

**New York State Department of Health Response to Comments Received from Pharmacy Associations and Focus Group Members Regarding Average Acquisition Cost (AAC) and Cost of Dispensing (COD)**

**2/5/2014**

**COST OF DISPENSING (COD)**

*The Department received a number of comments that generally challenge the data analysis and methodology employed by New York in developing its proposed tiered dispensing fee structure. Correspondents based their comments on the dispensing fees set by other states that engaged in a COD survey process, as well as a number of national COD studies.*

*While the methodology used by New York may not have been identical to those employed by other surveys, it is similar and produced conclusions consistent with those surveys. (See Table 1)*

*For instance, annual prescription volume is time and again identified as having the most significant impact on cost of dispensing. This is due to the inclusion of a number of fixed costs (i.e., rent) that do not vary significantly with increased volume. As is seen consistently in other COD surveys, pharmacies with higher total prescription volume have these fixed costs spread over a greater number of prescriptions, resulting in lower per prescription costs. Not only was this the case in New York, it is more significant in New York because of the large number of high volume pharmacies.*

*Also, when comparing final results of state COD surveys, one cannot look only at final results to draw conclusions as differences in survey methodologies may account for ultimate variables. Results can therefore be practically compared only when considering a variety of components such as the statistical methodology used; the pool of pharmacies and respondents; cost types included in the survey; etc. For example, unlike other COD surveys referenced during the comment period, New York mandated submission of information; thus leading to a larger data set than other states had for analysis. Additionally, business costs collected by each referenced study for calculation of a dispensing fee differed materially, with a resulting effect on COD.*

*See Page 2 - **Table 1** - Literature Review of COD on Cited States*

Survey - Vendor/Author	Total Survey Pool	Total # of Pharmacies Analyzed	% of Survey Pool Analyzed	# of High Volume Pharmacies (> 80,000 annual Rx)	Submission Mandatory	Statistical Methodology Used	How were smoothing, trimming and outliers handled?	Conclusion
Alabama Medicaid - Health Information Design, Inc.	1,357	569	42%	250	No	A multivariate linear regression was used to determine the relationship between several predictor variables and cost of dispensing.	10% upper and lower trim was performed to "smooth" the data and remove outliers.	"Total number of prescriptions for the year was by far the most predictive of the four variables."
MACDS & NCPA 2007 - Grant Thornton, LLP	24,400	23,152	95%	<2,560*	No	Descriptive statistics of central tendency and quartiles were reported.	Dropped about 1300 surveys per guidelines, removed 14 outliers and further reduced the data to +/- 4 standard deviations	"It is apparent that total prescription volume is a key variable related to a pharmacy's cost of dispensing."
Idaho Medicaid - Myers & Stauffer, LC	347	180	51%	50	No	Descriptive statistics of central tendency, Standard Deviation and Student's t test were used to determine if there were significant correlations between characteristics and cost of dispensing	Excluded 2 specialty pharmacies, adjusted for inflation and weighted by Medicaid volume.	"A significant correlation was observed between a pharmacy's total prescription volume and the dispensing cost per prescription."
Maryland Medicaid - Myers & Stauffer, LC	1,360	1,111	82%	283	Yes	See Idaho.	Excluded 65 specialty pharmacies, adjusted for inflation and weighted by Medicaid volume.	"There is a significant correlation between total annual prescription volume and dispensing cost." (3-tier more accurate but hard to administer.)
New York Medicaid - Ernst & Young, LLC and NYSDOH	4,635	2,693	61%	625	Yes**	Descriptive statistics of central tendency, correlation, and Standard Deviation were used to describe cost of dispensing. Generalized linear models were used to determine the single most deterministic attribute.	Excluded 143 surveys for the following reasons: No reported staffing (131), Medicaid volume > total volume (6), and triplicate records submitted (6). 10% lower bound trim, Upper bound Interquartile Range smooth.	Number of prescriptions is the attribute that is most predictive of cost of dispensing. Dispensing fee based on 3-tier total annual prescription volume
Oregon Medicaid - Myers and Stauffer, LC	723	262	36%	<72***	No	See Idaho	Excluded 3 specialty pharmacies, adjusted for inflation and weighted by Medicaid volume.	"There is a significant correlation between a pharmacy's total prescription volume and the dispensing cost per prescription." (Described in 3 "meaningful" tiers.)

\* This study's final high volume range started at 62,122.

\*\* A sampling strategy exempted approximately 40% of chain submissions

\*\*\* This study's final high volume range started at 70,000.

**Comment 1:** Comparing results from NYS DOH's COD tiered dispensing fee system by prescription volume; New York estimates lag well behind other state level tiered COD estimates. A clear pattern emerges, across all states and all tiered prescription volume ranges, COD in New York lags well behind other states, despite the fact that New York has one of the highest costs of living in the United States.

*Response: As mentioned above, differences in survey populations, collected costs and methodologies will affect final results. The conclusions of other states, whether they use a tiered dispensing or a flat fee, are consistent with the findings in New York which identified annual number of prescriptions as being the attribute that had the greatest impact on the NY COD. Final analyses of data collected in Oregon, Alabama, Idaho [11,1,3] and New York's COD surveys clearly reflect that a lower COD tends to occur at pharmacies that have higher prescription volume. New York has more pharmacies and larger Medicaid and general populations than any of the other survey states. Since results of all survey states support the premise of lower COD with higher prescription volume, it is expected that New York would have lower COD costs.*

**Comment 2:** The 2013 NCPA Digest found that an appropriate pharmacy COD is approximately \$12.00. NYS DOH's proposed COD falls well short of this figure.

*Response: The NCPA Digest [9] reports financial information only for independent community pharmacies. New York's COD survey includes data for both chain and independent community pharmacies. Therefore, NCPA Digest's COD does not provide a valid standard of comparison for New York's final COD.*

**Comment 3:** The recommended fees of \$8.33 and \$6.77 to be paid to 76% of participating pharmacies fall far below a 2007 Grant Thornton COD survey that concluded that the national average dispensing fee should be \$12.10. This calls into question the analytics, assumptions and policies that were used to "smooth" the data remove "outliers" and develop linear regression models.

*Response: New York's methodology is consistent both with other states (see Table 1) and with the national Grant Thornton study, which was conducted at the request of the National Association of Chain Drug Stores (NACDS)[2] and The National Community Pharmacists Association (NCPA) [9]. The referenced \$12.10 was the National mean COD (per pharmacy) from the 2007 Grant Thornton study. New York's median from that same study was \$11.27 and is a more comparable statistic to New York's methodology. The Grant Thornton study also found the distribution to be asymmetric and used Quartiles to describe COD dispersion.*

*The transformation of legitimate values New York performed on the tails of the skewed distribution, sometimes called "trimming" or "smoothing" are sound techniques to increase accuracy.*

**Comment 4:** It should be noted that the northeast region of the United States has historically demonstrated to be one of the highest COD regions.

**Response:** *This comment cannot be fully supported by review of existing surveys as there is conflicting information available. For example, while the northeast region is reported as being the highest COD region in the 2013 NCPA Digest, sponsored by Cardinal Health [9], the 2007 Grant Thornton National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies [2] identifies Pacific and Mountain states as having the highest cost of dispensing.*

**Comment 5:** NYS DOH chose to exclude outliers that would be vital to reflect an appropriate COD. Based on NCPA calculations it appears that only those outliers that would lower the proposed COD were utilized while outliers that would raise the proposed COD were excluded. Such action raises serious concerns as to the accuracy of resulting data.

**Response:** *This is not an accurate portrayal of the methodology used to address outliers. The Department received 2870 surveys of which an initial 34 were removed due to incomplete data or the inability to complete the verification process. An additional 143 were removed for other valid reasons (see Table 1). NY COD was also standardized to control for both high and low outliers. On the lower end, the values of 280 pharmacies that were below the 10<sup>th</sup> percentile of all pharmacies were raised up to values at the 10<sup>th</sup> percentile level and analyzed at that level. For example, the lowest COD in the analysis was \$0.31, which was smoothed by the 10% lower trim for its Interquartile range (brought up) to \$3.06. On the high end, the values of the 56 pharmacies that were above the 75<sup>th</sup> percentile, the highest being \$86.85, were brought down to the 75<sup>th</sup> percentile value of \$43.39 and analyzed at that level. This allowed us to retain these pharmacies in our analysis.*

*Other states used similar methodologies to address outliers and smooth the data. For example, for the Alabama survey a 10% upper and lower trim was performed to “smooth” the data and remove outliers [1]. Alternatively, the Grant Thornton nationwide study [2] reported dropping about 1300 surveys due to failure to meet reasonableness/completeness guidelines, removing 14 extreme outliers and further reducing the data to plus/minus 4 standard deviations.*

*Transformations of skewed distributions can take many forms but they all involve altering values further from the center of the distribution to improve the shape of the distribution. This is done in the pursuit of accuracy as well as to get a clearer understanding of center and area under the statistical bell curve. DOH chose a very conservative transformation, one that retained nearly all pharmacies in their general position along the curve.*

*The degree to which outlier data would be identified for the NY COD study was defined by DOH in conjunction with Ernst & Young long before the study had data. While it was a policy decision to determine that values beyond plus/minus 2 standard deviations from the median were to be excluded from analyses, it is a prevalent cut off for survey evaluation and indisputably, by its timing, done without bias.*

**Comment 6:** NYDOH developed a regression model to identify the attributes that had significant and consistent impact on COD. The model has an R-squared of 18.27, suggesting that model predicts only 18.27% of the variation in COD around its mean value. DOH needs to document what additional testing was done to assure a robust model.

**Response:** *The Department performed a large number of descriptive and correlative procedures as well as factor analyses before and during the process of developing Generalized Linear Models (predictive procedure). Generalized Linear Models (GLMs) start with a base model that includes all variables/attributes and then each iteration pares down variables/attributes, as they are determined to be not significantly predictive. Over 18 GLMs were run which evaluated attributes such as region, independent vs. chain, population density, prescription types and single ownership vs. multiple ownership. Most models were assessed in 20 mean groups that had the average actual COD and the average predicted COD calculated and plotted. The graph plots were analyzed for shape and overlap for validation purposes. There were models with higher R-squared values but they included 32 tiers, which would have been an unmanageable number of tiers.*

*Throughout all modeling, the single most predictive attribute was annual number of prescriptions. Additionally, the Department performed a literature review which found that similar studies either found a significant correlation of COD to number of prescriptions or found the number of prescriptions to be highly predictive of COD. [See Table 1]*

**Comment 7:** NYDOH should consider annual volume of Medicaid prescriptions filled and allow an additional incentive payment be added to the base dispensing fee when Medicaid prescriptions make up a certain percentage of a provider's annual prescription volume.

**Response:** *The Department analyzed the ranges of percent Medicaid prescriptions in increments of 1%, 5%, 10%, 30%, and unequal increments to determine that the best breakpoint was '0 to <30%' and '30%+'. That breakpoint was used in further analyses of mean and median as well as a set of GLM procedures.*

**Comment 8:** NY DOH excluded from COD analysis important expense categories. These include but are not limited to; account receivable expenses, bad debts, write offs, delivery cost and equipment depreciation, corporate overhead expenses and cost of carry inventory.

**Response:** *Initially, it should be noted that all components of the COD survey were identified based on guiding principles established during the March 2012 focus group meetings which included stakeholders representing all affected pharmacy business models. See Attachment A for a list of the COD Components.*

*Specific to this comment, delivery expenses and equipment depreciation are, in fact, collected in the NYS COD survey. Uncollectable accounts receivable are eligible to be written off against income at year end and therefore not included in New York's COD survey. While corporate overhead expenses are not reportable, expenses for support sites (i.e., utilities, rent, staffing, etc.) are included in the NYS COD calculation. The cost to carry inventory was*

*not included in the COD survey because to do so would be contrary to the NY State Medicaid reimbursement methodology used for other provider types.*

*The exclusion of bad debts and other write offs is consistent with state COD surveys (i.e., Alabama, Idaho, Oregon) [1,3,11] and provisions of the federal Provider Reimbursement Manual CMS Pub 15-1, Section 304, “The allowance of unrecovered costs attributable to such bad debts in the calculation of reimbursement by the Program results from the expressed intent of Congress that the costs of services covered by the Program will not be borne by individuals not covered, and the costs of services not covered by the Program will not be borne by the Program.”*

**Guiding Principles**

Included in the COD:

*An expense directly related to the dispensing of a Medicaid prescription*

Not included in the COD:

*An expense resulting from a discretionary business or marketing decision*

*An expense incurred to obtain a competitive advantage*

*An expense that can be reimbursed, written off or recovered elsewhere*

*An expense contrary to Medicaid policy, regulation, statute or standard reimbursement methodology for other Medicaid services*

**Comment 9:** Please provide a regional breakdown of where the remaining folks in Medicaid FFS live.

**Response:** See chart below. Numbers reflect non-dual FFS members only.

**Table 2** (Data source: DOH Salient 12/30/13 “Current MA Coverage:FFS”)

<b>Region</b>	<b>FFS Members</b>
Capital District	69,208
Central New York	87,130
NY Metro Long Island	77,468
NY Metro New Rochelle	78,986
NY Metro New York City	413,387
Western NY Buffalo	68,512
Western NY Rochester	58,219
<b>TOTAL</b>	<b>852,910</b>

**Comment 10:** Please provide a breakdown of the response and non-response rate for the COD survey. We believe the response rate for New York City is much lower than any of the other areas identified, which skews the COD downward.

*Response: The table below illustrates the 2012 COD survey receipt/non receipt counts, inclusive of both chain and independents. The data supports consistent submission percentages across statewide regions, including NYC, which accounts for 50% of surveys received.*

**Table 3**

Region	Total Number of Pharmacies in Study	Number of Surveys Received	% of Surveys Received	Number of Surveys Not Received	% of Surveys Not Received	Regional % of Total Received	Regional % of Total Not Received
Capital District	313	200	64%	113	36%	7.1%	6.3%
Central New York	353	229	65%	124	35%	8.1%	6.9%
NY Metro Long Island	568	334	59%	234	41%	12%	13%
NY Metro New Rochelle	448	274	61%	174	39%	9.7%	9.7%
NY Metro New York City	2,245	1,414	63%	831	37%	50%	46%
Out of State	102	4	3.9%	98	96%	0.14%	5.4%
Western NY Buffalo	346	221	64%	125	36%	7.8%	6.9%
Western NY Rochester	260	160	62%	100	38%	5.6%	5.6%
<b>Totals</b>	<b>4,635</b>	<b>2,836</b>	<b>61%</b>	<b>1,799</b>	<b>39%</b>	<b>100%</b>	<b>100%</b>

**Notes:**

1. Category of 'number of surveys received' includes pharmacies for which the surveys may have been excluded from statistical analyses.
2. Category of 'number of surveys not received' includes pharmacies that may have been exempted from participation or those that submitted incomplete or blank surveys.  
See SAS job cod\_non\_receipts.sas against CODAAC database.

**Comment 11:** The data from the NY COD survey does not compare well with the data collected by other states that are using an AAC/COD reimbursement methodology. In particular, data is much more skewed, whereas in other states the maximum difference between mean and median is less than \$2. Because New York's data is so different from other states, the median is not the best representation of the central location of the data. Unless an argument can be made that Medicaid patients will never use high-cost specialty pharmacies, the median does not accurately reflect, nor will it cover the costs for many pharmacies. For example, some

pharmacies specialize in high cost medications and offer specialized services that include patient care teams, side effect management, adherence counseling, compliance devices, 24/7 access to pharmacists and others. These costs must be considered in COD.

**Response:**

*Addressing first, the use of median in the New York analysis, mean and median are two measures of center in a distribution. When they are not close (as with the New York data), they are described as a skewed distribution. In such situations, median is considered the better measure of center or midpoint because the mean is susceptible to the influence of outliers. This is not a policy decision; it is an accepted principle of statistical analysis. [4,6]*

*Transformations of skewed distributions can take many forms but they all involve altering values further from the center of the distribution to improve the shape of the distribution. This is done in the pursuit of accuracy and to get a clearer understanding of center and area under the curve. The Department chose a very conservative transformation, one that retained nearly all pharmacies in their general position along the curve. Stratifying the dispensing fee, with each stratum having its own mean, allows for greater accuracy than a single midpoint for all pharmacies in New York. The final proposed dispensing fees of \$14.11, \$8.33 and \$6.77 represent the mean of each tier.*

*Beyond those pharmacies that were excluded through the verification and validation process, (see Table 1), pharmacies specializing in high cost medications were retained in the study and, as such, affected both mean and median for COD. Additionally, the use of the Generalized Linear Model procedure showed that pharmacies which indicated that they filled one percent or greater prescriptions under the categories of Long Term Care or Limited Distribution did not significantly affect the predictive estimates for COD.*

*Secondly, addressing the comment that costs associated with patient care teams, side effect management, adherence counseling, compliance devices and 24/7 access to pharmacists and others, the costs associated with these services did not meet the COD guiding principles that were established (see comment 8).*

**Comment 12:** Once New York arrived at the median dispensing fee of \$8.01, a decision was made to propose a three-tiered dispensing fee based on each pharmacy's annual prescription volume. This is concerning and seems to conflict with the assurances the Department has given throughout this process that the data would drive the results.

**Response:** *The data did in fact drive the results in this process. The Department did not arbitrarily jump from the initial \$8.01 median dispensing fee to the proposed tiered structure. The Department conducted additional testing to determine if those survey attributes identified in the initial analysis as being significantly different statistically from the \$8.01 median COD were being influenced by other attributes. We found that the most consistently significant attribute driving COD is total annual prescription volume. This finding led to the proposed three-tiered dispensing fee.*

*The levels proposed were not selected arbitrarily. The three-tier structure was arrived at by analyzing the distribution of pharmacies along the primary predictive attribute, number of*

prescriptions filled. There is more than one statistically sound/valid way to develop tiered dispensing fees. Since we had a skewed distribution, the use of an Interquartile range was indicated, as it is a better measure of distribution. As per Table 4 below, there are a similar number of pharmacies within each quartile.

**Table 4**

RXs Per Year, In 1,000s	# of Pharmacies Analyzed	% of Pharmacies
0 to < 10	55	2.0%
10 to < 20	208	7.7%
20 to < 30	341	12.7%
30 to < 40	383	14.2%
40 to < 50	382	14.2%
50 to < 60	260	9.7%
60 to < 70	257	9.5%
70 to < 80	193	7.2%
80 to < 90	151	5.6%
90 to < 100	108	4.0%
100 to < 120	126	4.7%
120 to < 140	82	3.0%
140 to < 160	51	1.9%
160 to < 200	39	1.4%
200 to < 250	26	1.0%
250 to < 300	8	0.3%
300 to < 500	6	0.2%
500 to < 700	7	0.3%
700 to < 1,000	5	0.2%
1,000 +	5	0.2%
<b>Totals</b>	<b>2,693</b>	<b>100%</b>

Please note that in the distribution, a single range of 0-29,999 would encapsulate 24% of the pharmacies, 30,000-79,999 the middle 54% and 80,000 and higher would categorize the final 22%. This roughly corresponds to the First and Third Quartiles around a median occurring in the 30,000-49,999 range where 50 percent falls within the Interquartile Range. Each quartile creates an approximately equivalent-sized group.

The only policy decision was to create a reasonable number of tiers that retained the highest predictive estimates of COD possible. It is important to note that using the proposed tiered structure, 78% of survey participants will realize a dispensing fee higher than they would have received using the original \$8.01 median.

**Comment 13:** NYDOH stated that the proposed volume-based tiers were based on the theory of economies of scale.

**Response:** The concept of 'economies of scale' was a discussion point brought up in the December 3, 2013 focus group meeting to merely provide thought as to why, perhaps, the lowest CODs were amongst some of the pharmacies with the highest volume of prescriptions filled. Discussion surrounded fixed costs driving down the cost of dispensing. As stated in other

*responses, the Department's finding that lower costs tended to occur at pharmacies which had higher volume, is clearly reflected in our data and is consistent with the findings of other states. The concept of economies of scale did not drive or impact DOH's study or final determinations; however, it is reasonable to conclude that economy of scale is at play in what drives the COD.*

**Comment 14:** A study conducted by Virginia Commonwealth University found that for closed door LTC pharmacies, the median COD was \$13.54. Compared to retail pharmacies, LTC pharmacies incur additional dispensing-related costs to serve residents' needs. The initial COD for LTC was identified as \$5.59. This calls into question the validity of the data.

**Response:** *Differences in surveys make a comparison inapposite. New York's preliminary median COD of \$5.59 was based on s an evaluation of any pharmacy that self-reported LTC prescriptions of greater than or equal to one percent. The referenced study surveyed only closed door pharmacies that service LTC facilities exclusively. It is important to note that the Department has never proposed a \$5.59 dispensing fee for LTC pharmacies.*

*The Virginia Commonwealth University School of Pharmacy, in conjunction with the National Community Pharmacy Association, published the 2013 Analysis of Costs to Dispense Prescriptions in Independently Owned Long Term Care Pharmacies. [12] While the Department cannot comment in detail without access to the full report, a review of the executive summary identifies over half of dispensing-related costs to be a result of personnel expenses. Without access to detailed survey components the Department questions whether the final COD discrepancy is a result of New York's exclusion of such personnel costs as nursing, case managers, etc.*

*In response to this concern, the Department reviewed the raw data for any pharmacy that reported LTC prescription volume of 50% or higher. We looked at the COD calculated for each individual pharmacy and calculated an average COD for each reported percent range. We did not remove outliers, but simply calculated averages. We did not include annual percentages less than 50%. The final average COD for all LTC reporting annual LTC prescription percentages of 50% or above is \$9.719774. See Table 5.*

**Table 5**

Reported Annual LTC Percentage	Number of Pharmacies in this Percent Range	Avg. COD for Percent Range
100.00%	18	\$11.371656
99.00%	15	\$11.117477
98.00%	12	\$8.534917
97.00%	7	\$6.548406
96.00%	5	\$7.264655
95.00%	7	\$4.243859
94.00%	5	\$11.690221
93.00%	2	\$11.267486
90.00%	10	\$7.283651
89.00%	3	\$4.096521
88.00%	3	\$15.723542
86.00%	1	\$6.728494
85.00%	4	\$7.249956
83.00%	1	\$1.859036
80.00%	9	\$8.548105
75.00%	4	\$7.414452
74.00%	1	\$12.102381
73.00%	1	\$4.381592
70.00%	6	\$28.777132
65.00%	2	\$6.033780
63.00%	1	\$7.916226
60.00%	4	\$4.196916
59.00%	1	\$3.952277
55.00%	1	\$36.301308
50.00%	2	\$8.390304
<b>TOTALS</b>	<b>125</b>	<b>\$9.719774</b>

**Comment 15:** The dispensing fee calculated for long-term-care (LTC) pharmacies is extremely low and lower than the lowest proposed community pharmacy dispensing fee.

**Response:** *The Department is not proposing a separate, or lower, dispensing fee for LTC pharmacies but rather dispensing fees based on prescription volume.*

**Comment 16:** LTC Pharmacies have different business models than community based retail or hospital based pharmacies. Including LTC in the models for the general population of pharmacies dilutes the federal mandates and requirements that LTC are obligated to.

**Response:** *Based on this comment, DOH revisited the Generalized Linear Modeling that provided the elements that predominantly predicted COD. The initial base model for pharmacies that reported 1% or more LTC prescriptions was not significantly predictive.*

**Comment 17:** LTC pharmacies have special handling and packaging requirements that should be reflected in the COD.

- Comprehensive inventory and inventory capacity
- Pharmacy operations and prescription orders
- Special packaging.
- IV meds
- Compounding capabilities
- Pharmacist on call

***Response:** The Department seeks clarification regarding the first bullet. All of the other expenses above were reportable in the NY COD survey. Providers were instructed to contact the Department if there were questions as to what could or could not be reported.*

**Comment 18:** In the initial findings by Ernst &Young, a number of issues stood out. Specifically:

- The COD survey found the median dispensing fee in Rochester to be higher than in New York City. This seems impossible when it is common knowledge that NYC is the most expensive city in the state to do business.

***Response:** The Department had similar questions, based solely on anecdotal evidence, after review of the initial data. It is important to note that this was an initial finding and it was for that reason that additional testing was conducted to determine what was actually driving the identified statistical differences. What was ultimately determined was that it is **not** region or any other attribute but rather total annual prescription volume that predominantly drives COD in New York State.*

- We question the rationale for using median COD of \$8.01 when the mean COD was calculated as \$11.01, which is more in line with other states. We believe use of the median is simply an attempt to reduce pharmacy reimbursement further rather than to compensate us fairly for the cost of doing business.

***Response:** Use of median was not a policy decision intended to reduce reimbursement. It is a statistically sound, generally accepted measurement of central tendency with skewed data. [4, 6]*

- NY reports an unweighted standard deviation of \$25.27 for the COD distribution well above what other states report. Even after adjusting for outliers, the standard deviation is above that is reported by other states, For example Alabama reports an unweighted standard deviation of \$7.24 and a weighted standard deviation of +\$3.58. NYS DOH must provide a rationale justifying the discrepancy.

***Response:** The Department reports a larger standard deviation than similar studies partially due to the inclusion of many types of pharmacies. Pharmacies that were included fall into self-defined categories such as 'Long Term Care', 'Limited Distribution', 'Clotting Factor', 'Infusion', etc., in varying percentages of prescriptions, that were often not included in other studies. Additionally, the Department survey reached both mail order and some out-of-state pharmacies that may contribute to the low end of the COD*

*spectrum. Such pharmacies can add to the volatility of the data yet are legitimate values for analysis. Also affecting the fullness of the range of received surveys inherent to the Department's study is that it was mandatory which could lead to responses from a wider range of pharmacies than the merely interested or the compliant. Please note that standard deviation should not be considered the best representation of spread in a skewed distribution as it squares each data point's distance from the mean. The most helpful and robust measures of spread are the first and third quartiles.*

**Comment 19:** Medicaid beneficiaries are not required to pay co-pays. Pharmacists should be able to account for such losses when completing a COD survey.

***Response:** Section 367-a (6) of NYS Social Service Law states that claims for certain Medicaid services, including pharmacy, shall be reduced by the specified copayment. Medicaid members are responsible for co-pays but cannot be denied services for non-payment. Including unpaid copayments in the COD survey would be contrary to NYS statute that requires that provider payments be reduced by the specified copayment amount.*

*The determination to exclude uncollected copayments from being recaptured in the dispensing fee is in line with the guiding principle to be consistent with Medicaid policy, statute and regulations and is also consistent with reimbursement methodology of non-pharmacy Medicaid services. However, consistent with federal Provider Reimbursement Manual CMS Pub 15-1, Section 310, the Department includes in the calculation of COD all expenses related to reasonable collection efforts associated with collection of copayments.*

*Exclusion of uncollected copayments is also consistent with other states that have implemented an AAC/COD reimbursement methodology. [1,3,7,11]*

**Comment 20:** The dispensing fee allowed by NYSDOH Medicaid fee-for-service should not vary due to annualized prescription volume because the Program continues to add more and more medications that require increased pharmacists intervention due to prior authorizations, DUR review and formulary compliance rules. Additionally, emerging trends such as patient centered medical homes and Medication Therapy Management services as required by Medicare Part D, will expand the responsibilities of practicing pharmacists.

***Response:** As discussed in other responses, annualized prescription volume is the survey attribute that most consistently and significantly affected COD. Staffing expense was not a separate descriptive attribute of pharmacies for comparative analysis. Expenses for time spent by pharmacists to perform all referenced services were collected in the COD survey in "Section B, Pharmacy Dispensing Area Staff," and used to calculate COD. The COD survey will be conducted annually and adjustments to the dispensing fee will be made as necessary to reflect changes in expenses (including those related to headcount if applicable).*

**Comment 21:** In order to ensure that specialty pharmacies can continue to support New York Medicaid members, we recommend that New York develop a separate dispensing fee for specialty pharmacies that address the high administrative, overhead and operating costs and costs for personnel such as nurses and social workers.

**Response:** The COD survey collected costs from all pharmacy business types to develop a dispensing fee that is directly related to dispensing prescription drugs to a Medicaid member. This includes expenses such as equipment, packaging, delivery and staffing costs. Expenses such as nursing and social worker expenses are not considered directly related to the cost of dispensing. Please see Attachment A for a list of items included and not included in NY's COD survey.

**Comment 22:** The COD survey was negatively impacted by Hurricane Sandy, which caused responses that were not representative of all stores in the state.

**Response:** Hurricane Sandy had a negligible, if any, impact on the COD survey. The COD survey was issued on September 27, 2012 and was closed on October 26, 2012, which is the date on which a State of Emergency was issued in New York. Hurricane Sandy did not make landfall in New York until October 29, 2012. The only impact to COD was a delay in collecting validating documents from pharmacies that had already submitted data.

*In response to the devastation caused by the storm, the Department delayed issuance of the AAC survey, initially scheduled for November 4, 2012, until December 10, 2012. Additionally, all stores in the Rockaway section of New York (identified by zip code) were exempted from the initial AAC survey, as was any store identified by the NYS Department of Education as having been closed or damaged by the storm or any store that requested exemption based on impact of the storm.*

**Comment 23:** Some pharmacies included supplies and over-the counter (OTC) products when reporting total annual prescriptions for COD. Please explain how this can be corrected.

**Response:** Pharmacies were required to submit costs associated with dispensing drugs that require a prescription. The Department did not request information for products dispensed by fiscal order as NY Medicaid does not pay a dispensing fee for these products. Any errors should be corrected on the next COD survey.

### **New York Average Acquisition Cost (NYAAC)**

**Comment 24:** Explain how you define how you got the "average". Was it all of the stores' data, or the selected stores after pulling out the "outliers?"

**Response:** Average pricing is derived using data submitted by all reporting NPIs in the 3 month survey period, minus the outliers. Outliers for this purpose are those NPIs that are not part of the selected pool of survey participants for the given time period. Each month all submitted surveys are downloaded from the Health Commerce System and NPIs are checked against the database of expected submissions for that month. Pharmacies with data in the database that were not scheduled for that survey period are not included in the calculation of NYAAC. See Attachment B for illustrative examples of how the NYAAC is calculated and our response to Comment 43, for a more detailed description of how "outliers" are handled.

**Comment 25:** After review of the top 100 drugs NYAAC is determined to be, on average, \$8.72 per unit lower than the National Average Drug Acquisition Cost (NADAC) price. This discrepancy must be reconciled.

**Response:** *There are significant differences between the methodologies used to calculate the NYAAC and the NADAC. The latter relies on unweighted data submitted by voluntary survey respondents, both of which considerations are generally recognized as undermining the validity of statistical survey results. [5, 6] Additionally, the NYAAC incorporates off-invoice pricing considerations, which the NADAC expressly excludes. Any of these factors could cause a difference in results and taken together they render it unlikely that NADACs and NYAACs will be the same values. Finally, the “average difference in unit cost” cannot be regarded as a valid measure of the statistical accuracy of an array with a range from \$0.85 through \$4,376.00, which is the case with NYAAC. The average percent difference between NYAAC and NADAC is 2.15%.*

**Comment 26:** NYDOH should publish NYAAC for all reimbursable products prior to implementing this initiative so providers can fully assess the impact.

**Response:** *Draft NYAACs have been posted on the Department’s web site. This will enable providers to assess impact.*

**Comment 27:** Please clarify if there will be one AAC for generics.

**Response:** *Each generic will be reimbursed at the Generic Code Level. This means that there will be one AAC for all generics having the same ingredients, strength, dosage form, and route of administration.*

**Comment 28:** During the December 3, 2013 focus group presentation, a representative from First Data Bank stated that the difference between NYAAC and WAC prices is generally within 1%. Review of the list of AAC pricing for the top 100 brand and generic drugs does not support this statement, which is very troubling. The Department attempted to clarify the statement via email, writing: “The statement that the NYAAC for brand name drugs was within 1% of WAC was based on historical review of the cumulative price average across all brand drugs; no weighting or volume discount measurement of any kind was factored into his statement. We find this explanation incomprehensible and unacceptable.

**Response:** *Over the course of 2013 FDB conducted snapshot comparisons of AACs and WACs for all brand and generic drugs collectively. Those reviews showed relatively small differences between WACs and AACs for brand drugs, but more substantial spreads for generics. (It is important to mention that WAC is identified as a manufacturer-reported value, defined in federal law as an “undiscounted list price”.) Significantly, these assessments did not target products based on their volume, in either cost or units dispensed, but were a simple average of the percentage differences between AACs and corresponding WACs. Also, survey participants’ reporting practices were demonstrably more irregular earlier in the year when the Department was not receiving as many responses as are currently received. Therefore, these comparisons that were made may have made those results different from more recent instances. In any case,*

*whatever those earlier results may have shown, the data contained in the Top 100 drugs represents the current and most completely developed results of the AAC survey and the relationship of AACs to other benchmarks.*

**Comment 29:** Pharmacies typically pay more than wholesalers for drugs and those states with a WAC reimbursement methodology use a WAC plus a % formula. We believe this demonstrates the inaccuracy and inadequacy of what NY is proposing with AAC pricing.

**Response:** *The NYAAC survey requires submission of invoice pricing by all enrolled pharmacies; meaning pharmacies are submitting the actual purchase price for a drug. As noted below, WAC is defined by federal law as an undiscounted list price and as such is not a reliable indicator of true wholesale costs.*

**Comment 30:** We request that the Department publish both NYAAC and a comparison to WAC as a mechanism to ensure that AAC is adjusting as market prices fluctuate.

**Response:** *While the Department will publish NYAAC, there is no plan to publish a comparison of NYAAC to WAC on a regular basis. As mentioned in other responses, the Department will review other pricing benchmarks between surveys to determine whether price adjustments, both increases and decreases, are required.*

*As detailed in the 2010 white paper from the National Association of State Medicaid Directors "Post AWP Pharmacy Pricing and Reimbursement,"[8] WAC is a manufacturer-reported value, defined in federal law as an "undiscounted list price" that is potentially vulnerable to the same manipulation that led to the downfall of AWP. Since New York defines AAC as the invoice price to the pharmacy of a prescription drug dispensed to a Medicaid recipient, minus the amount of all discounts and other cost reductions attributable to such dispensed drug, continued comparison to WAC is not relevant.*

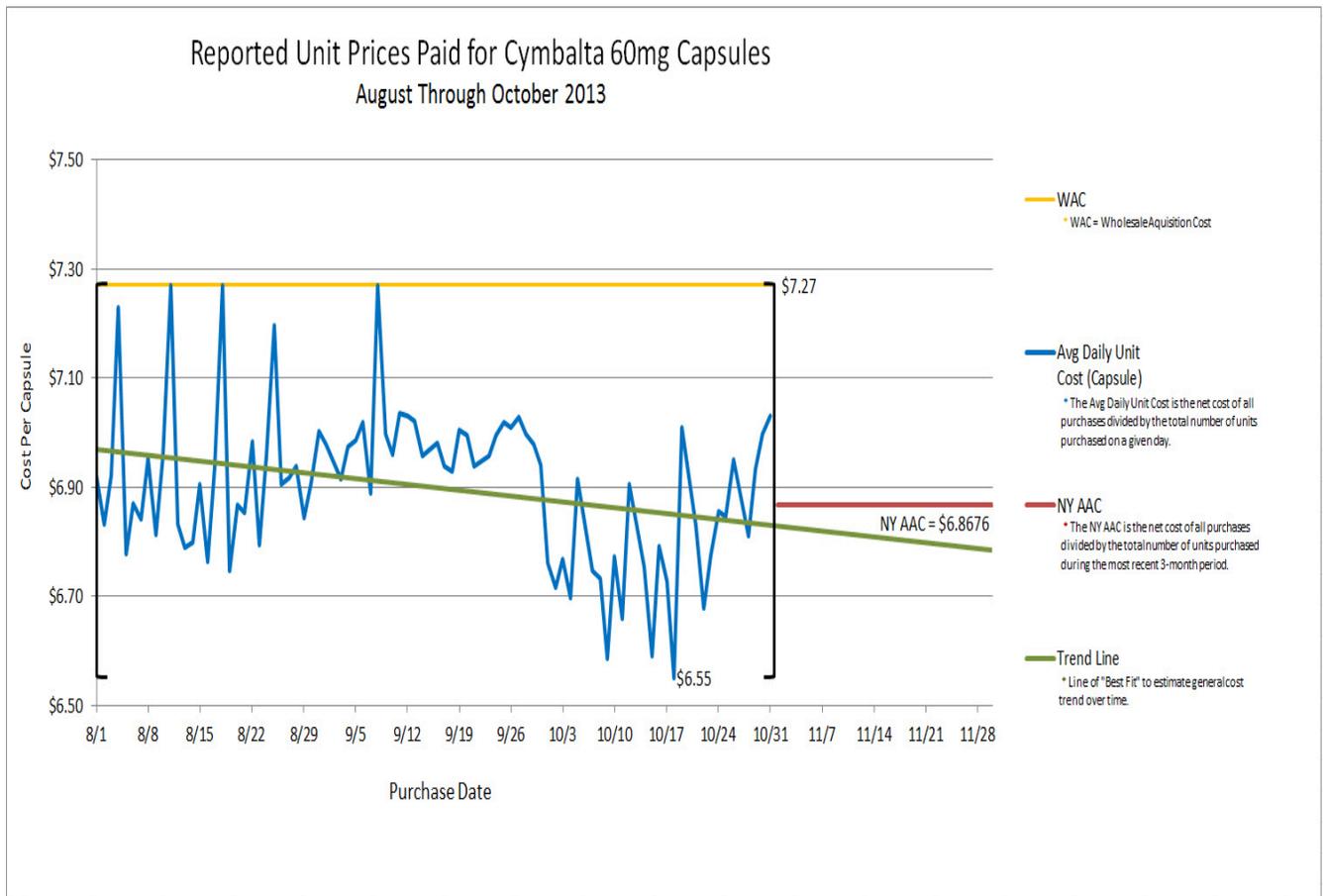
**Comment 31:** The Department's plan to keep AAC current is deeply flawed. The continuing survey method will not produce price points that are current or accurate for every product. Additionally, the Department's plan to not survey prices in December will mean a significant lag in price updates for that time period.

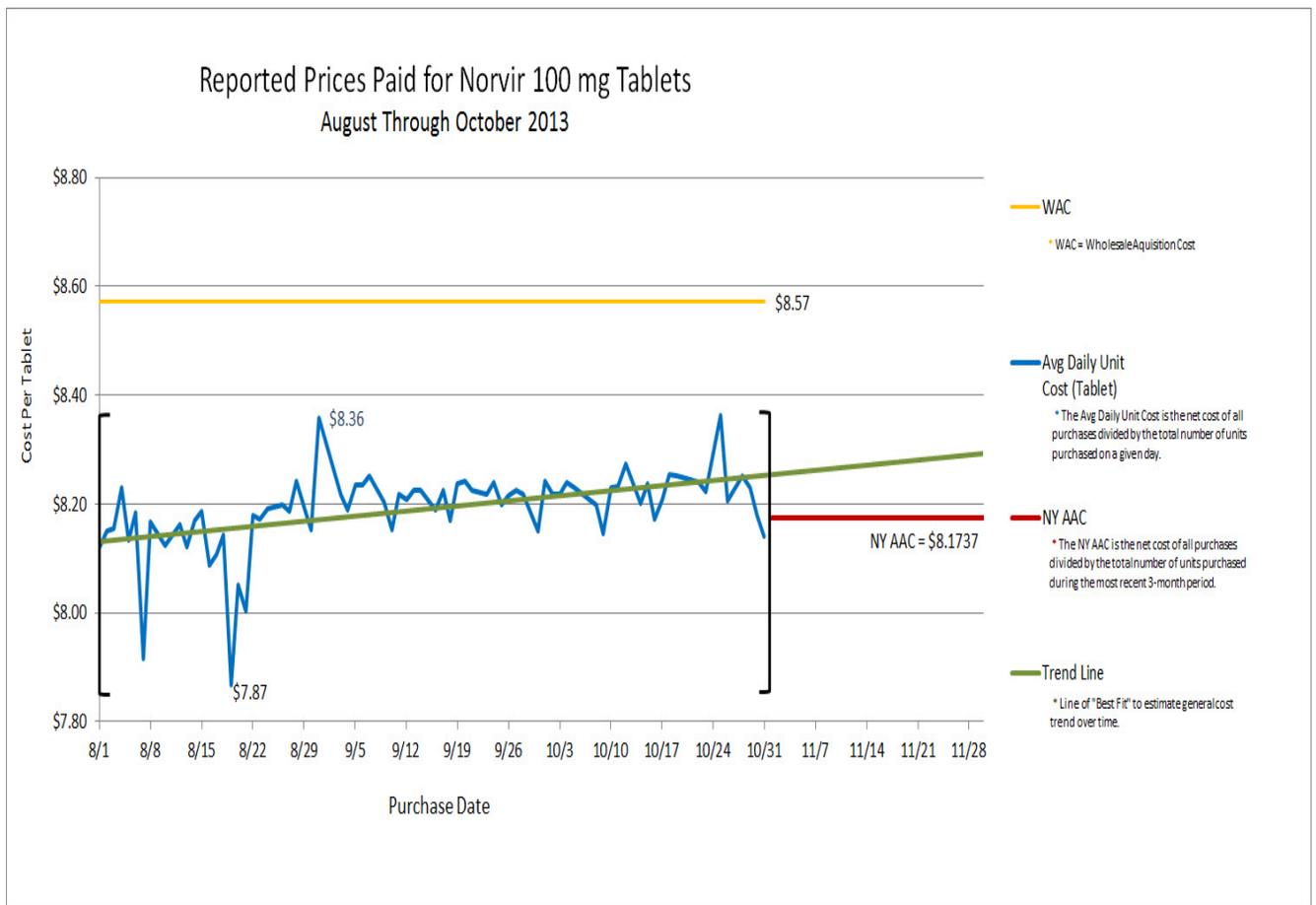
**Response:** *It is difficult to respond to comments that the NYAAC is flawed without specific information as to why the methodology is purportedly flawed. While we cannot respond without details, information on the methodology used by the Department is summarized in the General Questions section.*

*With regards to the monthly survey process, at the inception of this initiative, the Department proposed implementing the collection of each individual pharmacy's AAC at the point-of-service (POS). Focus group members indicated this was not an option as billing pharmacists likely would not have access to the invoiced price. The current survey method and tools were developed to address the expressed inability to submit pricing data through the POS system.*

New York is the only state that canvasses prices from providers monthly to confirm that current market conditions are reflected in pricing. This puts New York in the unique position of verifying market changes through actual invoice pricing.

The graphs below are illustrative examples of how acquisition cost trends over time for two drugs (Cymbalta 60mg Capsules and Norvir 100mg Tablets). It is important to note that while there may be a direct correlation between changes to AWP or WAC and reimbursement amounts, when reimbursement is based on AWP or WAC, such a correlation does not exist when reimbursement is based on acquisition cost. This again supports that average acquisition cost is the most accurate reflection of market conditions.





*Additionally, New York has committed to monitoring other published pricing benchmarks weekly and updating prices when necessary. Review of Frequently Asked Question pages on AAC websites for other states (i.e., <http://al.mslc.com/Faqs.aspx>) indicates that states develop baseline pricing and then monitor published pricing benchmarks and commit to reviewing baseline pricing "at least annually" and to monitoring the marketplace "periodically."*

*The Department's decision not to conduct AAC surveys in the month of December is based on discussions that took place during the March 2012 focus group meetings. At that time, participants indicated that it would be difficult for pharmacists to submit both COD and AAC surveys during the same month. Participants further indicated that January is the month during which the most significant number price updates occur. For these reasons, the Department proposes to conduct the COD survey in December and forgo an AAC survey for that month, once the project is fully implemented. The Department is reconsidering this decision based on comments received.*

**Comment 32:** We strongly encourage the Department to canvass the state’s pharmaceutical wholesalers to question whether their customers actually purchase medications so far below the WAC benchmark.

**Response:** *The NYAAC survey requires submission of invoice pricing by all enrolled pharmacies; meaning pharmacies are submitting the actual purchase price for a drug and attesting to the validity of those prices. The Department does not believe that canvassing wholesalers to provide information that has already been provided and attested to through the NYAAC survey adds value to the process. Additionally, the Department does not have the authority to require that wholesalers provide information regarding the wholesalers’ customers.*

**Comment 33:** When reviewing NYAAC for the top 100 drugs, we have determined that we will be reimbursed at below our cost for the majority of these drugs.

**Response:** *In response to this concern, Department staff reviewed the raw data submitted through the AAC survey process. A comparison was made with current reimbursement (MRA). Extreme differences were reviewed further. There were some product size conversion issues identified and corrected, such as prices that were not in the standardized billing units (e.g. price submitted as vials when the standard billing unit might be in milliliters). Overall, the submitted data confirms the validity of the final NYAAC pricing, which is based on an average of all reported costs minus rebates, credits and discounts.*

*The method for calculating NYAAC is outlined in the response to Comment # 43. Any average price benchmark will result in some providers being reimbursed below and some providers being reimbursed above the average price for certain products.*

**Comment 34:** Of the percentage of WAC-7.25, provide information as to how many stores were (or are) buying at this rate.

**Response:** *The WAC – 7.25% referenced is the aggregate average comparison of NYAAC (minus rebates, credits and discounts) to WAC for NY Medicaid’s top 100 brand drugs, identified by Medicaid spend, which was recently provided to pharmacies (see Attachment C). Based on more recent data, which includes submissions from pharmacies that were received after the distribution of Attachment C, the aggregate average comparison of NYAAC (minus rebates credits and discounts) to WAC for NY Medicaid’s top 100 brand drugs was WAC -5.35%, with 58% of pharmacies buying above and 42% below WAC-5.35%.*

**Comment 35:** Explain how pharmacies will have access to monthly updated NDCs so that regular comparison can be made and discrepancies reported.

**Response:** *When implemented, NYAAC will be reported on the Medicaid Pharmacy List of Reimbursable Drugs, found on the eMedNY website at <https://www.emedny.org/info/formfile.aspx>. Draft NYAACs have been posted on the Department’s website.*

**Comment 36:** The proposed AAC never guarantees that a particular pharmacy will be reimbursed at its actual cost.

**Response:** This statement is correct. The NYAAC is calculated as an average of all collected pharmacy pricing. By nature of any average benchmark, some pharmacies will pay above NYAAC and some will pay below NYAAC for any given drug.

### **Concerns with Application of Rebates to AAC pricing**

A number of comments were received related to the application of rebates, credits and discounts to NYAAC pricing. As a general response, consideration of any reduction to pricing is critical in the establishment of a transparent pricing methodology. Section 505.3 of Title 18 of the Official Compilation of Codes, Rules and Regulations of the State of New York requires the reporting of all rebates, credits and discounts associated with reported NYAAC pricing. While it would be the Department's preference to collect rebates, credits and discounts at the drug level, March 2012 focus group members clearly indicated that there was no consistent way to connect rebates, credits and discounts directly to an NDC; however, it was determined that aggregate rebates, credits and discounts could be reported.

The Department requires surveyed pharmacies to submit 12 months of aggregate rebates, credits and discounts. Application of these aggregate price reductions to NYAAC is accomplished by establishing a rebate discount rate for each pharmacy. The rebate discount rate is developed as follows:

Invoice costs reported by the pharmacy are adjusted by the pharmacy's discount factor. Each pharmacy's discount factor is equal to 1 minus the pharmacy's discount rate. The pharmacy's discount rate is the sum of the pharmacy's rebates, credits and discounts for the prior 12 months (minus any surcharges) divided by the sum of pharmacy's total invoicing for the prior 12 months as reported by the pharmacy in Part II of the NYAAC Survey data collection tools. The discount rate is applied if and only if data from Part II of the survey passes all of the following tests:

- One and only one entry exists for a given month for a pharmacy
- All months are represented in the data
- No Survey Part II reporting year-month is blank
- No Survey Part II monthly invoice total is blank
- No Survey Part II monthly invoice total is 0
- No Survey Part II monthly invoice total is less than 0
- No Survey Part II monthly invoice total is less than \$100.00
- No Survey Part II monthly discount data is blank
- No Survey Part II monthly discount data is less than 0
- No Survey Part II monthly discount data exceeds 30% of invoicing for the month
- No Survey Part II monthly surcharge data is blank
- No Survey Part II monthly surcharge data is less than 0
- No Survey Part II monthly surcharge data exceeds 30% of invoicing for the month

*An example of the pharmacy discount rate calculation is included as Attachment B.*

**Comment 37:** Explain how much rebate was applied to the drugs on the list of Top 100 drugs.

***Response:** As detailed above, rebates, credits and discounts are applied at the individual NPI level and applied to that specific provider's invoice price which is then used to calculate NYAAC. On December 20<sup>th</sup>, 2013 the Department provided the pharmacy associations with a list showing NYAAC with and without rebates, credits and discounts for each of the top 100 drugs, both brand and generic (See Attachment C). Examples of how rebates, credits and discounts are calculated were also provided. (See Attachment B)*

**Comment 38:** Rebates are not known to individual pharmacies at POS and can potentially lag behind invoice purchases.

***Response:** Surveys are collected from selected pharmacies via the monthly survey. Rebates, credits and discounts are reported for the 12 month period prior to the survey month.*

*The submission of aggregate rebates, credits and discounts by NPI for a 12 month period addresses the concerns raised that reductions to pricing are not always known to an individual pharmacy at the POS or time of invoice, as well as concerns related to rebates, credits and discounts potentially lagging behind drug purchases. The use of a twelve-month retrospective model permits the most complete collection of cumulative rebate, discount and surcharge information as a percentage of total purchases, and provides the best method of identifying a representative net cost.*

**Comment 39:** The attempt to capture rebates/credits is the reason NYAAC is below what pharmacies are purchasing drugs for in NYS.

***Response:** While it is likely that the application of rebates, credits and discounts is a reason why NYAAC appears to be below some pharmacies' invoice costs for certain drugs, it is irrefutable that drug prices are ultimately reduced by rebates, credits and discounts. Section 505.3 of Title 18 of the Official Compilation of Codes, Rules and Regulations of the State of New York defines drug acquisition cost as the invoice price of a prescription drug dispensed to a Medicaid recipient, minus the amount of all discounts and other cost reductions attributable to such dispensed drug Therefore those amounts must be considered in development of a transparent pricing methodology.*

*There was extensive discussion of this issue during the focus group process. Three options were presented to members:*

- 1. Collect discounts, rebates and free goods at NDC level.*
- 2. Collect aggregate total discounts, rebates and free goods per month for 12 months.*
- 3. Collect NDC level discounts and then cumulative rebates by year.*

*Focus group members indicated that NDC level rebates, credits and discounts are not available, therefore leaving Option #2 as the only viable option. The Department remains open to other*

*ideas and/or proposed methodologies for calculating rebates and discounts. To date, none have been received.*

### **Concerns with NYs proposed appeal process**

**Comment 40:** Explain how the Department will apply successful AAC appeals. Will it be retroactively and across the board?

***Response:** As is done with the current SMAC appeal process, if a price is adjusted retroactively, the Department will post the change to the DOH website for action by pharmacies. We have processes in place to address drug pricing fluctuations for SMAC prices and will use a process consistent with the SMAC updates for AAC updates.*

**Comment 41:** We have been told the State plans to use a pharmacy by pharmacy and drug by drug appeals process whereby pricing updates will be made only for the pharmacy appealing.

***Response:** This is not an accurate description of the process the Department proposes to use for appeals or to ensure timely updates to NYAAC.*

*First, the Department will monitor other pharmacy benchmarks, such as the National Actual Drug Acquisition Cost (NADAC) and Average Sale Price (ASP) on a weekly basis to determine if NYAAC pricing requires adjustment, either an increase or decrease, outside of the survey period. For brand drugs, the Department will consider a pricing change when there is a substantiated 5% increase or decrease in WAC. Changes to generic pricing will be evaluated on a case by case basis. Pricing updates will be made in the Medicaid POS system for reimbursement to all billing pharmacies.*

*Providers will also have the opportunity to appeal pricing at any time throughout the month using the same process that is currently in use today for NYS SMAC pricing.*

*While this process is generally consistent with other states that are using AAC reimbursement methodology, New York is the only state that canvasses prices from providers monthly to ensure current market conditions are reflected. Other states commit to reviewing baseline pricing “at least annually” and monitoring the marketplace “periodically.”*

### **Impact**

**Comment 42:** Pricing reduction could result in pharmacy closures, job losses and ultimately access issues.

***Response:** The Department agrees that it is important that Medicaid FFS members continue to be effectively served and that federal requirements are met. Federal regulations (42 USC 1396a (a)(30)(A) and 42 CFR 447.204) require state Medicaid programs “... assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area;...” The Department will continue to monitor pharmacy access through the use of geo-access reports,*

*which measure Medicaid fee-for-service access against Medicare Part D standards. [13] Current pharmacy reimbursement methodologies which are not transparent and based on manufacturer reported pricing do not ensure that Medicaid pays based on an efficient cost, as is supported by public resources.*

### **General**

**Comment 43:** We are very concerned about the methodology/data analysis used to develop NYAAC and COD.

**Response:** *The Department has received a number of comments expressing concern about the methodology and data analytics used. While specifics were not provided to which we could respond, we have outlined below our methodology for developing COD and NYAAC.*

*As discussed at the December 3, 2013 focus group meeting, the methodology used to develop COD and NYAAC is as follows:*

#### **COD:**

- Ernst & Young plotted de-identified, validated data on a frequency distribution graph (histogram) to determine the data distribution. This analysis identified New York data to be skewed and demonstrated the median to be the best representation of the central location of the data. The median COD was identified as \$8.01.*
- Ernst & Young then conducted null hypothesis testing to determine if sub-populations (i.e., region, chain/independent, population density, prescription type, etc.) were significantly different from the \$8.01 median COD.*
- Ernst & Young summarized their findings; identifying five sub-populations (urban, Capital District and Western NY/Rochester, pharmacies that fill 100 % standard prescriptions, pharmacies that fill standard and LTC prescriptions, and pharmacies that fill any clotting factor, limited distribution or infusion drugs) and that were significantly different statistically, either higher or lower, than the \$8.01 median COD.*
- The Department then conducted additional testing to determine if those survey attributes identified as being significantly different statistically from the \$8.01 median COD were being influenced by other attributes (i.e., was statistical difference the result of region or the fact that the region had a high number of chains or independent pharmacies.).*
- The Department performed Generalized Linear Modeling (multiple regression modeling) to determine the relationship between COD and pharmacy attributes. Based on the modeling done, Annual Number of Prescriptions was identified as being the attribute that had the most significant and consistent impact on COD. This is in line with the findings of other states that have developed an AAC/COD reimbursement methodology.*
- The Department also conducted an analysis to determine whether a single dispensing fee or tiered dispensing fee would provide more equitable compensation, as well as the potential levels for a tiered dispensing fee. Once this analysis was completed, the Department established the proposed tiered dispensing fees.*

**NYAAC:**

- *First Data Bank, Inc. (FDB) performs several steps to ensure the reasonableness of de-identified data: a baseline average drug price is calculated; catastrophic data errors (i.e., cost missing) are identified and removed; line items with incorrect NDCs are identified and removed; line items are reviewed for common mistakes and removed ; Item price less than 1/2 or greater than 2x NADAC are removed;*
- *FDB then conducts a Median Absolute Deviation analysis to identify and eliminate the influence of statistical outliers (both high and low).*
- *The average unit cost for a brand drug or generic product (same ingredients, form, strength and route of administration), is the sum of all costs (adjusted by pharmacy discount data) divided by the sum of all billing units. Calculation of an average requires that the survey period encompass at least three reported purchases from two different pharmacies, or at least five purchases from the same pharmacy.*

*The methodologies used to develop NYAAC and COD are sound and follow generally accepted statistical methods for data analysis.*

**Comment 44:** Other states have pursued invoice-based pricing reimbursement and have product reimbursement rates and dispensing fees that are significantly higher than what New York is proposing, despite the fact that New York is one of the most expensive states in which to do business.

**Response:** *The Department recognizes that there are a number of reports that identify New York as one of the most expensive states in which to do business. NYAAC is developed as an average of the actual costs of drugs as reported by New York State Medicaid enrolled pharmacies. Unlike other states, New York includes rebates, credits and discounts in development of NYAAC.*

*Similarly, the proposed dispensing fee is based on actual business costs as reported by pharmacy providers. Though New York does not collect every expense collected by other states, in general New York is consistent in expenses used to calculate COD.*

**Comment 45:** Given the diminishing number of individuals enrolled in Medicaid fee-for-service program as members are moved into managed care, please provide a rationale as to why the Department is conducting this survey and pursuing an entirely new reimbursement methodology.

**Response:** *The overall goal of the NYAAC/COD survey is to create a reimbursement benchmark that is valid, transparent, timely and sustainable. New York and other states began looking at other pharmacy reimbursement methodologies in response to a legal settlement that resulted in First Data Bank no longer publishing Average Wholesale Price (AWP). After reviewing other benchmarks, such as Wholesale Acquisition Cost (WAC) and Average Sale Price (ASP), the Department determined that AAC is the one pricing mechanism that does not have the same potential for manipulation that led to the unreliability of AWP.*

*Additionally, while it is true that the majority of New York Medicaid's drug spend is now included in the managed care benefit, there remains a number of covered lives in the fee-for-service program. It is critical to the sustainability of New York's Medicaid program that the Department continues to implement efficiencies, such as transparent pharmacy reimbursement, in the remaining fee-for-service program. Additionally, an acquisition cost based methodology may also be used by Medicaid managed care plans to benchmark against the reimbursement rates they are achieving.*

**Comment 46:** We request that you delay submission of State Plan Amendment (SPA) until the associations have met with the Commissioner and the Medicaid Director to discuss concerns related to this initiative.

***Response:** We intend to submit the SPA in January 2014. If discussions with the Commissioner and/or Medicaid Director result in the need to make changes to the SPA, we will initiate such changes.*

**Comment 47:** Please provide information as to the costs the State has incurred over the two years of this process.

***Response:** To date, the State has conducted all activity related to this initiative internally and by partnering with First Data Bank, Inc. the current Medicaid pharmacy pricing vendor. Costs for State staff involved in this project are accounted for as usual staffing costs in the Department's personal services budget. To date, we have not paid FDB any additional costs for this project. Ernst & Young has participated in the project as a contractor to FDB, with costs borne by FDB.*

**Comment 48:** We have concerns about NYS releasing AAC as other payors will view this as adequate payment and would result in reduction of payments through the managed care plans.

***Response:** New York draft NYAACs can be found on the Department's web site. Stakeholders will have an additional opportunity to comment on NYAAC during the regulatory process.*

**Question 49:** Can a pharmacy participate in Managed Care plans and not the Medicaid FFS program?

***Answer:** Yes; however, pharmacies must be enrolled in a specific managed care plan's network in order to bill services to that plan.*

**Question 50:** Can a company with multiple pharmacies opt to have some pharmacies participate in FFS and not others?

***Answer:** Yes. This initiative does not change the Medicaid provider enrollment policies.*

**Question 51:** What is the fiscal savings amount to the state that is being placed on the proposed AAC/COD changes?

***Answer:** Estimated gross annualized savings for the Medicaid fee-for-service program are \$21.4M.*

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Guiding Principles	Included In Cost of Dispensing?
Expense is directly related to the dispensing of the individual prescription	Yes
Expense considered a business decision (cost of doing business)	No
Expense was incurred to provide a competitive advantage	No
Expense can be reimbursed, written off or recovered elsewhere	No
Expense is contrary to Medicaid policy, regulation, statute or reimbursement methodology for other Medicaid services	No

Expenses Included
Annual depreciation on pharmacy dispensing area related equipment
Annual depreciation on facility
Claim transmission fees
Cleaning services
Delivery expenses
DME accreditation fees
Electricity
Electronic security monitoring system
Employee compensation and benefits
Facility rent
Facility repair and maintenance
Heating fuel
Internet
Legal, accounting and other professional fees
Mandated Reporting and Tracking (CSR and Ephedrine Reporting)
Medical waste
Pharmacy computer, software, and clinical reference material expenses
Pharmacy equipment expenses
Pharmacy liability insurance
Pharmacy license fee
Pharmacy supply expenses
Property insurance
Property tax
Security personnel
Sewage
Telephone
Translation fees
Waste removal
Water

Expenses Not Included
Account receivable expense*
Advertising/marketing
Anti-prompt payment discount (LATE FEE)
Bad debts/Uncollected co-pays and write-offs
Charitable contributions
Corporate overhead expenses
Cost to carry inventory
Franchise fee
Inflation
Minimum purchase charges
Profit
Returns
Shrinkage/spoilage/ stolen goods/expired goods
Travel expenses
Warehouse expense
Wholesaler surcharges (included in AAC survey)

\*expenses incurred to collect unpaid co-pays, should be included in "legal, accounting and other professional fees"

**NYAAC REBATE AND DISCOUNT CALCULATIONS**

**Illustrative Example of New York State AAC Calculation including rebates and discounts  
2/5/2014**

The table below is an illustrative example of three hypothetical pharmacies. The annual reported amount of rebates and discounts is converted to a % discount rate which is then applied to each NDC for which the pharmacy has submitted an acquisition cost.

Pharmacy NPI	Reported annual invoice total	Reported annual rebates and discounts	Discount rate	Discount applied to each NDC reported by this NPI	Pharmacy Discount Factor (1-(Discount Rate))
123456789a	\$100,000	0	0%	0%	1.0000
123456789b	\$100,000	\$500	.005%	.005%	0.9995
123456789c	\$5,000,000	\$800,000	16%	16%	0.8400

**Example #1 - NY Methodology for calculating AAC (Weighted)**

In this example there are three reporting pharmacies, one that purchased 10 sixty-pill bottles, a second that purchase 20 sixty-pill bottles and a third that purchased only one. The first two paid a higher price before the discount percentage was applied, and the gap was even bigger after the percentage was applied since only two pharmacies reported rebates and/or discounts. Therefore, weighting the discounted cost results in a more equitable AAC.

Pharmacy NPI	NDC	Quantity Purchased (Bottles of 60)	Reported Invoice Cost	Cost per bottle	Unit Cost (per pill)	Pharmacy Discount Factor	Discounted Cost (Reported Invoice cost x Pharmacy Discount Factor)	Units Purchased	AAC (Discounted Cost/Total Units Purchased)
123456789a	12345-1234-0x	10	\$21.10	2.11	0.03516	1.0000	\$21.10	600	0.03517
123456789b	12345-1234-0x	20	\$42.00	2.10	0.03500	0.9995	\$42.00	1200	0.03500
123456789c	12345-1234-0x	1	\$2.05	2.05	0.03416	0.8400	\$1.72	60	0.02866
<b>Total/Average</b>							<b>\$64.82</b>	<b>1860</b>	<b>0.03485</b>

**NYAAC REBATE AND DISCOUNT CALCULATIONS**

**Example #2 - Same Methodology as above (Not weighted)**

Pharmacy NPI	NDC	Quantity Purchased (Bottles of 60)	Reported Invoice Cost	Cost per bottle	Unit Cost (per pill)	Pharmacy Discount Factor	Discounted Cost (Cost per bottle x Pharmacy Discount Factor)	Units per bottle	AAC (Discounted Cost/Total Units Purchased)
123456789a	12345-1234-0x	10	\$21.10	2.11	0.03516	1.0000	2.11	60	0.03517
123456789b	12345-1234-0x	20	\$42.00	2.10	0.03500	0.9995	2.10	60	0.03500
123456789c	12345-1234-0x	1	\$2.05	2.05	0.03416	0.8400	1.72	60	0.02867
<b>Total/Average</b>								<b>60</b>	<b>0.03294</b>

NY State chose to go with the methodology used in Example #1, using the total costs (not per bottle costs), in order to weight the AAC values equitably. In these examples, you can see that without weighting, high discounted quantities will drive AAC downward.

NYS Average Acquisition Cost (NYAAC) pricing for Top 100 Brands

NDC	Drug Name	Brand Generic	GCN	Unit UOM	NYAAC	NYAAC Pre Discount	NADAC	WAC	NYAAC Compared to WAC	NYAAC Pre Discount Compared to WAC
61958070101	TRUVADA 200 MG-300 MG TABLET	B	23152	EA	38.89559	39.28306	39.59795	40.777	-4.61%	-3.66%
15584010101	ATRIPLA TABLET	B	27346	EA	59.52132	61.39373	61.42563	62.60766	-4.93%	-1.94%
00006022701	ISENTRESS 400 MG TABLET	B	98986	EA	17.08963	17.50536	17.25966	17.90133	-4.53%	-2.21%
59148000713	ABILIFY 5 MG TABLET	B	20173	EA	21.13883	22.04455	21.99765	22.30733	-5.24%	-1.18%
59148000813	ABILIFY 10 MG TABLET	B	18537	EA	21.10551	21.99377	21.85124	22.30733	-5.39%	-1.41%
0000362212	REVYFAZ 300 MG CAPSULE	B	97430	EA	34.80762	35.08342	35.45996	36.28333	-4.07%	-3.31%
00088221905	LANTUS SOLOSTAR 100 UNITS/ML	B	98637	ML	17.53715	17.98613	17.91217	18.38066	-4.59%	-2.15%
59148001013	ABILIFY 20 MG TABLET	B	18539	EA	29.91312	31.10998	30.70133	31.54533	-5.17%	-1.38%
59148000913	ABILIFY 15 MG TABLET	B	18538	EA	21.05338	21.96487	21.78712	22.30733	-5.61%	-1.54%
00173069600	ADVAIR 250-50 DISKUS	B	50594	EA	4.221079	4.402209	4.37987	4.46116	-5.38%	-1.32%
59148001113	ABILIFY 30 MG TABLET	B	18541	EA	29.81526	31.02023	30.74888	31.54533	-5.48%	-1.66%
59148000613	ABILIFY 2 MG TABLET	B	26305	EA	21.19421	22.02896	21.84043	22.30733	-4.99%	-1.25%
51167010001	INGIVIK 375 MG TABLET	B	29964	EA			127.70291	131.2601		
59676056630	PREZISTA 800 MG TABLET	B	33723	EA	34.54618	35.01353	35.01357	36.35933	-4.99%	-3.70%
00597007541	SPRIVA 18 MCG CP-HANDHALER	B	17853	EA	8.613824	9.004986	9.07528	9.365	-8.02%	-3.84%
00186504031	NEXIUM DR 40 MG CAPSULE	B	12868	EA	7.06237	7.335352	7.30957	7.44466	-5.14%	-1.47%
00074533330	NORVIR 100 MG TABLET	B	28224	EA	8.17966	8.260706	8.29707	8.57233	-4.65%	-3.64%
68546031730	COPAXONE 20 MG INJECTION RT	B	16431	EA	4.30815	4.449413	4.47698043	4.60449	-6.44%	-3.37%
49702020613	EPZICOM TABLET	B	23167	EA	32.85052	33.16046	33.30994	34.428	-4.58%	-3.68%
00088222033	LANTUS 100 UNITS/ML VIAL	B	13072	ML	15.76789	16.40918	16.23588	16.642	-5.25%	-1.40%
50458025115	ORTHO TRI-CYCLEN LO TABLET	B	18126	EA	3.61399	3.691281	3.64303	3.75144	-3.81%	-1.75%
12496120803	SUBOXONE 8 MG-2 MG FILM	B	28959	EA	6.759568	6.908813	6.83545	7.03833	-3.96%	-1.87%
61958110101	COMPLERA TABLET	B	30288	EA	61.56683	63.26245	62.33112	64.551	-4.62%	-2.00%
59676056201	PREZISTA 600 MG TABLET	B	99434	EA	17.22997	17.8007	17.69892	18.17966	-5.22%	-2.08%
50242010040	PUIMOZYME 1 MG/ML AMPUL	B	27200	ML	29.7398	31.10085	30.98573	31.59373	-5.87%	-1.56%
00006027731	JANUVIA 100 MG TABLET	B	97400	EA	8.160451	8.460379	8.44826	8.609	-5.21%	-1.73%
00310028440	SEROQUEL XR 400 MG TABLET	B	98524	EA	18.38495	19.13372	19.05805	19.492	-5.68%	-1.84%
00002327030	CYMBALTA 60 MG CAPSULE	B	23164	EA	6.867613	7.196667	7.12655	7.27	-5.53%	-1.01%
00078049471	TOBI 300MG/5 ML SOLUTION	B	61551	ML			22.96608	23.84575		
00169633910	NOVOLOG FLEXPEN SYRINGE	B	92336	ML	18.77633	19.30026	19.3169	21.65333	-13.29%	-10.87%
61958040101	VIREAD 300 MG TABLET	B	14822	EA	26.5808	26.70969	27.14936	27.74433	-4.19%	-3.73%
00074679922	KALETRA 200-500 MG TABLET	B	25919	EA	6.136538	6.27733	6.23369	6.40816	-4.24%	-2.04%
00173069700	ADVAIR 500-50 DISKUS	B	50604	EA	5.554557	5.786728	5.75102	5.86766	-5.34%	-1.38%
00052027303	NUVARING VAGINAL RING	B	17528	EA	83.4822	86.74181	85.92889	87.32666	-4.40%	-0.67%
00075150616	NASACORT AQ NASAL SPRAY	B	1214	GM	6.517367	6.785378	6.63423	6.88424	-5.33%	-1.44%
59310057922	PROAIR HFA 90 MCG INHALER	B	22913	GM	4.834795	5.070114	5.07294	5.23764	-7.69%	-3.20%
58468013001	RENVELA 800 MG TABLET	B	99200	EA	2.757516	2.860806	2.860806	3.10617	-13.74%	-10.51%
59627000205	AVONEX PREFILLED SVR 30 MCG	B	20147	EA	3903.432	4150.769	4420.95516	4545	-14.12%	-8.67%
00310028360	SEROQUEL XR 300 MG TABLET	B	98523	EA	15.63476	16.35779	16.25928	16.58533	-5.73%	-1.37%
61958120101	STRIBILD TABLET	B	33130	EA	75.18447	76.64566	75.4772	78.08233	-3.71%	-1.84%
00004110130	XELODA 500 MG TABLET	B	31612	EA	31.74424	32.69273	32.13427	33.23025	-4.47%	-1.62%
00173066518	MEPRON 750 MG/5 ML SUSPENSION	B	34490	ML	5.302989	5.434249	5.34505	5.53042	-4.11%	-1.74%
00074433902	HUMIRA 40 MCG/0.8 ML PEN	B	97005	EA	1108.809	1153.359	1148.02411	1170.54	-5.27%	-1.47%
65649030302	XIFAXAN 500 MG TABLET	B	28530	EA	20.58078	21.25471	21.37239	22.0245	-6.56%	-3.50%
0002324030	CYMBALTA 30 MG CAPSULE	B	23162	EA	6.876012	7.19807	7.05591	7.27	-5.42%	-0.99%
50458019215	ORTHO EVRA PATCH	B	15524	EA	32.20578	32.87741	32.34861	33.43	-3.66%	-1.65%
00186037020	SYMBICORT 160-4.5 MCG INHALER	B	98500	GM	22.19433	22.81975	22.6493	23.09117	-5.62%	-1.18%
59676057101	INTELENCE 200 MG TABLET	B	29424	EA	13.85421	14.15684	14.01213	14.462	-4.20%	-2.11%
00169750111	NOVOLOG 100 UNIT/ML VIAL	B	92326	ML	14.49513	15.12641	15.04175	16.815	-13.80%	-10.04%
0004036540	PEGASYS PROLICID 180 MCG/0.5	B	30738	ML			1500.2473	1542.54		
00944270006	GAMMAGARD LIQUID 10% VIAL	B	43709	ML				12.131		
44087004403	REBIF 44 MCG/0.5 ML SYRINGE	B	15918	ML	72.24879	74.0244	73.54827	75.3333	-4.09%	-1.74%
0002879959	HUMALOG 100 UNITS/ML KWIKPEN	B	96719	ML	18.80898	19.34925	19.10221	19.69	-4.47%	-1.73%
49702020218	COMBIVIR TABLET	B	89621	EA	14.27669	14.77941	14.65238	15.02366	-4.97%	-1.63%
62856058352	BANZEL 400 MG TABLET	B	98837	EA	9.57252	10.01647	9.87167	10.26733	-6.77%	-2.44%
00078043815	GLEEVEC 400 MG TABLET	B	19907	EA	219.2985	227.4572	226.49966	232.3553	-5.62%	-2.11%
00032122401	CREON DR 24,000 UNITS CAPSULE	B	26178	EA	3.590536	3.69521	3.67236	3.8042	-5.62%	-2.86%
50419052335	BETASERON 0.3 MG KIT	B	98376	EA	288.2231	303.4498	297.825	307.8264	-6.37%	-1.42%
58468002101	RENELAN 800 MG TABLET	B	16853	EA	3.452133	3.66585	3.86457	3.99594	-13.61%	-10.76%
59148001315	ABILIFY 1 MCG/ML SOLUTION	B	24062	ML	4.617393	4.841836	4.73227	4.9096	-5.95%	-1.38%
00064510130	SANTYL OINTMENT	B	21190	GM	5.602081	5.796677	5.72024	5.89733	-5.01%	-1.71%

Notes

1. NYAAC price for rolling 3-month period Aug, Sept, Oct 2013 at NDC-9 level
2. NADAC price effective 11/27/13. Source CMS: <http://medical.cms.gov/medicaid-clair-program-information/ny-facilities/brands/prescription-drugs/survey-of-retail-prices.html>
3. WAC pricing data source: First Data Bank 12/5/13
4. Shaded cells represent fields where there is no available or reliable data

NDC	Drug Name	Brand Generic	GCN	Unit UOM	NVAAC	NVAAC Pre Discount	NADAC	WAC	NVAAC Compared to WAC	NVAAC Pre Discount Compared to WAC
55533092410	NEUPOGEN 300 MCG/0.5 ML SYR	B	13309	ML	587.0046	610.0286	604.74162	620.3	-5.37%	-1.66%
00169643910	LEVEMIR FLEXPEN 100 UNITS/ML	B	22836	ML	16.8071	17.40142	18.38066	18.38066	-8.02%	-5.33%
00186198904	PULMICORT 0.5 MCG/2 ML RESPULE	B	17958	ML	4.866134	5.03199	5.03226	5.12866	-5.12%	-1.88%
00173068220	VENTOLIN HFA 90 MCG INHALER	B	22913	GM	2.096507	2.185712	2.15229	2.21555	-5.37%	-1.35%
00173093308	VALTREX 500 MG CAPLET	B	13740	EA	6.402284	6.602384	6.45927	6.69633	-4.39%	-1.40%
50458058601	CONCERTA ER 36 MG TABLET	B	12568	EA	6.931592	7.262328	7.23445	7.315	-5.24%	-0.72%
00006011231	JANUVIA 50 MG TABLET	B	97399	EA	8.166551	8.448604	8.42935	8.609	-5.14%	-1.86%
00173071920	FLOVENT HFA 110 MCG INHALER	B	53636	GM	12.8658	13.33802	13.90149	14.16416	-9.17%	-5.90%
59676034001	PROCRIT 400,000 UNITS/ML VIAL	B	25115	ML	739.6105	745.7121	789.86109	811.2	-8.83%	-8.07%
00456321060	NAMENDA 10 MG TABLET	B	3253	EA	4.191103	4.355864	4.30207	4.42416	-5.27%	-1.54%
00006057161	JANUMET 50-1,000 MG TABLET	B	98307	EA	4.082914	4.22234	4.22572	4.3045	-5.15%	-1.90%
00750622840	LOVENOX 80 MG PREFILLED SYRN	B	62772	ML	78.50874	81.14136	80.83188	82.78875	-5.17%	-1.99%
0002751001	HUMALOG 100 UNITS/ML VIAL	B	5679	ML	14.44502	15.13113	14.99265	15.29	-5.53%	-1.04%
0005022225	PATADAY 0.2% EYE DROPS	B	97848	ML	47.165117	49.18587	48.55711	50.08	-4.85%	-1.79%
9011048010	OXLYNTIN 80 MG TABLET	B	16286	EA	12.94181	13.39854	13.31374	13.6121	-4.92%	-1.57%
0074612390	TRICOR 145 MG TABLET	B	97003	EA	5.412131	5.770471	5.66389	5.82955	-7.16%	-1.01%
00173056504	VALTREX 1 GM CAPLET	B	13742	EA	11.21109	11.51173	11.2925	11.71866	-4.33%	-1.77%
50458055101	INVEGA ER 6 MG TABLET	B	97770	EA	19.10162	19.81675	21.57641	22.12766	-13.68%	-10.44%
55513007430	SENSIPAR 60 MG INHALER	B	21498	EA	29.31576	30.57967	30.10907	31.06	-5.62%	-1.55%
0085113201	PROVENTIL HFA 90 MCG INHALER	B	22913	GM	7.444433	7.704762	7.5624	7.78805	-4.40%	-1.07%
00430053014	LOESTRIN 24 FE TABLET	B	26629	EA	2.739768	2.882839	2.85678	2.96414	-7.57%	-2.74%
00078035752	TRILEPTAL 300 MG/5 ML SUSP	B	21723	ML	0.8006296	0.8663448	0.85871	0.881	-4.58%	-1.66%
00186199004	PULMICORT 1 MCG/2 ML RESPULE	B	62980	ML	9.752334	10.13272	9.86278	10.258	-4.93%	-1.22%
49702021118	ZIAGEN 300 MG TABLET	B	94668	EA	8.907608	9.134921	9.05913	9.31066	-4.33%	-1.89%
00056051030	SUSTIVA 600 MG TABLET	B	15555	EA	20.75618	21.41859	21.18666	21.83066	-4.92%	-1.89%
0004003822	VALCYTE 450 MG TABLET	B	13088	EA	56.93854	57.4177	57.64541	59.08166	-3.64%	-2.82%
00075062040	LOVENOX 40 MG PREFILLED SYRN	B	70022	ML	70.5215	72.3071	80.68722	82.69	-14.71%	-12.56%
58406043504	ENBREL 50 MG/ML SYRINGE	B	23574	ML	57.49421	59.42596	58.979008	60.2183	-4.64%	-1.44%
49702020718	LEXIVA 700 MG TABLET	B	20553	EA	13.84584	14.1811	13.92805	14.50283	-4.53%	-2.22%
54092038701	ADDERALL XR 20 MG CAPSULE	B	14636	EA	6.813448	7.040716	6.95607	7.1229	-4.34%	-1.15%
00075062300	LOVENOX 100 MG PREFILLED SYR	B	62773	ML	79.49801	81.97067	81.2911	82.787	-3.97%	-0.99%
58406044504	ENBREL 50 MG/ML SURCLICK SYR	B	97724	ML	58.4121	59.83453	59.83453	60.2183	-3.12%	-1.64%
49702021718	TRIZIVIR TABLET	B	87691	EA	25.68525	26.38755	25.876	26.82833	-4.26%	-1.64%
00310028260	SEROQUEL XR 200 MG TABLET	B	98522	EA	11.99523	12.47672	12.39678	12.64966	-5.17%	-1.37%
64764054411	PREVACID 30 MG SOLUTAB	B	18993	EA	7.334615	7.578156	8.16395	8.3792	-12.47%	-9.56%
59572041028	REVUMID 10 MG CAPSULE	B	26315	EA				419.48		
00169369619	NOVOLOG MIX 70-30 FLEXPEN SYRN	B	17075	ML	18.81858	19.04103	19.43686	21.65333	-13.09%	-12.06%
00187098935	ZOVIRAX 5% OINTMENT	B	31640	GM	23.3627	24.21936	23.76224	24.64433	-4.39%	-1.72%
55513007330	SENSIPAR 30 MG TABLET	B	21497	EA	14.60889	15.30632	15.32886	15.53	-5.93%	-1.44%
55513020910	NEUPOGEN 480 MCG/0.8 ML SYR	B	13308	ML	596.3279	609.7879	617.375	594.87646	0.24%	2.51%
00049399040	GEDOON 80 MG CAPSULE	B	13334	EA	11.18905	11.62164	11.9665	11.71374	-4.48%	-0.79%
00131247835	VIMPAT 100 MG TABLET	B	14339	EA	8.419621	8.637283	8.77683	8.57533	-1.82%	0.72%
00173069500	ADVAIR 100-50 DISKUS	B	50584	EA	3.390553	3.549412	3.5905	3.5216	-3.72%	0.79%
00173078302	LOVAZA 1 GM CAPSULE	B	23929	EA	1.388796	1.638072	1.7565	1.70515	-6.82%	-3.93%
64764054311	PREVACID 15 MG SOLUTAB	B	18992	EA	7.403386	7.58754	8.3792	8.19067	-9.54%	-7.36%
00025152531	CELEBRX 200 MG CAPSULE	B	42002	EA	5.43623	5.654432	5.727	5.61923	-3.27%	0.63%
50458058701	CONCERTA ER 54 MG TABLET	B	12248	EA	7.501369	7.873527	7.9595	7.75205	-3.23%	1.57%
00003631112	REVIAZ 200 MG CAPSULE	B	19953	EA	17.37089	17.9804	18.31466	17.67866	-1.74%	1.71%
49502050002	EPIPEN 2-PAK 0.3 MG AUTO-INJECT	B	19862	EA	125.2443	130.9823	151.955	145.72611	-13.72%	-10.12%
TOTAL/AVERAGE*					15513.46702	16117.14721		16853.34809	-7.95%	-4.37%

\*NVAAC is 7.95% less than WAC for drugs on this list that have both an AAC and WAC.