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TESTIMONY

for the

Legislative Health Budget Hearing
2014-2015 NYS Budget
Monday, February 3, 2014

Respectfully submitted by

Tracy Russell, Executive Director
Pharmacists Society of the State of New York

Thank you for this opportunity to address legislative leaders and members on behalf of the Pharmacists Society of the State of New York. My name is Tracy Russell. I am the Executive Director of the Pharmacists Society of the State of New York, a position I began in August, 2013. PSSNY members are practicing pharmacists throughout the state, some of whom are pharmacy owners.

As you know, surveys continue to find that the public places a great deal of trust in their local pharmacist by consistently ranking them in the top 2 most trusted healthcare professionals. Pharmacists are not only their most trusted healthcare provider, but also the most accessible. Everyday pharmacists are on the front line working with patients earning that trust and acting in a crucial role of preventative measures of care.

The direct personal contact that pharmacists have with members of the public is especially important in the Medicaid program. In October of 2012 when the pharmacy benefit went from fee for service to managed care, pharmacists spent many uncompensated hours working with Medicaid patients to solve new prescription coverage problems such as new formularies and prior authorization requirements. Pharmacists are the Medicaid program's front line, and medications used appropriately represent cost-effective healthcare.

In 2013 DOH required every pharmacy enrolled as a Medicaid provider to complete two extensive cost surveys, and based on its analysis of the survey results, the Department plans to implement a new pharmacy reimbursement formula as early as April 1, 2014.

In fact, current state law gives the Commissioner the authority to change dispensing fees and to reimburse for medications using Average Acquisition Cost as a new benchmark. The Department set out to determine a New York specific Average Acquisition Cost for each individual medication at each dosage level and package size, and citing its statutory authority, the Department issued regulations that required every pharmacy to report its individual invoice cost for thousands of products as well as a detailed report of its cost of operations.

The Average Acquisition Cost (AAC) and Cost of Dispensing (COD) surveys were burdensome, time-consuming and costly, and the Department's plan is to continue the surveys - monthly AAC surveys and an annual COD survey. *The fundamental question, never answered to our satisfaction, is why were these fee-for-service cost surveys such a priority when the goal is to move everyone into managed care?*

Nothing to hide

It is important to note that pharmacists, pharmacies and pharmacy associations actively participated throughout the process, providing input and offering suggestions. Gauging survey results in other states, pharmacists were optimistic that a new transparent payment system would validate actual costs and would yield a reasonable and accurate reimbursement methodology.

Questionable analysis and flawed results

When the survey results were finally announced in early December, pharmacists in every practice setting were stunned. During a presentation of the statistical methods and analysis, we learned that *some* "outliers" were not considered and data was *"smoothed"* and *"cleansed"*. The Department maintains that "the data drove the results," however, not all of the data presented was used. If all of the data were considered, at least some pharmacies would find the results reasonable. All sectors of pharmacy agree that the methodology used to obtain the results are deeply flawed and should never be adopted as New York's new pharmacy reimbursement formula. **It is critical that if NY AAC's are allowed to be implemented, they must be fair, accurate and sustainable. The current results as reported by DOH are not fair, accurate or sustainable.**

Unprecedented unified response

Every organization representing pharmacists in New York, the Senior Care Pharmacy Alliance, our national affiliates, the National Community Pharmacists Association and the National Association of Chain Drug Stores found enough common ground to issue three joint letters to the Commissioner with serious challenges to the statistical methods used to analyze the data and question the results. (Included with this testimony)

"New York Average Acquisition Cost"

As requested by the associations, the Department provided a list of the 100 most frequently prescribed brands and generics in Medicaid fee for service. Because the New York Average Acquisition Cost (NYAAC) is calculated individually for each drug, it was helpful to analyze the NYAAC values against a benchmark, which the Department provided. From this report it is accurate to state that on average NYAACs fall significantly below a recognized benchmark. Reimbursement at NYAAC would be a substantial cut.

If Implemented, NYAACs Will Be Published

The Department's consultant on the AAC survey is First Data Bank, the national publisher of prescription pricing information that includes AWP, Wholesaler Acquisition Cost (WAC) and other benchmarks. The NYAAC price list will be available from First Data Bank.

- Once published, NYAACs will immediately be a new benchmark available to any payer in the state and in the nation.
- NYAACs therefore can have far-reaching impact beyond Medicaid. If a substantial number of NYACCs are at or below cost, even for a short time, pharmacies will close.
- Individual price-setting such as the proposed NYAAC has the potential to disrupt access to certain products, thereby affecting patient care
- Individual price setting such as the proposed NYAAC has the potential to change distribution patterns of certain products, thereby affecting market share
- With such potential, how much should we trust First Data Bank?

NYAACs Will Always Lag Behind Actual Cost

The Department plans to monitor invoice costs by conducting monthly surveys with a subset of New York pharmacies. If the cost of an individual product changes in late January, it will be reported in the February survey and potentially change in March. Pharmacies purchasing the product in February will therefore be dispensing below their actual cost, ***if, in fact, the AAC is adjusted and adjusted accurately.***

- DOH does not guarantee that AAC values will change on the basis of survey results alone.

- DOH plans to "validate" the surveys by using "other benchmarks" such as AWP and Wholesaler Acquisition Cost (WAC) available from First Data Bank. *Why, then move away from benchmarks?*

NYAAC's will be set by A "Three-Month Rolling Average"

If the cost increases in January, under this proposed three-month cost averaging policy, it will take at least three months (April) for the NYAAC to be fully adjusted.

Potential Negative Impact on Healthcare

In 2012, Doxycycline (100mg tablets), a first-line anti-biotic used to treat Lyme disease had a Wholesale Acquisition Cost (WAC) of $30.95. In 2013, the same medication had a WAC of $2,458.77. Under NYAAC policy as described in the DOH presentation, no pharmacy could afford to stock and dispense the product.

NYAAC's Appeals Process

When a pharmacy appeals for an adjustment to NYAAC, the appeal applies only to a single claim for payment for that pharmacy. A successful appeal will not result in an adjustment in the NYAAC across the board.

Reject AAC as new Medicaid fee-for-service benchmark

- ✓ Diminishing fee-for-service population diminishes the need for a new pharmacy reimbursement benchmark.
- ✓ To maintain the New York AAC methodology DOH is committed to monthly cost surveys ad infinitum. Why should the state have this ongoing administrative cost?
- ✓ Benchmarks such as Wholesaler Acquisition Cost (WAC) are widely available and used by other states in CMS-approved programs. Do we need NYAAC?
- ✓ If implemented, NYAAC will be published and could become widely accepted. Any error or inaccuracy could, therefore, cause significant changes in the marketplace. Should the state shoulder this liability?
- ✓ New York's AAC survey results are out of line with similar surveys in other states.

- ✓ To have medications available for patients, pharmacies must be able to purchase them and maintain them in their inventory.

Does AAC Jeopardize Manufacturer Rebate Revenues?

In OBRA'90, federal laws were changed to require pharmaceutical manufacturers to contract with CMS and pay rebates to bring the net cost to Medicaid down to the lowest cost in the market. Would NYAAC jeopardize manufacturer rebate dollars to the General Fund?

AACs Are Another in a Series of Drastic Cuts to Pharmacies

The plain truth is that the AAC and COD surveys are nothing more than a vehicle by which to justify another drastic cut in pharmacy reimbursement, as evidenced by the savings projection of $21.4 million ($10.7 million state share).

Look Ahead to a Broader Role for Pharmacists

Pharmacists are equipped to offer much in evolving healthcare systems that focus on outcomes. Consider the value of drug regimen reviews during transitions of care. Medicare Part D reimburses pharmacists for Medication Therapy Management services and has implemented a star rating system for pharmacies. Now is not the time to short change these valuable healthcare providers

Reject the AAC Reimbursement Methodology and New Tiered Dispensing Fees

This testimony is focused on the AAC methodology because it lies at the heart of the new proposed reimbursement formula. We also have similar concerns about the Cost of Dispensing Survey (COD). In the COD Survey we strongly question

- the statistical manipulation of the cost data submitted,
- the decision to eliminate certain real costs, such as uncollectable co-payments,
- the finding that the cost of dispensing in New York is so much lower than in other states,
- and the recommendation to tie a range of fees to total prescription volume.

The combination of the new proposed Average Acquisition Cost plus the new proposed dispensing fees represents a substantial and unsustainable reduction if pharmacy reimbursement.

PSSNY

210 Washington Avenue Ext.
Suite 101
Albany, NY 12203

Tel: 518.869.6595
Toll Free: 800.632.8822
Fax: 518.464.0618

E-mail: staff@pssny.org
Web: www.pssny.org

December 23, 2013

Nirav V. Shah, Commissioner
New York State Department of Health
Empire State Plaza
Albany, NY 12237

Jason A. Helgerson, Deputy Commissioner
Medicaid Director
Office of Health Insurance Programs
NYS Department of Health
1 Commerce Plaza
Albany, NY 12210

Dear Commissioner Shah and Deputy Commissioner Helgerson:

We write on behalf of the Society's members to underscore the deep concern we have about both the methodology employed for and results obtained from the Medicaid Fee for Service Average Actual Acquisition Cost (AAC) and Cost of Dispensing (COD) surveys released to pharmacy associations and AAC-COD focus group members on Tuesday, December 3. If the proposed AAC and COD are approved and implemented, they will become de facto benchmarks, setting a new standard for pharmacy reimbursement in the New York market. For this reason the survey methodology, analysis and results must be carefully examined from every aspect before they are implemented as new policy. Any error or inaccuracy carries the potential to disrupt health care delivery systems and ultimately cause patient harm. The Society is concerned and alarmed.

Cost of Dispensing

The recommended fees of $8.33 and $6.77 to be paid to 76% of participating pharmacies fall well below CMS-approved dispensing fees in other states. It is simply illogical that the cost of dispensing in the high-cost state of New York is significantly lower than in Alabama where the Medicaid fee is $10.64 per prescription. Furthermore, in 2007 the Grant Thornton cost of dispensing survey concluded that the national average overall COD per pharmacy was $12.10. The NYS COD survey results therefore should call into question the analytics, assumptions and policies that were used to "smooth" the data, remove "outliers" and develop "linear regression models." All of those terms were used by DoH representatives in their attempt to explain the results. The results are flawed.

Of even greater concern is that the proposed dispensing fee ignores completely the growing urgency for programs in pharmacies that promote medication adherence, disease management, disease prevention, medication reconciliation and the mandatory counseling. Stratifying the dispensing fee by prescription volume is another example that the professional role and responsibilities of practicing pharmacists was considered through a very narrow lens, at odds with emerging trends such as patient-centered medical homes and medication therapy management services as they are required in Medicare Part D.

Actual Acquisition Cost

In reviewing the list of AAC prices in light of the fact that these represent the Average Acquisition Cost, it is reasonable to assume that a percentage of pharmacies pay more than that so-called *average* price while others pay less. Based on the survey results, the Department clearly knows which pharmacies and how many are paying more than others.
By proposing to both utilize the average and paying a low dispensing fee, which will be further eroded by uncollectible copayments, department leaders and staff are attempting to institute an unsustainable reimbursement model for pharmacies caring for Medicaid fee-for-service patients. With every new calculation of AAC, a new group of pharmacy providers will fall into the "below actual cost" group and will be forced to drop out of the program.

In discussing the reported Average Acquisition Cost results, Patrick Lupinetti of First Data Bank stated that the NY AAC for brand name drugs was "within 1% of WAC". In fact, comparing NY AAC to WAC in the 100 drugs' AAC prices we find

WAC minus 0 to WAC minus 0.99% - 3 instances
WAC minus 1 to WAC minus 1.99% - 4 instances
WAC minus 2 to WAC minus 2.99% - 3 instances
WAC minus 3 to WAC minus 3.99% - 39 instances
WAC minus 4 to WAC minus 5.99% - 33 instances
WAC minus 6 to WAC minus 7.99% - 8 instances
WAC minus 8 to WAC minus 9.99% - 2 instances
WAC minus 10% or greater - 8 instances

The Department attempted to clarify Mr. Lupinetti's statement in an email, writing: "The statement that the NY AAC 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 measurement of any kind was factored into his statement." We find this explanation incomprehensible, hence unacceptable in light of the clear facts presented above.

Our analysis of WAC shows that the NY AAC price for **90%** of the 100 brand name drugs listed is equivalent to **WAC minus 3%** or more; and in **51%** of the cases equivalent to **WAC minus 4%** or more. AAC supposedly represents the ***average*** acquisition cost; hence a number of pharmacies are buying at "WAC minus" values both higher and lower than that ***average.*** PSSNY strongly encourages the Department to canvas the state's pharmaceutical wholesalers to question whether their customers actual purchase medications so far below the WAC benchmark. The individual focus group members among the Society's leaders challenge the accuracy of the reported AAC values for the top 100 brands and generics.

Going forward, the Department's plan to keep the AAC values *current* is also deeply flawed. Surveying a subset of pharmacies monthly ad infinitum is an ongoing administrative expense. More importantly, this methodology will absolutely yield price points that will lag actual cost fluctuations by at least two months. Please note that PSSNY pointed out this serious flaw in a letter to the Department dated May 31, 2012. In addition, if the randomly selected pharmacies surveyed in a given month do not dispense a specific NDC in that timeframe, then any large cost increase will not be recorded in the survey. In short, the proposed survey method to determine AAC will not produce price points that are current or accurate for every product.

How will pharmacies have access to monthly updated NDC's so that a regular comparison can be made and discrepancies reported?

We request that the Department publish on a regular basis not only NY AAC but also a comparison with WAC as a mechanism to assure pharmacy providers that, in fact, AAC is adjusting as market pricing fluctuates. WAC and AWP are well established benchmarks that are used in contracts and throughout the distribution system. If and when AAC becomes the official NYS Medicaid FFS policy, it sets a precedent that is very likely to be used in other public and private prescription benefit programs. The adoption and publication of NY AAC's is therefore a policy

development with dire consequences, both seen and unforeseen. The proposed AAC reimbursement methodology never guarantees that a particular pharmacy will be paid at its actual cost.

Rebates

The reported AAC results have factored in rebates. Rebates are not earned by every pharmacy, and if they are they do not apply uniformly across all product lines. The decision to factor in rebates is therefore controversial and makes the New York survey itself an "outlier". We acknowledge receipt on December 20th, a document entitled "NYACC Rebate and Discount Calculations" for generics. The Society has not had sufficient time or resources to fully evaluate and comment on these documents.

AAC Appeals Process

On the surface, AAC appeals process initially appears to be fair and reasonable. Upon closer examination, the proposed process is very limited. First of all, the Department should have a guaranteed response timeframe. An appeal is based on the claim for payment of a single prescription. The result therefore will reverse that single claim for which the pharmacy would be expected to re-bill. Each refill of the same prescription would require a new appeal. In fact, every successful AAC challenge should be applied retroactively and across the board if the Department agrees that the AAC payment amount is not sufficient to offset product cost. A fair and reasonable AAC Appeals Process would be a litmus test for the accuracy of AAC's in real-time. The proposed process is not reasonable, does not serve this purpose and should be changed.

Conclusion

Pharmacists, pharmacies and associations have steadfastly worked with the Department, optimistic that the results of both surveys would yield reasonable and credible results. Sadly, this is not the case. Viewed from the perspective of a new pharmacy reimbursement policy, the findings in these surveys have the potential to destabilize the network of community pharmacies throughout New York that provide the medications and services that keep people away from more costly levels of healthcare. We urge the Department to consider these results as preliminary, agree to further assessment and review and postpone any effort at implementation.

Sincerely,

James A. Walsh, PharmD
President

Cc:

Courtney Burke, Deputy Secretary for Health to Governor Cuomo
Jim Clancy, Assistant Commissioner, Office of Governmental Affairs, NYS DOH
Gregory Allen, Director, Division of Program Development and Management, NYS DOH
Janet Elkind, Deputy Director, Division of Program Development and Management, NYS DOH
Honorable Speaker Sheldon Silver, Speaker of the Assembly
Senator Dean Skelos, Co-Leader of the Senate Majority
Senator Jeffery Klein, Co-Leader of the Senate Majority
Honorable Kemp Hannon, Chair Senate Health Committee
Honorable Member Richard Gottfried, Chair of Assembly Health Committee
Honorable John DeFrancisco, Chair of Senate Finance Committee
Honorable Member Herman Farrell, Chair of Assembly Ways and Means
PSSNY Board of Directors

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

WWW.NCPANET.ORG

Nirav R. Shah, Commissioner
New York State Department of Health
Empire State Plaza
Albany, NY 12237

December 19, 2013

Submitted Via Email: dohweb@health.state.ny.us & Jah23@health.state.ny.us

RE: NCPA Concerns Regarding Proposed Cost of Dispensing and AAC Analysis

Dear Commissioner Shah:
I write to you on behalf of the National Community Pharmacists Association's (NCPA) to voice community pharmacy's serious concerns regarding New York State Department of Health's (NYS DOH) Medicaid Fee for Service (FFS) Actual Acquisition Cost (AAC) and Cost of Dispensing (COD) program developed by NYS DOH and consultants First Data Bank and Ernst & Young. NCPA fully supports New York's attempt to modernize their reimbursement model to appropriately reflect an accurate pharmacy reimbursement cost and COD. However, we feel there are serious deficiencies in the proposed data and methodology that New York has chosen to utilize. To provide an accurate reimbursement and dispensing fee such concerns must be addressed. Furthermore, NCPA has serious concerns regarding NYS DOH's plan to utilize the currently flawed data for the purposes of submitting a State Plan Amendment (SPA) to CMS by the end of December. We respectfully request that any such plans be delayed until corrective action is taken.

NCPA believes that when properly determined, with all factors being appropriately considered, an AAC/COD model can be an effective benchmark. However, an AAC benchmark and dispensing fee must be considered together. Moreover, all relevant criteria must be considered to determine an appropriate dispensing fee. Such criteria would include costs of ordering, stocking, packaging, uncollected co-pays, labeling and dispensing medication. Such costs should also include drug utilization review (DUR) and appropriately allocated indirect and overhead operations costs. NCPA noted during our analysis that NYS DOH excluded multiple criteria from their analysis. NCPA is concerned that the current AAC/COD methodology is notably flawed and implementing this benchmark in its current form could impact many community pharmacies to a degree of placing many Medicaid beneficiary's access to pharmacy services in question.

NCPA represents the owners and operators of approximately 23,000 privately-held small business independent community pharmacies across the United States and our members provide approximately 41 percent of all outpatient prescriptions in the United States. More than 2,200 NCPA independent pharmacies operate in the state of New York and more than 90 percent of independent pharmacies' business is derived from prescription revenues as opposed to other, "front-end" retail items. Nationwide, Medicaid represents an average 18 percent of all prescriptions filled by community pharmacy which is roughly double that of chain pharmacy. NCPA has been involved with the implementation of similar AAC/COD models in other states as well as at the national level with the implementation of the National Average Drug Acquisition Cost (NADAC) survey which was recently finalized by CMS. Please note that NCPA continues to have concerns with NADAC. Any reference to NADAC in this letter is done so only to provide a comparison and does not reflect NCPA overall support for the NADAC model.

At this time, we offer the following observations and concerns regarding NYS DOH's AAC/COD implementation and are hopeful that you will take them under serious consideration. NCPA supports and echoes the message made by many state and national pharmacy organizations voicing concern over the implementation of AAC/COD in New York. We are also hopeful that our comments will be used in a manner to vastly improve the current AAC/COD proposal before such information is submitted to CMS for review. NCPA has reached these conclusions after comparing NYS DOH's proposed AAC/COD figures to NADAC data,

100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX

reviewing similar benchmark programs implemented previously by other states, having direct conversations with New York pharmacy organizations and pharmacy owners and analyzing data provided for NYS DOH AAC/COD process.

Concerns & Observations

Cost of Dispensing (COD) Survey:

- 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 and also of those COD figures from states previously implementing an AAC/COD model. The average COD of $9.33 in New York is $3.64 lower than the average COD of $12.97 in Alabama, $3.89 lower than the average COD in Idaho and $1.82 lower than average COD in Oregon. All of the aforementioned states determined their figures through a survey process. It should also be noted that the northeast region of the United States has historically demonstrated to be one of the highest COD regions.

- 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. Average COD for pharmacies in New York dispensing fewer than 30,000 prescriptions annually was $14.11. In Alabama, the average COD for pharmacies dispensing fewer than 43,000 prescriptions annually was $19.39, and the comparable figure for pharmacies dispensing fewer than 40,000 annual prescriptions in Idaho was $15.11. 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.

- 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.

- NCPA noted that 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. Furthermore, Medicaid beneficiaries are not required to pay co-pays. Pharmacists should be able to account for such losses when completing a COD survey.

- New York estimated a median COD for long term care (LTC) pharmacies of $5.59, well below COD estimates from other studies. A study conducted by Virginia Commonwealth University found that for closed door LTC facilities, median COD was $13.54. Compared to retail pharmacies, LTC pharmacies incur additional dispensing-related costs to serve residents' needs. These include services such as specialized packaging, 24-hour on-call pharmacy services and providing deliveries to pharmacies several times a day. Given these additional costs, it is hard to imagine that the NYS DOH estimate is accurate. This brings into question the methodology used to derive these estimates.

- NYS DOH 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 what 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 such discrepancies.

- To control for outliers, NYS DOH removes any COD value more than two standard deviations away from the median COD. For a normal distribution, the standard deviation is a very appropriate measure of variability (or spread) of the distribution. But for skewed distributions, the standard deviation gives no information on the asymmetry. It is better to use the first and third quartiles, since these will give some sense of the asymmetry of the distribution.

- NYS DOH develops 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 percent of the variation in COD around its mean value. NYS DOH needs to document what additional testing that was conducted to assure a robust model.

- Community pharmacists have historically served a higher percentage of Medicaid beneficiaries in comparison to other pharmacy options. There are discrete yet impactful differences between providing pharmacist care services to those that are commercially insured and the Medicaid population. The Medicaid population typically faces multiple chronic conditions that warrant increased pharmacist oversight and patient counseling, increasing the operational costs to serve these patients. NYS DOH should consider such additional costs when determining an accurate COD.

- NYS DOH's proposed tiered dispensing fee structure is based solely on total prescription volume. NYS DOH may also wish to take into consideration the total number of Medicaid prescriptions a particular pharmacy fills annually or the percentage of their total prescription volume that is made up of Medicaid prescriptions. For example, pharmacies that serve a significant number of Medicaid beneficiaries or where Medicaid claims make up at least a certain percentage of their total prescription volume might receive an additional amount (perhaps $0.50) added to their base dispensing fee. NYS DOH could also provide this "incentive" payment to pharmacies that dispense a significant number of generics—or for those pharmacies for whom generics make up at least a certain percentage of their total prescription volume.

Actual Acquisition Cost (AAC) Survey:

- NCPA feels that rebates should NOT be considered in the calculation of AAC because of the inconsistencies inherent in this data. The drug pricing and pharmacy purchasing marketplace is extremely complex and must be considered on a case-by-case basis. There is not a consistent way for pharmacies – be they chain, independent, specialty, etc. to report this data. NCPA feels that NYS DOH's insistence on including such rebates may be significantly skewing data results.

- When reviewing the top 100 dispensed brand drugs, 93 out of 100 times, NYS DOH average acquisition cost (NYAAC) is determined to be lower than NADAC. On Average, NYAAC is $8.72 per unit lower when compared to NADAC. NCPA feels that before either of these benchmarks is finalized the notable discrepancies in both of the models must be reconciled.

- When reviewing the top 102 dispensed generic drugs, 100 out of 102 times, NYS DOH average acquisition cost (NYAAC) is determined to be lower than NADAC. On Average, NYAAC is $.67 per unit lower when compared to NADAC. Again, NCPA feels that before either of these benchmarks is finalized the notable discrepancies in both of the models must be reconciled.

- NYS DOH should justify what constitutes a minimum number of pricing data for a particular drug before reporting an updated AAC. Currently NYS DOH simply states "that if no pricing data for a particular drug is reported in a monthly survey, ACC will be developed using an average of the previous two months." Does this suggest that if NYS DOH receives one pricing data point for a particular drug, NYS DOH will update AAC based on that single pricing data point? NYS DOH must clarify what type of geographic distribution and pharmacy type distribution will be required to result in a statistically significant response. The number of observations for each entry should be included in the file.

We offer these comments for your consideration and hope they will result in a more extensive conversation into the details of this matter. At this time NCPA believes that due to the significant flaws and omissions in the methodology used to determine COD and NYAAC, New York should **not** move forward with proposing to utilize the data in question. Also, NCPA believes that due to the notable discrepancies listed above any existing appeals processes that are currently or made available to New York pharmacy would not provide adequate protections. If the current data is utilized both pharmacists and NY DOH would be burdened with countless hours dealing with and processing appeals.

NCPA continues to commend New York on their efforts to develop a reimbursement method that reflects true costs of providing pharmacy services. We understand that developing such a model is no easy task and is a process that must be refined before an appropriate and effective system is considered fully operational. NCPA hopes to work closely with your office to develop such a system and feels our experience and expertise will be beneficial. Please do not hesitate to contact me at matt.diloreto@ncpanet.org or at (703) 600-1223 to further discuss this matter.

Sincerely,

Matthew J. DiLoreto
Senior Director, State Government Affairs

Cc:
Jason Helgerson
Courtney Burke
Jim Clancy
Greg Allen
Janet Elkind
Senator John DeFrancisco
Senator Kemp Hannon
Senator Dean Skelos
Senator Jeffrey Klein
Speaker Sheldon Silver
Assemblyman HermanFarrell
Assemblyman Richard Gottfried

Chain Pharmacy Association of NYS
National Association of Chain Drug Stores
New York State Council of Health-system Pharmacists
Pharmacist Society of the State of New York
Senior Care Pharmacy Alliance

December 23, 2013

Nirav R. Shah
Commissioner
New York State Department of Health
Empire State Plaza
Albany, NY 12237

Jason A. Helgerson
Deputy Commissioner
New York State Medicaid Director
Office of Health Insurance Programs
New York State Department of Health
1 Commerce Plaza
Albany, NY 12210

RE: NY Medicaid Fee for Service Average Actual Acquisition Cost/ Cost of Dispensing Proposal

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

discuss them in greater detail prior to New York taking any further actions with CMS or its regulatory process.

Pharmacy Concerns with Proposed New York AACs/Dispensing Fees

I. 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.

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

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.

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%

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,

Michael Duteau R.Ph.
President, Chain Pharmacy Association of New York State

Carol Kelly, Senior Vice President, Government Affairs and Public Policy
National Association of Chain Drug Stores

Qazi A. Halim, M.S., R.Ph.
President, New York State Council of Health-system Pharmacists

James Walsh, PharmD
President, Pharmacist Society of the State of New York

Vincent Galletta MS, R.Ph.
Senior Care Pharmacy Alliance

Cc: Courtney Burke, Deputy Secretary for Health to Governor Cuomo
James Clancy, Assistant Commissioner, Office of Governmental and External Affairs, NYSDOH
Gregory Allen, Director, Division of Program Development and Management, NYS DOH
Janet Elkind, Deputy Director, Division of Program Development and Management, NYS DOH
Senate Majority Coalition Leader Skelos
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