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PHARMACISTS SOCIETY OF THE STATE OF NEW YORK

TESTIMONY

JOINT LEGISLATIVE BUDGET HEARING

HEALTH AND MEDICAID

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Honorable Finance Chairs Senator Young and Assemblyman Farrell, Senator Hannon, Assemblyman Gottfried and distinguished members,

My name is Roger Paganelli. I am a practicing pharmacist in the Bronx and third-generation owner of Mount Carmel Pharmacy. I currently serve as President of the Pharmacists Society of the State of New York. Joining me is Kathy Febraio, the Society's Executive Director.

The Pharmacists Society is a 138-year old statewide organization advocating for more than 25,000 New York pharmacists practicing in a variety of settings. We have affiliated organizations throughout the state. A majority of PSSNY's members practice in community pharmacies as owners, supervising pharmacists and dispensing pharmacists. Issues of concern to community pharmacies from the Governor's proposed budget will be the focus of our remarks today.

Thank you. We begin by thanking leaders of both houses and individual Senate and Assembly members for your continued support for the services pharmacists provide to New Yorkers on a daily basis. You have recognized the value that community pharmacies offer to the neighborhoods we serve and have supported our efforts to remain a steady and reliable presence in healthcare delivery in this state. Specifically, thank you for your strong support in the past two budget cycles. The legislature kept the Department of Health from driving pharmacy reimbursements below our costs when you rejected efforts to put into place the flawed results of the Department of Health's pharmacy costs and drug pricing surveys. You helped pharmacies to remain viable and you also helped take away an administrative burden for each pharmacy to document all pharmaceutical purchases on an ongoing basis and submit such records in an electronic file to the Department of Health. . Thank you for that common sense change. More importantly, Medicaid patients continue to have access to the medications they need and to the pharmacists in their communities who they trust.

Another challenging Medicaid proposal is in this year's budget: "to better align fee for service payments for specialty drugs". This is a plan to cut pharmacy reimbursement for certain brand-name drugs dispensed to the small number of Medicaid patients who remain in Fee for Service. **We are again calling on the legislature to reject this budget initiative.**

The plan. Medicaid officials are asking for legal authority to remove an undetermined number of brand-name prescription drugs from the current Fee for Service reimbursement formula and replace established benchmarks with a new reimbursement amount to be determined by a department survey. The legislature has rejected a similar plan in the past, and we ask the legislature to reject this year's initiative.

The first step DOH would take is to develop a list of so-called "specialty" drugs by conducting a survey of what the market considers "specialty" drugs. Since managed care plans rely on pharmacy benefit managers, in reality the Department's plan is to allow these

unregulated entities to play a key role in defining a "specialty drug" in the NYS Medicaid program. Facts to consider:

- "Specialty" is an artificial term used by and for business entities for their own advantage. "Specialty" is not a scientific or clinical term. It has no meaning for the Food and Drug Administration, the U.S. Pharmacopeia Convention, the National Association of Boards of Pharmacy, the New York State Board of Pharmacy or any other recognized legal authority that regulates prescription drugs in this country. The term "specialty drugs" should therefore have no place in law or public policy. Specialty Drugs have recently attracted national news as some pharmaceutical manufacturers have designated common non patented pharmaceuticals (which happen to lack any generic competition) as specialty and then increase the price over night. For example, Turing Pharmaceuticals recent activity.

- Turing acquired Daraprim (pyrimethamine) – an FDA-approved product on the market since 1953 – for $55 million on August 10, 2015, from Impax Laboratories. The drug's use is for anti-malarial and antiparasitic values, in conjunction with leucovorin and a sulfonamide, to treat patients with toxoplasmosis, found in the AIDS populations. Daraprim patent expired in 1953, and no generic version was produced due to weak demand. Once the product was designated as a specialty drug, in the summer of 2015, the price of a single tablet of the drug in the U.S. market increased from $13.50 to $750 per pill, overnight, a 5451% increase. This is just one example of the industry smokescreen that is developing on "specialty drugs". There are other examples but I do not want to spend your precious time sharing these nightmare scenarios which just add to the costs associated with health care expenditures which our state government spends on our Medicaid patients.

- Deriving a list of "specialty drugs" through a market survey means that such a list has the potential to include unlimited number of drugs this year and beyond as I just demonstrated in the prior example.

- In 2011 the Department proposed creating a list of "specialty" drugs through a similar market survey. The list had approximately 600 individual drug products. When challenged in court on the definition and related problems, the Department was forced to abandon the effort.

The second step is to remove so-called "specialty drugs" from the current Medicaid reimbursement formula for brand-name drugs that is based on Average Wholesale Price (AWP-17%) or the alternative benchmark, Wholesaler Acquisition Cost (WAC-.41%).

- AWP and WAC are published benchmarks commonly used in contracts to describe terms for both purchase and reimbursement for brand-name drugs.

- AWP and WAC are updated as drug prices change. Because they move with the market they are considered reliable statistical references from a business perspective.

- The Department's plan to reject AWP or WAC-based reimbursement for a potentially sizeable number of brand-name drugs would be financially destabilizing for pharmacies and could lead to inventory decisions that would affect patients.

The third step is one the legislature has rejected in the past. The Department would survey health plans for their costs for these products, analyze the cost data and determine the pharmacy reimbursement amount for each brand-name drug on their evolving "specialty drug list."

- The legislature stopped the Department from conducting cost surveys in previous budget cycles on the basis of unreasonable and inaccurate results, lack of transparency, questionable statistical analyses and overall flawed methods.

- DOH appears to have no plan to monitor price fluctuations and make the necessary adjustments when brand-name drug prices increase as they frequently do.

- DOH proposes no process by which to adjust payments that are below the cost of brand-name drugs that pharmacies purchase for their inventories.

- DOH proposes no vetting or validating process to assure that its new payment levels are realistic or reasonable.

- DOH offers no explanation of how they will analyze the health plan submitted data, and how will DOH confirm the accuracy of the health plan information submitted, nor has DOH provided any assurances that its statistical analysis will be valid or transparent.

- DOH is ill-equipped to manage drug pricing policies and keep them current as has been demonstrated in their recent efforts to conduct cost of dispensing and cost of Drug surveys.

- In all likelihood we believe that pharmacies will be reimbursed below cost on these "Specialty Drugs "with no recourse.

Pharmacists are concerned about the negative impact of this budget proposal. What would happen to patients if certain medications simply become unavailable from a local pharmacy? Would draconian payment policies force pharmacies to withdraw from Medicaid Fee for Service? Could a pharmacy continue to service Medicaid managed care patients and not Fee for Service patients?

Dangerous precedent. This is a deceptively modest proposal with a small fiscal ($1.8 million state share), but it has the potential to drive reimbursement below-cost for an unpredictable number of brand-name drug products, in fee-for-service this year with a potential to migrate further in future years into Medicaid managed care and the private market. The logical consequence of consistently below-cost reimbursement is that medications will become less available from local pharmacies, ultimately a disservice to the Medicaid program and every New Yorker who prefers or relies upon the convenient, in-person services of their neighborhood pharmacist. For many pharmacies, the ultimate impact could be devastating.

Uncollected $95 million rebates. The Comptroller has in recent weeks reported the NYS Medicaid program is owed $95 million in manufacturer rebates that the Department has failed to collect. A management failure of this magnitude should cast serious doubt on the agency's ability to manage such a broad-reaching pharmacy reimbursement proposal with such a clear potential for serious harm.

On behalf of the vulnerable and clinically complex patients who remain in Medicaid fee-for-service, their pharmacists and their pharmacies, we respectfully urge the legislature to reject this dangerous budget proposal.