from the characteristics of all 3,147 eligible hospitals.

Compared to the overall population, respondent hospitals were slightly more likely to have lower OPPS drug claims volume, be smaller, be located in a rural area, and not be major teaching hospitals (*Table 6*, *Charts 2a–2d*). For example, while 73.7% of all survey-eligible hospitals were located in metropolitan areas, 71.9% of respondents reporting drug acquisitions were metropolitan, a slight underrepresentation. Given these slight differences in hospital characteristics between the overall population and respondents, CMS performed IPW adjustment to confirm that reweighting the respondent population to more closely resemble the overall population did not impact results obtained from respondents' acquisition data, as discussed in Section 4.4.

Table 6. Hospital Characteristics of ODACS Population by Response Status (Refined Population)[31]

Hospital Characteristic	All Survey-Eligible Hospitals		Respondents Reporting Drug Acquisitions		Nonrespondents	
	Number	Percentage	Number	Percentage	Number	Percentage
All Hospitals	***3,147***	***100.0%***	***1,304***	***100.0%***	***1,804***	***100.0%***
OPPS Drug Claims Volume						
Bottom Quintile	591	18.8%	287	22.0%	287	15.9%
Second Quintile	622	19.8%	327	25.1%	284	15.7%
Third Quintile	626	19.9%	256	19.6%	364	20.2%
Fourth Quintile	627	19.9%	221	16.9%	403	22.3%
Top Quintile	628	20.0%	160	12.3%	466	25.8%
No Billing	53	1.7%	53	4.1%	0	0.0%
Hospital Size (Number of Beds)						
Bottom Quintile	502	16.0%	263	20.2%	230	12.7%
Second Quintile	542	17.2%	236	18.1%	293	16.2%
Third Quintile	647	20.6%	267	20.5%	373	20.7%
Fourth Quintile	715	22.7%	284	21.8%	424	23.5%
Top Quintile	741	23.5%	254	19.5%	484	26.8%
Geographic Rurality						
Metropolitan	2,320	73.7%	937	71.9%	1,356	75.2%
Micropolitan	544	17.3%	224	17.2%	315	17.5%
Rural	283	9.0%	143	11.0%	133	7.4%
Teaching Status						
Major Teaching Hospital	400	12.7%	134	10.3%	265	14.7%
Not Major Teaching Hospital	2,657	84.4%	1,128	86.5%	1,495	82.9%
Unknown	90	2.9%	42	3.2%	44	2.4%

Charts 2a–2d. Hospital Characteristics of ODACS Population by Response Status (Refined Population)



4.3 Acquisition Cost Margins

CMS evaluated the received survey data to determine the difference between hospitals' survey-reported acquisition costs and their equivalent ASP+0% Medicare payment amounts. *Table 7* displays that for drugs acquired outside the 340B Program, hospitals reported acquisition costs that were, in aggregate, approximately 2.7% above the mean ASP and 2.8% above the median ASP. More notably, for drugs acquired through the 340B Program, hospitals reported acquisition costs that were, in aggregate, 33.4% below both the mean and median ASP.

Table 7. Aggregate Acquisition Cost Margins for 340B and Non-340B Drugs

Drug Acquisition Type	Mean ASP Margin	Median ASP Margin
Non-340B Drugs	+2.7%	+2.8%
340B Drugs	–33.4%	–33.4%

Notably, 49.5% of survey records (after applying data refinements and excluding geometric mean outliers) for 340B drugs reported per-unit acquisition costs that equaled the ceiling price.[32] Responses at the ceiling price represent an upper bound of what 340B hospitals pay to acquire 340B drugs, and some hospitals may have access to additional discounts to further lower their acquisition costs. This is substantiated when excluding these survey records from margin calculations, which yields 340B acquisition cost margins that are 47.5% below both the mean and median ASP.

These large negative percent margins for 340B-acquired drugs highlight a substantial difference between the amount that hospitals report paying to acquire drugs through the 340B Program and the ASP-based reimbursement amount that they receive from Medicare for these drugs. Following the GAO recommendation to validate Medicare payment rates using hospital acquisition costs, this misalignment has prompted CMS to reevaluate the appropriateness of existing ASP reimbursement methodologies and propose appropriate adjustments, as discussed at length in the CY 2027 OPPS/ASC Proposed Rule.

Sections 4.3.1 through 4.3.3 provide further context and details on these results. Section 4.3.1 evaluates whether these acquisition cost margins varied depending on weighting methodology. Section 4.3.2 stratifies margins by individual therapeutic classes to identify variation in acquisition cost margins along drug type. Finally, Section 4.3.3 calculates an analogous margin between 340B ceiling prices and ASP.

4.3.1 Acquisition Cost Margins with Alternate Methodological Specifications

To assess whether the margins described in *Table 7* precisely reflected the relationship between hospitals' acquisition costs and ASP, and did not substantially change under different methodological specifications, CMS tested the impact of weighting acquisition cost margins by OPPS claims volume (*Table 8*), as described in Section 3.1.2.1.

Table 8. Comparison of Acquisition Cost Margins Between Volume-Weighting Methodologies

Aggregate Margin Calculations: Methodology Specifications		Non-340B Drugs		340B Drugs	
		Mean ASP Margin	Median ASP Margin	Mean ASP Margin	Median ASP Margin
Geometric Mean Outliers Removed	Weighted by ODACS Acquisition Volume	+2.7%	+2.8%	–33.4%	–33.4%
	Weighted by OPPS Claims Volume	+6.7%	+6.7%	–31.2%	–31.1%

Calculating acquisition cost margins with these specifications emphasizes two key points about 340B-acquired drugs. First, across both methodologies, there are considerable differences between hospitals' acquisition costs for 340B drugs and ASP-based payment amounts for 340B drugs. Second, weighting by OPPS claims volume had minimal impact on the acquisition cost margins for 340B-acquired drugs; hospitals' survey-reported 340B acquisition costs remained relatively consistent at either 31.2% or 33.4% below the mean ASP and at either 31.1% or 33.4% below the median ASP. These findings reinforce the conclusion that there exists a substantial and persistent difference between hospitals' 340B acquisition costs and the ASP-based reimbursement rate for 340B drugs.

Weighting by OPPS claims volume resulted in more variation in the margin between acquisition costs and ASP for drugs acquired outside the 340B Program. This greater variability can be attributed to wider distributional spread in the reported acquisition costs for non-340B drugs; this, in turn, causes the non-340B margins to be more sensitive to application of different weighting methodologies.

4.3.2 Acquisition Cost Margins by Drug Class

To assess whether the magnitude of margins remained the same across different drug categories, CMS examined acquisition cost margins by therapeutic class. *Table 9* displays these margins for all high-spending drug classes for 340B drugs, defined as those that each had more than $100 million in survey-reported acquisition costs.

Table 9. Acquisition Cost Margins by Drug Therapeutic Class

Drug Class	340B Drugs	
	Mean ASP Margin	Median ASP Margin
Antineoplastics and Adjunctive Therapies	–28.9%	–28.8%
Hematopoietic Agents	–38.3%	–37.8%
Endocrine and Metabolic Agents	–52.6%	–52.8%
Passive Immunizing and Treatment Agents	–30.8%	–30.4%
Gastrointestinal Agents	–29.3%	–29.1%
Psychotherapeutic and Neurological Agents	–31.2%	–31.3%

Drug Class	340B Drugs	
	Mean ASP Margin	Median ASP Margin
Miscellaneous	–29.6%	–29.6%
Analgesics	–71.4%	–71.4%
Neuromuscular Agents	–31.8%	–31.9%

Hospitals' survey-reported 340B acquisition costs were at least 28.9% below the mean ASP—and for some therapeutic classes far lower than that—for drugs in all high-spending therapeutic classes. This consistency across drug classes again reinforces the substantial differences between hospitals' acquisition costs for 340B-acquired drugs and ASP-based payment amounts for these drugs.

The margins for non-340B drugs displayed greater variation, which is likely attributable to greater heterogeneity in drug mix, provider type, and purchasing arrangements present outside the 340B Program. Analogous Margin Between ASP and 340B Ceiling Price

In light of the substantial differences between acquisition costs and ASP-based payment amounts for 340B drugs, CMS calculated an analogous percent margin between 340B ceiling prices and ASP as additional context for the 340B acquisition cost margins.[33] According to this analysis, 340B ceiling prices were, in aggregate, 28.0% below the mean ASP and 29.2% below the median ASP during the ODACS study period.

These findings help validate the reasonableness of the received ODACS data on 340B acquisitions, as the ceiling price generally represents the maximum acquisition cost—and therefore minimum discount amount—at which a hospital can acquire 340B drugs. Nevertheless, because hospitals can negotiate additional discounts resulting in a sub-ceiling acquisition cost, the aggregate 340B acquisition cost margin of 33.4% below the mean ASP, calculated using survey data, is several percentage points lower than the aggregate ceiling price margin of 28.0% below the mean ASP.

As mentioned in Section 4.3, 49.5% of survey records for 340B drugs had per-unit acquisition costs at the ceiling price. The frequency at which hospitals reported purchasing 340B drugs at the ceiling price is a primary factor in explaining the consistency in 340B acquisition cost margins across methodological specifications (as described in Section 4.3.1) and for several high-volume drug classes (Section 4.3.2).

4.4 Survey Representativeness and Statistical Validity

To support the statutory objective of estimating acquisition costs from survey responses that are accurate and reflect the outpatient drug acquisition costs incurred by all survey-eligible hospitals, CMS evaluated the statistical representativeness and validity of the acquisition cost margin results described in Section 4.3, especially the margins calculated for 340B-acquired drugs.

Section 4.4.1 discusses how applying IPW adjustment to the received sample produced a respondent population with observable hospital characteristics that align with the characteristics of all OPPS hospitals included as survey candidates. Section 4.4.2 describes how the IPW-adjusted margins and CI

results confirm that the received sample is sufficiently large and robust to yield acquisition cost estimates that are reflective of the overall OPPS hospital population, particularly for 340B drugs.

4.4.1 Impact of IPW Adjustment on Sample Representativeness

Applying IPW adjustment improved the alignment between the distribution of respondent hospital characteristics and the broader population of survey-eligible hospitals. IPW-adjusted respondents more closely resembled the full population across 340B participation, hospital size, geographic rurality, Census region, and teaching status (*Table 10*). Accordingly, the IPW-adjusted respondent population is more representative of the full universe of included OPPS hospitals.

Table 10. Impact of IPW Adjustment on ODACS Hospital Characteristic Breakdown (Refined Population)

Hospital Characteristic	Non-340B Drugs			340B Drugs		
	All Survey-Eligible Hospitals	Unadjusted Respondents	IPW-Adjusted Respondents	All Survey-Eligible Hospitals	Unadjusted Respondents	IPW-Adjusted Respondents
340B Participation						
340B Hospital	48.1%	32.8%	50.0%	100.0%	100.0%	100.0%
Non-340B Hospital	51.9%	67.2%	50.0%			
Hospital Size (Number of Beds)[34]						
Bottom Quintile	15.8%	20.0%	16.2%	7.4%	9.6%	6.9%
Second Quintile	17.1%	18.3%	16.9%	13.8%	16.7%	13.7%
Third Quintile	20.6%	20.6%	20.8%	17.5%	17.0%	17.7%
Fourth Quintile	22.7%	21.6%	23.4%	26.4%	27.0%	26.6%
Top Quintile	23.8%	19.6%	22.7%	35.0%	29.7%	35.2%
Geographic Rurality						
Metropolitan	73.8%	71.8%	74.6%	71.8%	69.5%	71.9%
Micropolitan	17.3%	17.2%	16.7%	20.0%	19.2%	20.3%
Rural	8.9%	11.0%	8.7%	8.3%	11.3%	7.8%
Census Region						
New England	4.3%	2.6%	4.6%	4.8%	3.4%	4.5%
Middle Atlantic	10.9%	9.7%	10.7%	12.1%	9.8%	13.1%
South Atlantic	16.6%	16.8%	16.0%	14.1%	11.8%	15.0%
East North Central	15.5%	12.9%	16.3%	17.0%	18.4%	16.6%
East South Central	8.3%	9.9%	8.3%	8.6%	9.8%	8.6%
West North Central	7.5%	6.6%	7.0%	8.3%	8.1%	8.1%
West South Central	15.8%	22.7%	15.9%	12.9%	18.2%	12.6%
Mountain	7.2%	7.7%	6.4%	6.3%	3.9%	6.4%
Pacific	12.6%	9.7%	13.0%	15.4%	15.0%	14.6%
Puerto Rico	1.2%	1.4%	1.9%	0.5%	1.5%	0.5%
Teaching Status						
Major Teaching Hospital	12.8%	10.2%	11.8%	19.5%	16.7%	19.5%
Not Major Teaching Hospital	84.4%	86.6%	85.6%	77.3%	79.1%	77.4%
Unknown	2.8%	3.3%	2.6%	3.2%	4.2%	3.1%

4.4.2 Impact of IPW Adjustment and Confidence Interval Calculation on Acquisition Cost Margins

Applying IPW adjustment had minimal impact on acquisition cost margins for either non-340B or 340B-acquired drugs. For drugs acquired outside the 340B Program, hospitals' survey-reported acquisition costs were 2.7% above the mean ASP before IPW adjustment and 2.8% above the mean ASP after IPW adjustment. For drugs acquired through the 340B Program, hospitals' survey-reported acquisition costs were 33.4% below the mean ASP before IPW adjustment and 33.1% below the mean ASP after IPW adjustment (*Table 11*). The consistency between unadjusted and IPW-adjusted results supports the robustness and representativeness of the acquisition cost margins derived from survey responses.

Table 11. Comparison of Unadjusted to IPW-Adjusted Acquisition Cost Margins and CIs

Aggregate Margin Calculations: Methodology Specifications	Non-340B Drugs			340B Drugs		
	Mean ASP Margin	95% CI Lower Limit	95% CI Upper Limit	Mean ASP Margin	95% CI Lower Limit	95% CI Upper Limit
Unadjusted	+2.7%	–3.8%	+6.9%	–33.4%	–34.7%	–32.3%
IPW-Adjusted	+2.8%	–1.6%	+6.5%	–33.1%	–34.3%	–32.1%

The 95% CIs for both unadjusted and IPW-adjusted acquisition cost margins did not substantially differ from each other, indicating that the weighting adjustment had minimal impact on the resulting estimates. For non-340B drugs, the CIs spanned 3.8% below the mean ASP to 6.9% above the mean ASP for the unadjusted margin and between 1.6% below the mean ASP to 6.5% above the mean ASP for the IPW-adjusted margin. For 340B-acquired drugs, the CIs were much narrower and spanned 34.7% to 32.3% below the mean ASP for the unadjusted margin and from 34.3% to 32.1% below the mean ASP for the IPW-adjusted margin.

The narrow CIs for 340B-acquired drugs support the statistical validity of the survey results on 340B drugs and indicate that the received sample is sufficiently large to produce reliable estimates of hospital outpatient drug acquisition costs for 340B drugs. The CIs for the non-340B drugs span a wider range of potential acquisition cost margins, which is expected given the greater distributional spread in the survey data for non-340B drugs as discussed in Section 4.3.1.

5. Appendix: Definitions and Data Sources

Table A1 provides definitions for the terms, concepts, and stratifications used in the analysis of ODACS data and its relevant data source.

Table A1. Definitions and Data Sources Used in ODACS Analyses

Term	Definition	Source(s)
340B participation status	A CCN was classified as a 340B hospital if it was listed as participating in the 340B Program at any point between July 1, 2024 and June 30, 2025	HRSA OPAIS 340B Entities

Term	Definition	Source(s)
	(identified using the Start Date and Term Date of the HRSA OPAIS 340B database)	
340B ceiling price	Maximum statutory amount that drug manufacturers can charge covered entities for outpatient drugs, calculated by subtracting the unit rebate amount (the Medicaid rebate manufacturers must pay to the government) from the average manufacture price (the average price paid to the manufacturer by wholesalers for a given drug)	HRSA Internal Files
Drug volume	The number of HCPCS units billed for survey-relevant HCPCS codes during the study period	Common Working File FFS Claims Data
Drug class	The therapeutic class identified using the Generic Product Identifier (GPI) classification system based on the first two digits of an NDC	Wolters Kluwer – Medi-Span
Hospital size	Defined as the number of inpatient beds. If a CCN was present in both the Impact File and CASPER, the number of beds from each source was averaged. Values of "Unknown" indicate that the CCN was not present in the Impact File or CASPER.	FY 2025 IPPS Impact File Certification And Survey Provider Enhanced Reporting (CASPER) System Data
Hospital type	Defined as one of the following based on CCN: • *Short-term/acute care hospital:* final four digits of CCN in the range 0001–0899 • *Long-term care hospital:* final four digits of CCN in the range 2000–2299 • *Rehabilitation hospital:* final four digits of CCN in the range 3025–3099 • *Children's hospital:* final four digits of CCN those in the range 3300–3399 • *Psychiatric hospital:* final four digits of CCN in the range 4000–4499 • *Inpatient rehabilitation unit:* third digit of CCN is T • *Psychiatric unit:* third digit of CCN is S or M • *IPPS-exempt freestanding cancer hospital:* CCNs 050146, 050660, 100079, 100271, 220162, 330154, 330354, 360242, 390196, 450076, and 500138	CMS Manual System Pub 100-07 Change Request 5490 CMS List of IPPS-Exempt Freestanding Cancer Hospitals
Teaching status	• *Major teaching hospital:* CCNs with a resident-to-bed[35] ratio ≥ 0.25 • *Non-major teaching hospital:* (i) CCNs with a resident-to-bed ratio < 0.25 and (ii) CCNs in neither the IPPS Impact File nor the Open Payments list of teaching hospitals Values of "Unknown" indicate that the CCN was not listed in the IPPS Impact File but was listed in the Open Payments data, therefore having conflicting information between the two sources.	FY 2025 IPPS Impact File Open Payments (Program Years 2024 and 2025)

Term	Definition	Source(s)
Region type (RUCA)	Defined as metropolitan, micropolitan, or rural based on the rural-urban commuting area (RUCA) for the zip code in which a provider is located. A Census tract is classified into one of ten codes: • 1: Metropolitan Area Core (>= 50,000 people) • 2: Metropolitan High Commuting Area • 3: Metropolitan Low Commuting Area • 4: Micropolitan Area Core (10,000 to 49,999 people) • 5: Micropolitan High Commuting Area • 6: Micropolitan Low Commuting Area • 7: Small Town Core (2,500 to 9,999 people) • 8: Small Town High Commuting • 9: Small Town Low Commuting • 10: Rural Areas Codes 1, 2, and 3 were assigned as metropolitan. Codes 4, 5, and 6 were assigned as micropolitan. Codes 7, 8, 9, and 10 were assigned as rural.	Department of Agriculture – Economic Research Service
Census region	States were classified into nine different regions as follows: • *New England:* Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont • *Middle Atlantic:* New Jersey, New York, Pennsylvania • *South Atlantic:* Delaware, District of Columbia, Florida, Georgia, North Carolina, South Carolina, Virginia, West Virginia • *East North Central:* Illinois, Indiana, Michigan, Ohio, Wisconsin • *East South Central:* Alabama, Kentucky, Mississippi, Tennessee • *West North Central:* Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota • *West South Central:* Arkansas, Louisiana, Oklahoma, Texas • *Mountain:* Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming • *Pacific:* Alaska, California, Hawaii, Oregon, Washington Puerto Rico is not included in a Census region and is listed as a separate category.	Census Bureau

[1] Donald J. Trump, Executive Order 14274, "Lowering Drug Prices by Once Again Putting Americans First," 90 *Federal Register* 16441, April 18, 2025, https://www.whitehouse.gov/presidential-actions/2025/04/lowering-drug-prices-by-once-again-putting-americans-first/.

[2] U.S. Centers for Medicare & Medicaid Services (CMS), "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Rating; Hospital Price Transparency; and Notice of Closure of a Teaching Hospital and Opportunity To Apply for Available Slots," 90 *Federal Register* 53755, November 25, 2025.

[3] "ODACS Provider CCN Table," *CMS*, accessed June 16, 2026, https://www.cms.gov/files/document/odacs-provider-ccn-table.pdf.

[4] As stated in 42 CFR § 419.20(b), the following hospital types are not paid under the OPPS: critical access hospitals; Maryland waiver hospitals; hospitals located outside the 50 states, the

District of Columbia, and Puerto Rico; Indian Health Service hospitals; and rural emergency hospitals. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-419/subpart-B/section-419.20.

[5] "ODACS Acquisition Data Template," *CMS*, accessed June 15, 2026, https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/outpatient-prospective-payment-system-opps-drug-acquisition-cost-survey.

[6] In some instances, more than one NDC was associated with a given HCPCS code and vice versa. Additionally, some NDCs changed HCPCS code assignment during the ODACS study period; in these cases, both relevant HCPCS codes were included.

[7] In other words, each reported unit should correspond to a complete package of that NDC, regardless of the number of individual items (e.g., vials or bottles) that the package contains.

[8] Five subunits in the ODACS population also have A as the fourth character in their CCN, which denotes a subunit in a long-term care hospital. For these subunits, the SA or TA in their CCN was replaced with "20." This methodology was applied in accordance with "Provider Base Facility CMS Certification Number (CCN)," *ResDAC*, accessed June 18, 2026, https://resdac.org/cms-data/variables/provider-base-facility-cms-certification-number-ccn.

[9] There were 66 subunits that responded to the survey and reported acquisitions either in addition to its parent unit or instead of its parent unit. In these cases, the acquisition data reported by the subunit was not excluded (unless it was a duplicate response; refer to Section 3.3.4) but instead aggregated with data from its parent unit in margin calculations.

[10] Using the ASP and OPPS Addendum B pricing files for 2024Q3 to 2025Q2. Refer to "ASP Pricing Files," *CMS*, accessed June 15, 2026, https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files and "Quarterly Addenda Updates," *CMS*, accessed June 15, 2026, https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/quarterly-addenda-updates. There were 11 NDCs whose associated HCPCS code never had a payment limit published during the ODACS study period; these NDCs were not reported as purchased by many hospitals and were excluded from margin calculations.

[11] NDC-HCPCS adjustment factors were obtained using NDC package size and HCPCS billing unit information from CMS's public NDC-HCPCS crosswalks and Medi-Span, as well as additional manual review to confirm each value.

[12] The per-unit furnishing fee was $0.250 in 2024 and $0.258 in 2025. Refer to "Annual Clotting Factor Furnishing Fee Update 2024," *CMS* (August 10, 2023), https://www.cms.gov/files/document/r12201cp.pdf and "Annual Clotting Factor Furnishing Fee Update 2025," *CMS* (August 15, 2024), https://www.cms.gov/files/document/r12795cp.pdf.

[13] Included claims met most of the same criteria as outlined in Section 2.1, with the exception that both paid and unpaid claim lines were included in order to capture all FFS drug utilization.

[14] 340B units were identified as units billed on claim lines with modifier codes JG or TB. Non-340B units were identified as units billed on claim lines without either of those two modifiers.

[15] Defined as the unique combination of CCN, NDC, and 340B or non-340B acquisition from each ODACS response.

[16] Although CMS conducted outreach to some entities with anomalous reported values and was able to successfully support their resubmission, there was insufficient time and resources to reach out to every entity that submitted anomalous data meeting one of these scenarios, particularly because a large number of entities did not submit their response until the end of the reporting period.

[17] The 340B PVP website states that "The [PVP]…works with 155 manufacturers to obtain lower drug pricing for [340B covered entities] on non-340B items, such as vaccines…." https://www.340bpvp.com/covered-entities.

[18] "HCPCS Codes For Which ASP Reporting Is Done In Unit Other Than NDC, Updated April 2026," *CMS*, accessed June 15, 2026, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Downloads/ASP-Report-in-units-other-than-NDC.pdf.

[19] "Medicare CY 2026 Outpatient Prospective Payment System (OPPS) Final Rule Claims Accounting," *CMS*, accessed June 16, 2026, https://www.cms.gov/files/document/2026-nfrm-opps-claims-accounting.pdf.
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[22] Arefeh Mazarei et al., "Online boxplot derived outlier detection," *International Journal of Data Science and Analytics* 19 (2025): 83–97, https://doi.org/10.1007/s41060-024-00559-0.
[23] "Behavioral Risk Factor Surveillance System: Weighting the Data (2011 Weighting Formula)," *U.S. Centers for Disease Control and Prevention (CDC)*, last modified July 19, 2013, https://www.cdc.gov/brfss/annual_data/2011/2011_weighting.htm.
[24] "National Health and Nutrition Examination Survey – Weighting," *CDC*, n.d., https://www.cdc.gov/nchs/nhanes/tutorials/weighting.aspx.
[25] "Weighting," *U.S. Census Bureau*, last modified January 12, 2022, https://www.census.gov/programs-surveys/cps/technical-documentation/methodology/weighting.html.
[26] "Weighting," *U.S. Census Bureau*, last modified August 19, 2022, https://www.census.gov/programs-surveys/sipp/methodology/weighting.html.
[27] "Consumer Expenditures and Income: Calculation," *U.S. Bureau of Labor Statistics*, last modified September 12, 2022, https://www.bls.gov/opub/hom/cex/calculation.htm.
[28] Hospitals in the refined population that submitted a survey response but reported zero acquisition data were treated as nonrespondents for the purposes of IPW analyses.
[29] Consequently, 340B hospitals that only reported 340B drug acquisitions are excluded from the respondent population for non-340B drugs.
[30] Unadjusted acquisition cost margins are the margins calculated as described in Section 3.2.
[31] The number of hospitals in the columns "Respondents Reporting Drug Acquisitions" and "Nonrespondents" slightly undercount the number of hospitals in the "All Survey-Eligible Hospitals" column because 39 hospitals that submitted a survey response in which they reported zero drug acquisitions have been omitted from this table. Of them, 71.8% (28 CCNs) are non-340B hospitals and 28.2% (11 CCNs) are 340B hospitals. The majority of these hospitals have low claims billing volume for OPPS drugs, are smaller, and are located in metropolitan areas. Only one of these hospitals is a major teaching hospital.
[32] Survey records at the ceiling price were identified as those with a per-unit acquisition cost between the minimum and maximum ceiling price across the four quarters of the ODACS study period.
[33] This margin compared aggregate 340B ceiling prices for all 1,843 survey NDCs to the aggregate ASP payment amounts for their equivalent HCPCS codes during the ODACS study period. Because this calculation does not include any ODACS data, the ASP-based payment amount was volume-weighted by the number of 340B units billed on OPPS claims by survey-eligible hospitals for survey-relevant HCPCS codes during the ODACS study period.
[34] The shares of All Survey-Eligible Hospitals in each hospital size bin are not equal because these quintiles are determined across 340B and non-340B hospitals together, such that when stratifying the population by 340B participation status and 340B drug purchase the bins are no longer equal.
[35] The number of medical residents divided by the number of inpatient beds at a hospital as defined using the FY 2025 IPPS Impact File.