NYS MEDICAID FEE-FOR SERVICE PHARMACY

AVERAGE ACQUISITION COST (AAC)

&

COST OF DISPENSING (COD)

Purpose of Meeting

To provide focus group members, representatives of NYS pharmacy associations and the Pharmacy Advisory Committee (PAC) with information on the methodologies used to develop AAC and COD.

PROJECT PARTNERS

- **First Data Bank**:
  1. Current State pharmacy pricing vendor;
  2. Analyzed de-identified pricing data;
  3. Assisted in development of survey tools; and
  4. Assisted in development of AAC.

- **Ernst & Young**:
  1. Assisted in identifying pertinent business expenses;
  2. Analyzed de-identified business expense data; and
  3. Assisted in development of dispensing fee.

- **NYS DoH Division of Program Development and Management**
  1. Oversight of survey process;
  2. Provider technical assistance;
  3. All project policy decisions; and
  4. Data management.

- **NYS DoH Bureau of Health Informatics/ Health Care Analytics:**
  1. Developed linear regression models; and
  2. Identified predictors of COD.

COST OF DISPENSING

COD

Development of Dispensing Fee

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

COD Survey Overview

- **Information solicited from all FFS enrolled pharmacies with Medicaid claims in 2011.**
  - Chains submitted a representative sample (1444 of 2195)
  - Independents each required to submit (1392 of 2440)*
  - Evaluated sample size of 2,693 represents a confidence level of 95% with a 1.15% margin of error; exceeding the goal of 95% with a 5% margin of error.
- **Initial validation done by DoH staff to identify and correct data issues prior to submission to E&Y.**
  - Data validation is a basic check of data to ensure it has been submitted in the correct format and in the correct field, that required fields are populated, etc.
- **All data de-identified by DoH pharmacy staff and sent to Ernst & Young for verification and analysis.**
  - Verification is a check of the data accuracy and requires that more detailed analysis is done on submitted data.
  - E&Y identified specific data points for verification from a variety of outliers reports and through random selection.
  - DoH staff conducted verification.
  - Data that could be verified by DoH was corrected, retained and analyzed.
  - Data that could not be verified was removed from data set and analysis.
  - Corrected data was again de-identified and returned to E&Y.

* Note- Total figure of 2440 enrolled pharmacies includes those with no Medicaid billing in the survey year and those that did not have a full year of information. Additionally, DoH approved several exemptions (issues obtaining HCS accounts, technical difficulties, etc). Overall compliance rate for Independent pharmacies was considered to be excellent. Submitted surveys (1444 for chains and 1392 for independents), excludes 34 surveys that were incomplete or unverified by pharmacies.

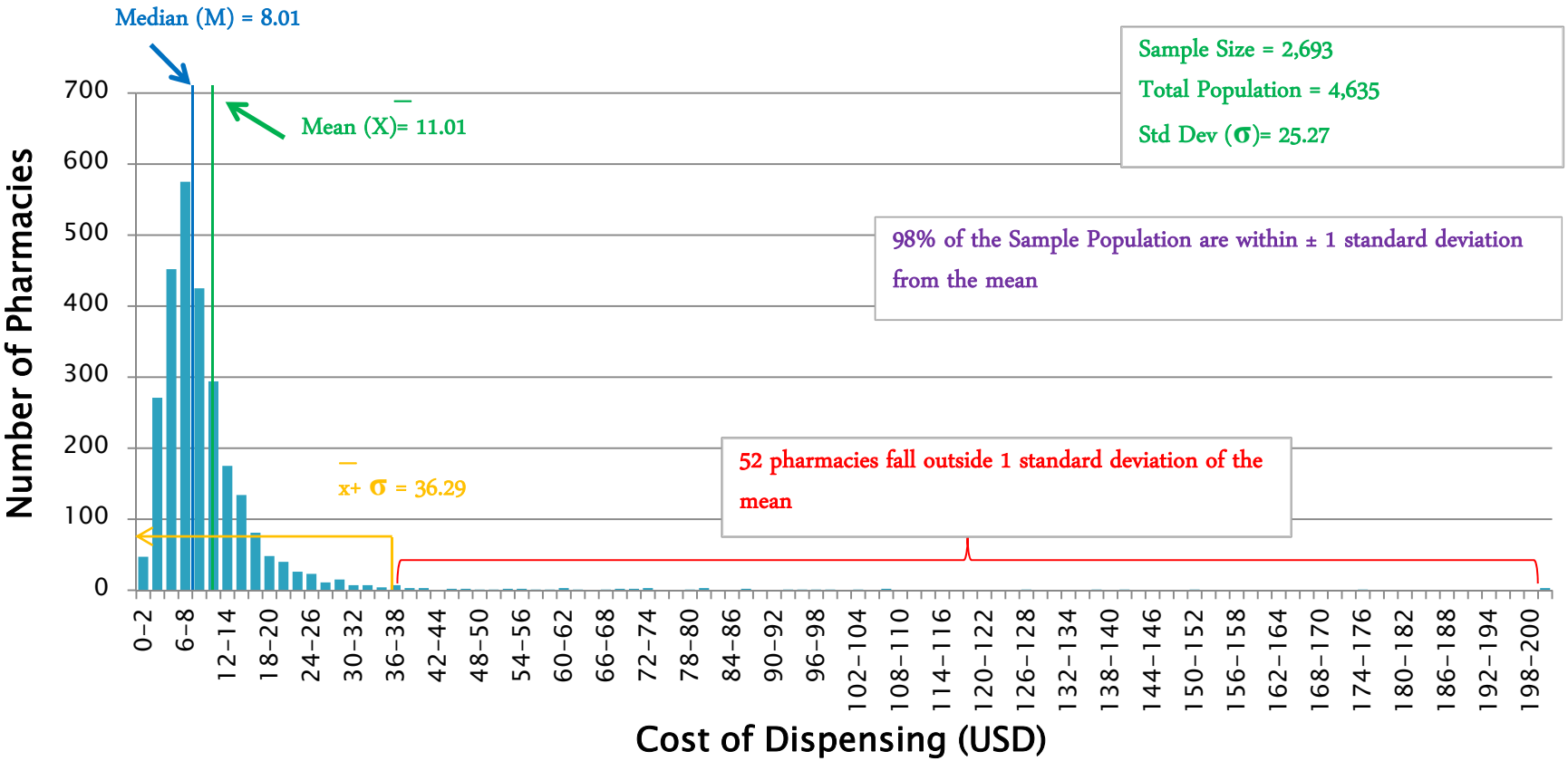
COD Data Validation & Cleansing Process

- DoH staff completed initial data validation to ensure survey business rules were met (i.e., all required fields were populated, fields that require a value greater than zero had appropriate values, etc.).
  - DoH staff contacted each individual pharmacy to validate any questionable data points.
  - Any pharmacy provider that did not respond to data validation requests, either implicitly (no response provided within the allowable period) or explicitly (by an unreserved statement of non-compliance), had all of their pharmacy's data points removed from the survey.
  - De-identified data sent to Ernst & Young.

COD Data Verification

- **E&Y calculated the mean, median and standard deviation from validated data:**
  - Participants that were greater than one standard deviation from the median COD were asked to verify accuracy of data. One standard deviation was selected to ensure an ample pool of pharmacies were reviewed. Additionally, pharmacies with individual variables that fell 3 standard deviations or more from the mean were identified and then reviewed by DoH staff.
- **E&Y identified additional COD data points for verification:**
  - Pharmacies with high COD
  - Pharmacies with low COD
  - A pool of randomly selected pharmacies.
- **DoH staff completed the data verification process:**
  - DoH analyzed the cost per prescription count for each variable for each pharmacy identified in the first 2 bullets on this slide.
  - When necessary, pharmacies were contacted and asked to provide supporting documentation. Data that could not be verified was removed.
- **Verified data was de-identified and returned to E&Y.**
  - E&Y plotted data on a frequency distribution graph (histogram) to see if data followed normal distribution and to identify additional outliers.
  - Hypothesis testing was then conducted on sub-populations (i.e., chain/independent, population density, region, prescription type, etc.) to determine if they were significantly different with 95% confidence interval.

Graphing the frequency distribution illustrates that the data is skewed and therefore the $8.01median is the best representative of the population



When data is skewed, the mean is being dragged in the direct of the skew. In these situations, the median is generally considered to be the best representative of the central location of the data. The more skewed the distribution, the greater the difference between the median and mean, and the greater emphasis should be placed on using the median as opposed to the mean. A classic example is income (salary), where higher-earners provide a false representation of the typical income if expressed as a mean and not a median.

Hypothesis testing was then used to determine if sub-populations were significantly different with 95% confidence Interval

The following steps were used to determine if there was a significant difference between sub-populations (i.e., region, chain/independent, population density, prescription type, etc.).

1. Outline the null hypothesis and the alternative Hypothesis in which the null hypothesis is that there is no difference between the sub-population and the total population (H_0: $\mu_{Test}=\mu_{Remaining}$) and the alternative hypothesis that the sub-population and the total population are different (H_1: $\mu_{Test}\neq\mu_{Remaining}$)
2. Determine the conditional probability (p -value) for the sub-population whereby when the p value is: Test the sub-population mean against the total population to determine the probability of observing the sub-population within the total population.

P Value	Observed Difference	Confidence Interval
p value ≤ .10	marginally significant	90% confidence interval
p value ≤ .05	significant	95% confidence interval
p value ≤ .01	highly significant	99% confidence interval

3. Test the sub-population mean against the total population to determine the probability of observing the sub-population within the total population.
4. Since we selected 95% confidence interval, if the probability is ≤.05 then we would reject the null hypothesis and accept the alternative hypothesis that the populations are significantly different.

Summary of Initial Findings

- Since the frequency distribution graph (slide 9) demonstrates that the data is skewed to the right, the median is the best representation of the central location of the data.
- The median COD is $8.01.
- There is no statistically significant difference between the COD for independent and chain pharmacies.
- Urban was found to be significantly different statistically from Rural and Urban Cluster with a median COD of $7.24.
- Capital District and Western NY Rochester were both found to be significantly different statistically than other regions with a median COD of $7.46 and $8.40, respectively.
- Pharmacies that fill 100% standard prescriptions were significantly different statistically from those that dispense at least 1% non-standard type prescriptions, with a median COD of $7.59.
- Pharmacies that filled standard and long-term care prescriptions were significantly different statistically with a median COD of $5.59.
- Pharmacies that fill any clotting factor, limited distribution, or infusion drugs are significantly different statistically from those that do not with median CODs at $13.51, $8.84, $9.06, respectively.

See Appendices (slides 27-30)

ADDITIONAL ANALYSIS

- DoH statisticians from the Bureau of Health Informatics and Health Care Analytics conducted further analysis on the cleansed data to determine if those survey attributes identified as having a significant statistical difference in E&Y's analysis were being impacted by other survey attributes. This allowed us to determine equitable compensation.

- Statistical analysis was conducted using least square multiple regression modeling on COD-standardized data set [N=2,693 plus 143 "outliers" – (see Table 1 in Response to Comments document)]
- Stepwise backwards elimination process was employed to identify most parsimonious (compact) model that quantifies the relationship between COD and pharmacy attributes that were deemed logical to be included in the model (location, independent vs. chain, Medicaid volume, dispensing area, total Rx volume, etc.).

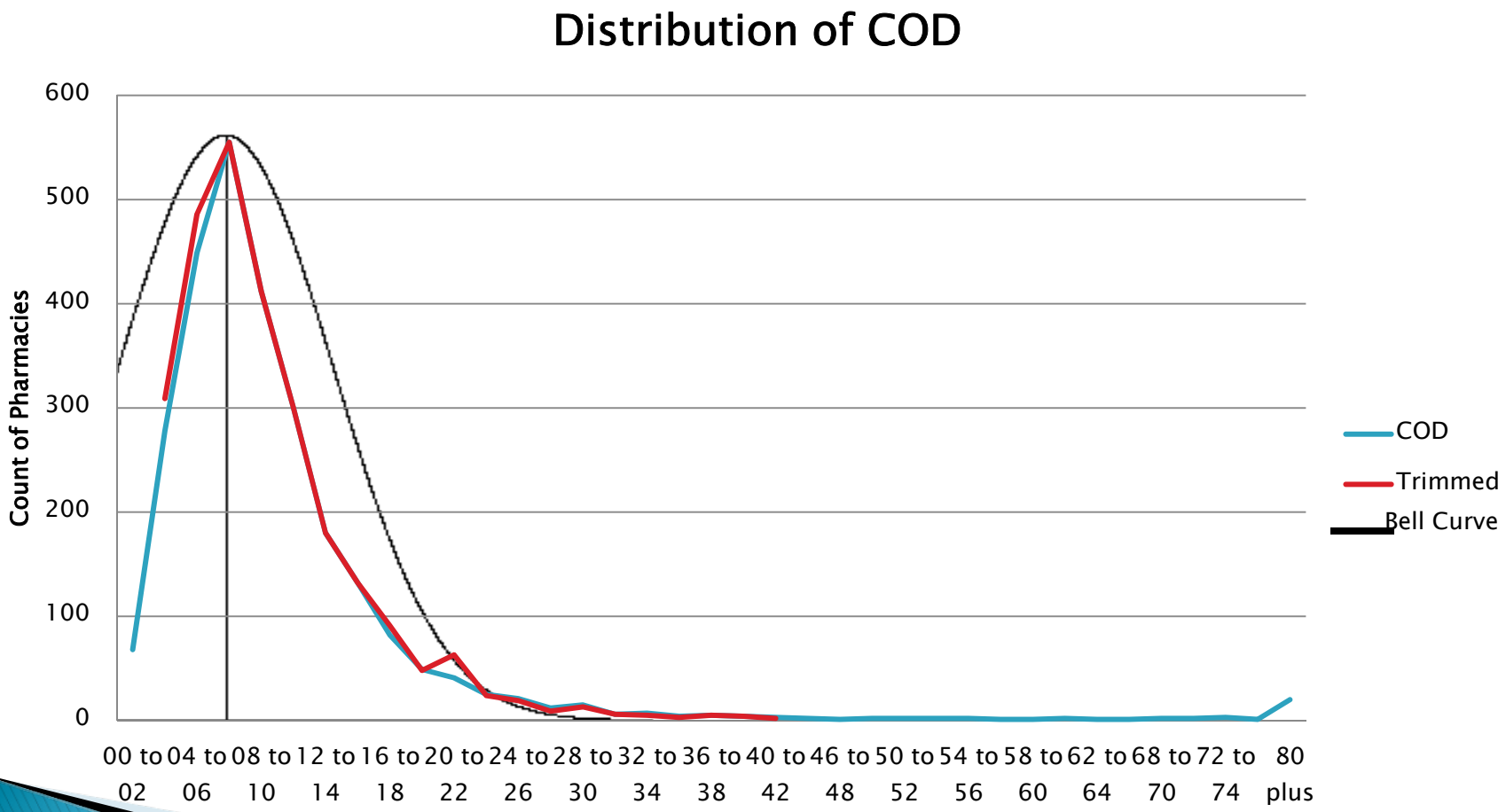
Methodology

- Development of Model:
  - Outliers were removed, per Any COD value more than 2 standard deviations away from the median COD identified by E&Y was to be excluded from the analysis.
  - CODs that reflected incomplete survey submissions (compensation, total number of prescriptions, etc.) were also removed.

- Model Outcome: COD
  - COD was standardized to control for very low and high costs.
  - Within each volume group
    - Lower trim point: 10th percentile (280 pharmacies)
    - Upper trim point: [(IQR)*2.0] + 75th percentile, where IQR=75th – 25th percentiles (56 pharmacies)

Methodology (Con't)

New Overall Mean: $9.71, much closer to median identified on slide #9.



Note: 143 outliers were removed, see slide #13 for explanation

Methodology (Con't)

- Model Predictors:
  - Model predictors (pharmacy attributes) were derived from the results of the pharmacy survey and were categorized taking into account that:
    - Categories are meaningful
    - Predictors are not "gameable"
    - Each category has adequate number of pharmacies

- Model Performance:
  - Controlled for R-squared
  - Final Model with Annual Number of Prescriptions had R-squared = 18.27 %.

Conclusions

- The analyses afforded DOH the ability to identify the attributes that had significant and consistent impact on COD.

- “Volume of Prescriptions” was the attribute that had the most impact in the predictive model. Additional testing was done to ensure that this attribute was independent of other categories as well.

Results

- The Department will institute a tiered dispensing fee based on a pharmacy's annual reported total prescription volume.*

Annual Prescription Volume	Dispensing Fee	% of Enrolled Pharmacies
0 -29,999	$14.11	24%
30,000- 79,999	$8.33	54%
80,000 and greater	$6.77	22%

Pharmacies that do not comply with annual COD survey requirements will receive a dispensing fee of $3.50, unless exempted by DOH prior to the end of the survey period.

* Subject to approval by CMS.

AVERAGE ACQUISITION COST

AAC

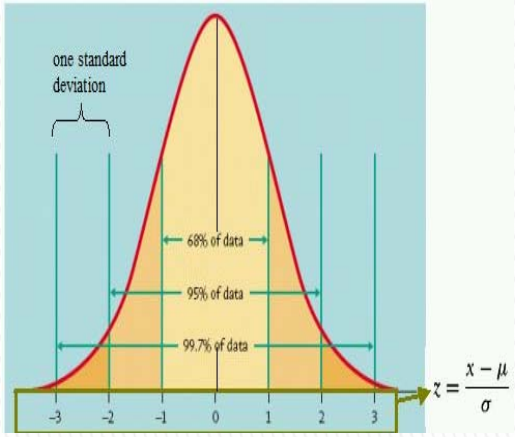
AAC

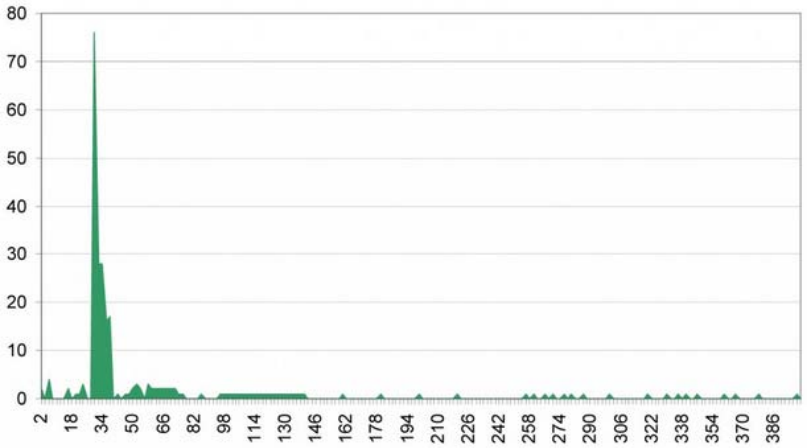
- Initial comprehensive survey in November 2012.
- Successive monthly surveys from January 2013 through present.
- Survey data de-identified and sent to FDB.
- Survey data cleansed and analyzed.

Data Validation & Cleansing Process

- Survey period outliers are identified using a table of pharmacies selected to participate in the current month. Outliers are removed from calculation.
- All submissions are checked for “catastrophic” errors.
- Data is scanned for common submission problems.
- Invalid or incorrect NDC information is removed from calculation.
- NADAC, AMP or ASP values will be used as a standard of reasonableness to identify extreme outliers
- Data is normalized by applying a Median Absolute Deviation analysis to the data, a method that variance from the median and is therefore less subject to influence by outliers.
- Invoice line items within +/-2.5 times the median absolute deviation from the median are used in calculating the final average AAC for an NDC; those above or below that range are ignored.

Elimination of Statistical Outliers





- **Normal Distribution**: Sampled values in a normal distribution follow the pattern in the graph at left, where 95.45% of the observations fall within +/- 2 standard deviations from the mean.
- **Standard Deviation** deviation measures the dispersion of values around the mean, providing an indication of the variability or diversity of the data.
- **Median Absolute Deviation** is considered a robust indicator of central tendencies and variability within an array because, unlike conventional mean-based assessments, the Median Absolute Deviation is not sensitive to outliers and "long-tail" distributions as in the chart at left.
- **Application of this standard**: prices within +/- 2.5 times the median absolute deviation from the median are used to calculate an average acquisition cost.

AAC Calculation Methodology

- Average unit cost for each formulation is calculated from cleansed data.
- Quantities are converted to NDC billing units.
- Costs are adjusted at the NPI level by the pharmacy's discount rate (defined as the sum of all reported discounts and rebates for the prior 12 months divided by the sum of total invoicing for the prior 12 months).
- Average Unit Costs are calculated using FDB clinical formulation class that groups like drugs based on active ingredients and strengths, routes of administration, and dosage forms (aka GCN Sequence Number).
- Brand and generic identification is made using current NYS method for determining that status.

Methodology for updating AAC

- AAC will be updated based on monthly surveys of a stratified and randomly selected sample of approximately 380 enrolled NPIs. Pricing will be posted monthly.
  - If no pricing data for a particular drug is reported in a monthly survey, AAC will be developed using an average of the previous 2 months.
  - If a 3-month survey period produces no cost data for a brand drug or for all generic equivalent forms of a drug, the last reported AAC will continue to be reported until DOH determines that an adjustment of that price is necessary.
  - There will be one AAC for all generic products within a GCN
  - Brand AAC will be calculated for each brand NDC-9.
  - If there is no established AAC, reimbursement will revert to the current "lower of" methodology with a dispensing fee of $3.50.
  - Other available pricing, including WAC, AMP and NADAC, will be monitored to evaluate the need for changes in AAC values.
  - An invoice-based appeal process will be implemented
  - Clotting factor will not be part of this initiative and will continue to be reimbursed as it currently is, with current dispensing fee.

Summary/Next Steps

- Draft AACs are posted at http://www.health.ny.gov/health_care/medicaid/program/pharmacy.htm
- Power Point and "Response to Comments" document will be posted on the Department's web site
- Obtain CMS approval
- Complete regulatory process
- Reimburse at AAC & new dispensing fee

QUESTIONS?

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APPENDICES

Population Density : Urban Area was found to statistically significantly different from Rural and Urban Cluster

Sub-Population: Population Density	No of records Represented	P-value	Significantly different?	Sub-Population Median COD	Difference between median COD of the sub-population(s) and total sample population ($8.01)
Rural	74	0.160	No	$11.09	$3.08
Urban Cluster	1721	0.103	No	$8.28	$0.27
Urban Area	898	0.045	Yes	$7.24	($0.77)

Region: Capital District and Western NY Rochester were both found to be statistically significantly different than other regions

Sub-Population: Region	No of records Represented	P-value	Significantly different?	Sub-Population Median COD	Difference between median COD of the sub-population(s) and total sample population ($8.01)
Capital District	196	0.008	Yes, Highly	$7.46	($0.55)
Central New York	225	0.485	No	$7.59	($0.42)
NY Metro Long Island	322	0.156	No	$8.92	$0.91
NY Metro New Rochelle	259	0.392	No	$8.64	$0.63
NY Metro New York City	1309	0.273	No	$7.75	($0.26)
Out of State	4	Do not have a large enough population to make any statistically valid conclusions			
Western NY Buffalo	220	0.238	No	$7.87	($0.14)
Western NY Rochester	158	0.034	Yes	$8.40	$0.39

Prescription type permutations: pharmacies that filled 100% standard prescriptions were significantly different statistically than those that dispense ≥1% non-standard prescriptions

Sub-Population: Prescription Type Permutations	No of records Represented	P-value	Significantly different?	Sub-Population Median COD	Difference between median COD of the sub-population(s) and total sample population ($8.01)
Standard Prescriptions	1634	0.0002	Yes, Highly	$7.59	($0.42)
Standard Prescriptions and Compounded	616	0.154	No	$8.63	$0.62
Standard Prescriptions and Clotting Factor	98	0.103	No	$16.60	$8.59
Standard Prescription, Long Term Care, Compounded	42	0.234	No	$6.83	($1.18)
Standard Prescription, Limited Distribution, Compounded	39	0.719	No	$8.18	$0.17
Standard Prescription, Long Term Care	34	0.006	Yes, Highly	$5.59	($2.42)
Standard Prescription, Clotting Factor, Compounded	30	0.078	No	$12.06	$4.05
All Other Permutations	≤19	Do not have a large enough population to make any statistically valid conclusions			

Standard Prescription: Any prescription that is not one of the specific types listed above

Number of pharmacies under common ownership: individual pharmacies were NOT significantly different statistically from chains

Sub-Population: No of Pharmacies under Common Ownership	No of independent and chains pharmacies represented	P-value	Significantly different?	Sub-Population Median COD	Difference between median COD of the sub-population(s) and total sample population ($8.01)
1	976	0.274	No	$6.79	($1.22)
2-10	7	0.099	No	$6.79	($1.22)
11-250	15	0.048	Yes	$9.63	$1.62
251-500	1	<0.0001	Yes, Highly	$12.01	$4.00
501+	7	<0.0001	Yes, Highly	$6.67	($1.34)

Other States Using AAC

Oregon: Reimbursement is AAC.

Dispensing Fee Tier
less than 30,000 claims per year =$14.01
between 30,000 and 49,999 claims per year= $10.14
greater than or equal to 50,000 claims per year= $9.68

Idaho: Reimbursement is AAC. If no AAC, reimbursement is WAC.

Dispensing Fee Tier
less than 40,000 claims per year =$15.11
between 40,000 to 69,999 claims per year= $12.35
greater than or equal to 70,000 claims per year= $11.51

Colorado: Reimbursement is the lower of U&C or "allowed ingredient cost" (defined as lesser of AAC or submitted ingredient cost) . If no AAC, Reimbursement is lesser of WAC or submitted ingredient cost.

Dispensing Fee Tier
less than 60,000 total prescriptions per year =$13.40
Between 60,000 and 90,000 total prescriptions per year = $11.49
Between 90,000 and 110,000 total prescriptions per year= $10.25
Greater than 110,000 total prescriptions per year = $9.31
Rural pharmacies get $14.14 dispensing fee

Iowa: Reimbursement is AAC. If no AAC, reimbursement is WAC.
Dispensing fee is $10.02

Louisiana: Reimbursement is AAC. If no AAC, reimbursement is WAC.
Dispensing fee is $10.13 (which includes State provider fee)

Alabama: Reimbursement is AAC. If no AAC, reimbursement is WAC plus 9.2%
Dispensing fee is $10.64 ($10.00 tablet splitting; $10.00 long-term maintenance)

Data source medicaid.gov for quarter ended 6/30/13