Dear Commissioner Shah and Deputy Commissioner Helgerson:

We are writing to you on behalf of the vast majority of pharmacies across New York State represented by the undersigned organizations to comment on the New York State Department of Health’s (NYS DOH) Medicaid Fee for Service (FFS) Actual Acquisition Cost (AAC) and Cost of Dispensing (COD) survey results released to pharmacy associations and AAC/COD focus group members on December 3, 2013.

Our member pharmacies and associations have reviewed the Department’s presentation on the methodology used and results developed by the NYS DOH and its consultants at First Data Bank and Ernst & Young for the proposed AACs (pharmacy invoice-based prices minus rebates/discounts received) and dispensing fees tiered by volume. Collectively, we have grave concerns as outlined below related to both the methodology/data analysis and the AACs and dispensing fees proposed by NYS DOH. Fundamentally, we believe they are flawed and lack credibility. We understand that the Department has an ambitious plan to submit the proposal as a State Plan Amendment to the federal Centers for Medicare and Medicaid Services (CMS) by the end of December and to begin the New York regulatory process for implementation. However, given our strong, shared concerns and the very significant impact that these changes will have on the state’s pharmacies and potentially have on those we serve, we would respectively request that our concerns be considered and that our organizations together be granted a meeting with you to
Pharmacy Concerns with Proposed New York AACs/Dispensing Fees

1. Concern with Application of Rebates to AAC Prices

   While several states have pursued an AAC pharmacy reimbursement methodology collecting invoice-based pricing data from pharmacies, New York is unique in asking for rebate and discount information in addition to invoice prices from pharmacies. As we have cautioned from the start, drug purchasing is complex and can involve rebates, discounts and other price concessions between certain parties and for certain drugs. At any given time rebates can lag behind the actual drug purchase and may be received by pharmacies months later. Further, rebates are not always known to an individual pharmacy at point of sale or at the time of a specific invoice.

   Rebates are often based on national sales for larger pharmacy companies so it is very difficult to separate rebates and discounts at a store-by-store or individual drug NDC level. Also some rebates are based on performance (i.e. you must sell a certain amount to achieve a rebate). In one quarter a pharmacy may qualify for a rebate and in the next quarter lose the rebate for not meeting a performance level. In addition, a contract with the manufacturer can change at any time and the rebate can vanish.

   As discussed at the AAC/COD focus group meetings, there is not a consistent way for all pharmacies to report this data and as a result inconsistent methods and differing assumptions may be used to arrive at discount data, if able to be reported at all. This is the reason we believe that all other states that have pursued AAC pricing initiatives have based prices on invoices exclusively and have not tried to collect or apply rebate information.

   In looking at the proposed AAC prices for the top 100 drugs by drug spend for the Medicaid FFS population, based on the analysis that the state has provided, the New York AAC prices being proposed are below what pharmacies are paying to acquire the prescription medications. We believe that the attempt to capture rebate/discounts to be a key reason for the AAC prices to be below what pharmacies are purchasing drugs for in New York.

   To assist us in further studying this issue, we requested that NYS DOH provide us with the AAC prices for the 100 drug previously shared prior to the application of rebates. We received this information at 5pm on Friday, December 20th so are just beginning our analysis of this data.

II. Comparing New York AACs to Wholesale Acquisition Cost (WAC)

   During the December 3rd presentation, a representative for First Data Bank stated that the difference between the New York AAC prices and WAC prices (prices paid for drugs by wholesalers) for brand name drugs is generally “within 1 percent.” Upon review of the 100 New York AAC prices provided for brands we are very troubled by the inaccuracy of this statement. Specifically, 90% of the drug prices listed are at a level of WAC minus 3% or more, and in 51% of the cases at WAC minus 4% or
more. This is very meaningful since pharmacies typically pay more than wholesalers for drugs and those states that use a WAC pricing methodology use a WAC plus a % formula. We believe this demonstrates the inaccuracy and inadequacy of what New York is proposing with AAC prices.

Given the diminishing number of individuals enrolled in Medicaid FFS in New York as they move into Managed Care, we have asked the state for their rationale in conducting this survey and pursuing an entirely new reimbursement methodology. This initiative has been very resource intensive for the state’s pharmacies and continues to be with ongoing AAC monthly and COD annual surveys. We would also question what it has cost the state since New York has hired consultants and been working on this for the last two years. We would submit that it may make more sense to focus limited resources on the continued transition of individuals into managed care, rather than pursuing AAC/COD. When the state further reduced Medicaid FFS reimbursement levels for brand name drugs and generics in recent years (most recently in 2011), we were told that those levels were needed to be consistent with what is paid in the commercial market. Given this, we would again ask why moving to AAC/COD is necessary at this juncture?

III. Concerns with New York’s Planned AAC Appeals Process

Given the below-cost prices that are reflected in the top 100 brand and generic drug charts provided to us by NYS DOH, we anticipate there will be a frequent need to appeal the prices paid by Medicaid FFS as it compares with actual pharmacy prices. This is particularly true since drug prices fluctuate frequently and when we have asked NYS DOH how they will address these price fluctuations we have been told that prices will be updated within two to three months from when monthly surveys are conducted. This is very problematic because the price paid will always be two or even three months out of date from what is actually paid.

For these reasons, we need an easy and industry-wide appeals process whereby pharmacies and associations should be able to appeal numerous drugs at one time, which should be followed by a very timely review and a retroactive adjustment of prices for all pharmacies that are paid the inaccurate AAC price. At this time, we have been told that NYS DOH plans to use an appeals process that is pharmacy by pharmacy and drug by drug where price adjustments are made only for the one pharmacy appealing. We have very strong concerns with this process and request that it be re-considered.

IV. Concerns with Using the Median Dispensing Fee Amount instead of the Mean

In general, the cost of dispensing report prepared by NYS DOH and its consultant Ernst & Young makes conclusions that are inconsistent with the findings of similar cost of dispensing studies conducted in other states and nationally.

Six states have implemented acquisition cost reimbursement: Alabama, Colorado, Idaho, Iowa, Louisiana, and Oregon. In those states, the cost of dispensing (and current dispensing fee) was found to be $10.64, $9.31 (at highest volume), $11.51 (at highest volume), $10.02, $10.13, and $9.68 (at highest volume), respectively. By
comparison, a 2006 study conducted by the accounting firm Grant Thornton, LLP of all state dispensing costs revealed that the cost of dispensing in New York was $10.96. Interestingly, the NYS DOH study did produce an initial mean value of $11.01 for a New York dispensing fee which seems very consistent with regard to these values. However, we were told during the December 3rd presentation that certain outliers were removed (or smoothed) reducing the $11.01 by approximately $2 and then the decision was made to use the median of $8.01 rather than the mean for the cost of dispensing for pharmacies.

The data from the New York COD survey do not compare well with data collected by other states doing acquisition cost reimbursement. In particular, the data are much more skewed than other states’ data, where the maximum difference between the mean and the median is less than $2. We believe that because of the timing of the survey that the responses are not representative of the stores in the state. In particular, responses were due immediately after Hurricane Sandy hit. Using data from the focus group slide presentation and a July 2013 NCPDP database, we have constructed the following table of New York survey respondents.

<table>
<thead>
<tr>
<th>MSA</th>
<th>Retail Pharmacies (NCPDP)</th>
<th>NY Respondents</th>
<th>Est. % Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albany/Schenectady/Troy</td>
<td>196</td>
<td>196</td>
<td>100%</td>
</tr>
<tr>
<td>Buffalo</td>
<td>276</td>
<td>220</td>
<td>80%</td>
</tr>
<tr>
<td>New York City</td>
<td>3798</td>
<td>1890</td>
<td>50%</td>
</tr>
<tr>
<td>Rochester</td>
<td>229</td>
<td>158</td>
<td>69%</td>
</tr>
</tbody>
</table>

As you can see, the response rate for New York City is much lower than any of the other areas identified. We believe that pharmacies in New York City (MSA) are underrepresented in the sample and therefore the estimated mean and median are skewed downward (since we believe that costs are higher in New York City). We would like to verify this; but the data are so different from the other states that have done this process that we distrust the results that New York has obtained.

In addition, since the skew is so different from other states, it is not clear that the median is the best choice as the point to use for reimbursement. It was stated that the median is the best representation of the central location of the data because the distribution is skewed. However, unless there is some argument to be made that Medicaid patients will never use high-cost pharmacies (which may have perfectly valid reasons for their high costs, such as a high proportion of specialty drugs or infusion products); the median does not accurately reflect, nor will it cover costs for many pharmacies.

For instance, some pharmacies specialize in high cost medications that are responsible for keeping patients out of the hospital or other expensive institutional settings and improving clinical outcomes. They are accredited to do so and offer specialized services including patient care teams, side effect management, adherence counseling and reporting, compliance devices, 24/7 access to pharmacists and others. The costs of these pharmacies must be considered and accounted for in the new
AAC/COD methodology. They should not simply be viewed as outliers and removed from the survey data.

We are very troubled by the fact that while we have been told throughout the AAC/COD survey process that the data will drive the results, based on the presentation and discussion at the December 3rd meeting, it appears that policy decisions were made to reduce the mean dispensing fee number and to ultimately use the median as the average or midpoint, rather than what the actual data found.

V. Concerns with Three-Tier Dispensing Fee Proposal by Volume

Once New York arrived at the median dispensing fee of $8.01 as discussed above, a decision was then made to propose a three-tiered dispensing fee based on each pharmacy’s annual reported total prescription volume (see box below taken from the NYS DOH December 3rd presentation). When asked the rationale for using a volume-based tiering system and how the collected COD data supported the volume and dispensing fee levels, the Ernst & Young representatives at the December 3rd meeting said that the volume and dispensing fee levels were not their conclusions based on the collected data but rather policy decisions made by NYS DOH. This is very concerning particularly since we were assured that the survey data would drive the results.

On their rationale for volume-based tiering, NYS DOH stated it is based on the theory of economies of scale. In other words that the costs are significantly less for a pharmacy filling many more prescriptions per year than one filling fewer. Given all of the labor, materials and resources that go into filling each prescription accurately and safely, we think that it is imperative that the entire sample be included when attempting to determine both the mean cost of dispensing and whether tiers would be used.

Further, we question what appears to be very arbitrary volume levels and corresponding dispensing fee levels (chart below) being proposed which as discussed at the December 3rd meeting were policy decisions made by NYS DOH. Based on this chart, over ¾ or 76% of pharmacies fill at annual volumes of 30,000 prescriptions per year or greater and thus would receive only $8.33 or $6.77 for every prescription filled as compared to less than ¼ of low volume pharmacies that would receive $14.11. As demonstrated by other state dispensing fee amounts and the Grant Thornton study, 76% of pharmacies would be paid dispensing fees that are well below their actual cost of dispensing. What’s more, the difference between $6.77 or even $8.33 and $14.11 are so great that we have to question the validity of this proposal (policy decision) which appears to be arbitrary in nature. We believe that these numbers represent a truncated distribution and do not reflect the totality of pharmacy costs.

<table>
<thead>
<tr>
<th>Annual Prescription Volume</th>
<th>Dispensing Fee</th>
<th>% of Enrolled Pharmacies</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 –29,999</td>
<td>$14.11</td>
<td>24%</td>
</tr>
</tbody>
</table>
VI. Concerns with Dispensing Fee Analysis and Findings

In looking at the methodology and initial COD survey findings, a number of issues stood out to us. First, the COD survey results found that the median dispensing fee in Rochester was higher than in New York City, $8.40 to $7.75 respectively. This seems impossible when it is common knowledge that New York City is the most expensive city in the state to do business in (i.e. real estate, labor costs, transportation etc.)

Further, the survey found that the median COD for long term care pharmacies is $5.59 as compared to those dispensing standard prescriptions at $7.59 (a $2 difference per prescription). This finding contradicts numerous other studies including CMS’ decision to pay more for long term care prescriptions due to the fact that CMS requires long-term care pharmacies to meet certain minimum performance and service criteria in order to serve this complex and frail patient population. These include medication delivery to facilities no fewer than three times per day, monthly drug utilization reviews by consultant pharmacists for each patient served, specialized packaging (unit dose, blister packs, cassettes, etc.), 24/7 pharmacist on-call service for facilities, drug compounding to provide special dosage forms, and maintaining emergency medication supplies in nursing facilities.

Finally, in looking at other state dispensing fee amounts as discussed above, we have to question the rationale for New York using a median dispensing fee of $8.01. New York’s mean cost of dispensing as calculated by the state is $11.01 which compares to Alabama at $10.64, Louisiana at $10.13 and Iowa at $10.02. It is not really plausible that the cost of doing business for pharmacies in New York State is that much lower than in these Southern or Midwest states. We do not believe so particularly when countless studies point to the Northeast and New York in particular as the most expensive states to do business. We believe that the use of the median is simply an attempt to reduce pharmacy reimbursement further rather than compensate fairly for the cost of doing business.

VII. Impact

As previously stated, there is a consensus that the proposed reimbursement of AAC and COD when taken together would reimburse pharmacies at below their costs for filling Medicaid FFS prescriptions. It is important to note that this is on top of uncollectible Medicaid co-pays which we requested be considered in the cost of
dispensing survey but were not. One pharmacy company shared that on an annual basis they have $300,000 in uncollectible copayments under Medicaid. This is considerable and, if pharmacies are paid at below cost reimbursement, it could have far reaching consequences since uncollectible co-pays further reduce the dispensing fee. We ask NYS DOH to consider how those consequences may impact patient access to pharmacy services in the state.

We also have very serious concerns with New York publically releasing this AAC and tiered dispensing fee information since it sends a signal that the data is accurate and fairly represents the true acquisition and dispensing costs for New York pharmacies. While it would be the required reimbursement levels under Medicaid FFS, it would have a ripple effect with every other payer viewing it as adequate payment to pharmacies, thus significantly reducing their reimbursement rates under Medicaid Managed Care and in the commercial market. The impact of this on pharmacies including closures and job losses and those they serve cannot be overstated.

VIII. Questions
As asked at the December 3rd meeting, we have been asked to request a written response to the following questions

- Can a pharmacy participate in Medicaid Managed Care plans and not the Medicaid FFS program?
- Can a company with multiple pharmacies opt to have some participate in FFS and others not to participate?
- What is the fiscal savings amount to the state that is being placed on the proposed AAC/COD changes?

In conclusion, we would like to thank you for your consideration of our detailed comments on the proposed AAC/COD reimbursement levels as shared by NYS DOH. We would be happy to follow up with your offices shortly on our meeting request in this regard. Also, we would appreciate a written response to the three questions we posed above at the Department’s earliest convenience.

Sincerely,

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Senate Majority Coalition Leader Klein
Assembly Speaker Silver
Senator DeFrancisco, Chair, Senate Finance Committee
Senator Hannon, Chair, Senate Health Committee
Assemblyman Farrell, Chair, Assembly Ways & Means Committee
Assemblyman Gottfried, Chair, Assembly Health Committee