

THE PHARMACY PATIENT'S RIGHT TO CARE

The Pharmacists Society of the State of New York
LEGISLATIVE AGENDA

January 15, 2017



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Transforming access to healthcare for the pharmacy patient in New York State

The Pharmacists Society of the State of New York (PSSNY) represents the interests of more than 25,000 licensed pharmacists in New York State. PSSNY's vision is to serve New York pharmacists and the profession of pharmacy with advocacy and resources to improve patient care.

Pharmacists are the second most trusted profession according to a 2016 Gallup Poll and the most frequently seen healthcare professional for most patients, providing unique opportunities to improve patient care and the overall public health of the communities pharmacists serve.

Pharmacists are licensed healthcare professionals who have completed a pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) to ensure that graduating students are "practice-ready" and "team-ready," that is, prepared to directly contribute to patient care working in collaboration with other healthcare providers.¹ The ACPE Standards focus on the

- (1) development of students' professional knowledge, skills, abilities, behaviors, and attitudes, including scientific foundation, knowledge application, and practice competencies;
- (2) the manner in which programs assess students' acquisition of knowledge and application of knowledge to practice;
- (3) mastery of skills and achievement of competencies; and
- (4) the importance of both curricular and co-curricular experiences in advancing the professional development of students.¹

As of 2000 the Doctor of Pharmacy has been the entry degree for professional licensure in the United States. The ACPE standards ensure that pharmacists are clinicians well prepared to collaborate with other licensees on the healthcare team and to work directly with patients to use prescribed medications safely and appropriately. Pharmacists are well-rounded as they enter the workforce and maintain competency throughout their careers by meeting rigorous ACPE-approved continuing education requirements.

Pharmacists are professionally committed to assisting patients to access their prescribed medications and, equally important, to have the information and support to use them correctly. Today's pharmacists are providing a broad spectrum of services within their scope of practice that include conducting health and wellness testing, managing medications prescribed for chronic diseases and administering immunizations. In hospitals and health systems pharmacists are healthcare team partners working to advance health and wellness and helping to reduce hospital readmissions.²

Pharmacists practice in a variety of settings including community pharmacies, hospitals, nuclear pharmacies, outsourcing facilities, clinics, home healthcare facilities, home infusion facilities, long-term care settings, managed care facilities, Armed Services, veterans' administration, local, state, and federal government, consultant pharmacy practices, pharmaceutical sales and marketing, drug research and development, universities and specialized physician practices.

The Pharmacists Society of the State of New York proposes a nine point agenda to optimize the practice environment of pharmacists with concurrent benefits to patients and the quality of patient care.

¹ Wadelin, Jeffrey W. "ACCREDITATION STANDARDS AND KEY ELEMENTS FOR THE PROFESSIONAL PROGRAM IN PHARMACY LEADING TO THE DOCTOR OF PHARMACY DEGREE." (2015): n. pag. Acpe-accredit.org. ACPE, 25 Jan. 2015. Web. 19 Dec. 2016.

² "Pharmacists Provide Care." Pharmacists Provide Care. American Pharmacists Association, 2015. Web. 19 Dec. 2016. <<http://www.pharmacistsprovidecare.com/>>.



EXPAND PATIENT ACCESS TO CARE

Millions of Americans lack adequate access to primary healthcare and this is only expected to worsen as demand increases. Over the next two decades, the number of Medicare enrollees is expected to grow from roughly 50 million to over 80 million.³ In addition, approximately 45% of Americans have at least one chronic condition, and 27% have multiple chronic conditions, rates that are expected to continue to rise.^{3,4} Further, the Congressional Budget Office (CBO) estimates that an additional 25 million individuals have gained health coverage under the Patient Protection and Affordable Care Act (PPACA) and according to Governor Cuomo's recent *State of the State Address*, it is estimated that over 2.7 million New Yorkers would lose health coverage if the PPACA is repealed. Given the uncertainty of the Federal landscape it is now more important than ever to protect the patient's right to care.

Factoring all of this in, the Association of American Medical Colleges projects that, by 2020, there will be a shortage of over 91,000 doctors to meet demand, and the impact will be most severe on underserved populations. The clinical background and convenient access to a pharmacist can fill this growing need.

Expand Patient Access to Simple Lab Tests

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations include federal standards applicable to all US facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease. The CDC, in partnership with CMS and FDA, supports the CLIA program and clinical laboratory quality. "Waived" testing, as defined by CLIA, are simple tests with a low risk for an incorrect result.

For example, CLIA-waived tests:

- Screen to monitor/diagnose various diseases/conditions, such as diabetes or strep throat;
- Monitor the state of the kidney or urinary tract, and urinary tract infections;
- Monitor blood glucose levels and cholesterol levels; and
- Detect the presence of drugs and medications in the blood or urine.

FDA-approved CLIA-waived tests must be administered according to manufacturer's test instructions. State law in New York considers any site where CLIA-waived tests are administered to be a laboratory that is supervised by a qualified medical director.

Patients would benefit from a bill that would:

- Authorize a licensed pharmacist to qualify as a laboratory director; and
- Add pharmacists to the list of licensed healthcare professionals authorized to administer CLIA-waived tests to patients under their care consistent with written agreements or protocols.

Expanded patient access to CLIA-waived tests would improve the management of patient outcomes by primary care providers and pharmacists and by delivering important health status information in a timelier manner.



3 U Davis, Patricia A. "Medicare Financing." Congressional Research Service (2013): Federation of American Scientists. CRS, 19 Sept. 2013. Web. 19 Dec. 2016.
 4 SY, Wu, and A. Green. "Projection of Chronic Illness Prevalence and Cost Inflation." RAND Health 18 (2000): n. pag. Print.

Expand Immunization Authority for Pharmacists

The *Prevention Agenda 2013-2018: New York State's Health Improvement Plan* is the blueprint for state and local action to improve the health of New Yorkers in five priority areas and to reduce health disparities for racial, ethnic, disability, and low socioeconomic groups, as well as other populations who experience them. Focus Area 2 of the blueprint focuses on preventing vaccine-preventable diseases.⁵

The goals of Focus Area 2 include:

- Decrease the burden of pertussis disease;
- Decrease the burden of influenza disease;
- Increase the number of providers who offer pneumococcal vaccine to adults;
- Decrease the burden of disease caused by human papillomavirus; and
- Increase adult immunization rates for Tdap, influenza, pneumococcal, and human papillomavirus.⁵

Since 2008, when the State Education Department first authorized the certification of pharmacists to immunize adults against flu and pneumococcal disease, the response from pharmacists, the medical community, public health officials, insurers and the public has been overwhelmingly positive. Over this time, the state's adult immunization rates have improved through expanded access, and more than 12,000 pharmacists have completed the additional requirements to become certified.



To support the Department of Health's plan and increase adult access to immunizations, the following should be implemented:

Remove Sunsets and Add All CDC-Recommended Vaccines for Adults

- Authorizes pharmacists to administer all Centers for Disease Control and Prevention (CDC) recommended adult immunizations;
- Removes the requirement that the authorized practitioner issuing the patient-specific or standing order be in the same or adjoining county where the immunization is to be administered; and
- Makes the statute permanent.

Authorize Pharmacy Interns to Immunize Adults

- Allows a pharmacy intern who has successfully completed the immunization certification training to administer an authorized vaccine to adults when the intern is under the direct supervision of a licensed, certified pharmacist;
- Expands access to immunization services in communities; and
- Helps to fill gaps in the state's 153 medically underserved areas; and
- Provides an additional resource for immunizations during a declared emergency.

Expanding pharmacists' and pharmacy interns' ability to administer more immunizations in greater geographic areas would improve patient access to critical vaccinations and improve the health of underserved areas.



⁵ "New York State's Health Improvement Plan." *Prevention Agenda 2013-2017*. NYS Department of Health, 1 Aug. 2016. Web. 19 Dec. 2016. <https://www.health.ny.gov/prevention/prevention_agenda/2013-2017/>.

Facilitate Synchronization of Medication Refills

The management and treatment of patients with chronic diseases accounted for eighty-six percent of the total healthcare spend in America in 2010. Prescription medications are an important aspect of treatment for the management of chronic diseases, yet only 50% of patients who are prescribed medications adhere to the therapy. Medication adherence and compliance are critical to positive patient outcomes.⁶

The term *medication synchronization* refers to voluntary programs initiated by pharmacists in which medication refills are coordinated so that every prescription refill is due on the same day each month. This coordination is more convenient for patients and creates an opportunity for a more complete medication consultation. This strengthens the patient's relationship with his/her pharmacy provider. This patient-pharmacist interaction promotes more successful clinical outcomes.

This initiative:

- Requires insurers to reimburse pharmacies for an initial, partially filled prescription and to pro-rate the co-payment based on the days' supply; and
- Requires insurers to pay the full professional dispensing fee because the required record-keeping, consultation and associated services are the same regardless of the quantity of medication dispensed.

Patients who see their pharmacists regularly are more adherent, have better therapeutic outcomes and are less costly to the healthcare system overall. The above legislation is consistent with good patient care.



Improve the Appeals Process for Below-Cost Payments for Generic Drugs

In March 2016, a new state law gave local pharmacies a mechanism for recovering amounts due when reimbursement from pharmacy benefit managers is below cost. Pharmacy benefit managers are the unseen and largely unregulated middlemen that manage pharmacy networks. Amendments are needed to strengthen provisions of current law so that it works to assure patients that local pharmacies will continue to have an inventory sufficient to provide prompt access to prescribed medications.

This initiative:

- Allows local pharmacies to maintain sufficient inventory to meet patient demand;
- Ensures patient access to prescribed medications and a health care provider from local community pharmacies; and
- Promotes pharmacy services of consistent quality and reliability.

When state law provides pharmacies with an effective process for resolving below-cost payments from pharmacy benefit managers, patients are assured that local pharmacies are stable businesses they can count on to provide prescription medications as needed and reliable access to a local pharmacist.

Establish Ground Rules for Fair Pharmacy Audits

Establishing standard pharmacy audit protocols in state law benefits patients by optimizing the time pharmacists are available to them. A pharmacist's professional time is best spent verifying prescriptions, checking patient profiles for allergies and drug interactions, preventing patient harm, preparing medications, answering questions, counseling patients, and consulting with providers.

Today's audits can distract pharmacists from their professional duties and dominate the pharmacist's time and attention, to the detriment of patient care. Until state law is changed, unstandardized audits will continue to rob patients of pharmacists' valuable time and attention.

As in other states that lack such laws, pharmacies in New York can be overwhelmed by unrealistic demands, unreasonable criteria and audit practices that are clearly excessive, prejudicial and unfair. Not every pharmacy audit is abusive, but without standard audit protocols, the possibility does exist.

Codifying fair pharmacy audit practices in state law is a way to ensure that New York's pharmacies can deliver patient-focused care and operate at maximum efficiency.

⁶ Moore MS, Gary, Bri Morris PharmD, and Jacob Painter PharmD, MBA, PhD. "Addressing Medication Non-Adherence Through Implementation of an Appointment-Based Medication Synchronization Network." Arkansas Report (2015): n. pag. Web. 19 Dec. 2016. <<http://ncpa.co/uploads/Arkansas-Report-Final.pdf>>.

PROTECT PATIENTS FROM THE HIGH COST OF PRESCRIPTION MEDICATIONS

Governor Cuomo's proposal to protect New Yorkers from soaring prescription drug prices recognizes that drug prices, especially branded and specialty drugs, have increased at exorbitant rates throughout the nation. Even drugs that have been available at low prices for decades are experiencing unjustified and sudden price spikes. One of the most publicized examples of this is the recent spike in the cost of the EpiPen, which has shot up in price by 500 percent since 2007.

This rapid rise in drug prices has forced New York taxpayers to subsidize a \$1.7 billion drug-related cost increase in the Medicaid program over the last three years and it places a heavy burden on businesses. The cost of drugs has been the biggest driver of premium rate increases for New York's commercial insurance market. In 2015, pharmacy expenses were 26 percent of total premiums in New York, significantly greater even than in-patient hospitalization which represented only 18 percent of total premiums. Perhaps most importantly, high prices for prescription drugs prevent families from accessing life-saving medicine. Approximately 77 percent of Americans currently say they cannot afford their prescriptions and have chosen to forgo taking their medications because of their price.⁷

When people are hit with higher drug costs, they are more likely to take unhealthy measures such as skipping doctor appointments, tests, or procedures, or not filling their prescriptions or taking them as directed.



Several initiatives would assist in creating more drug pricing transparency in New York State:

Patient Protection from Clawbacks

According to a recent report from Kaiser Health News, at the pharmacy counter, patients pay their share of the cost — the copay—as set by their pharmacy benefit manager (PBM) and insurance plan. Days or weeks later, the PBM firm takes back a portion of that patient payment from the pharmacy after the PBM determines what it will actually pay for the drug — a practice sometimes called a “clawback.” That money does not necessarily go to the patient, but is generally kept by the PBM. This model has the patient directly improving the bottom line of the PBM with no additional benefit to the patient's healthcare.

This initiative:

- Protects the patient from paying more for the drug than the dispensing pharmacy's everyday retail cash price;
- Promotes transparency in drug pricing; and
- Deters excessive co-payment charges to the patient.

This represents an effort to restrict the unfair business practices of Pharmacy Benefit Managers, from charging patients co-payments that are higher than what the pharmacy is reimbursed.

Transparency/PBM as a Fiduciary

Initially, pharmacy benefit managers (PBMs) were put into place to create a streamlined, transparent process for adjudicating

pharmacy insurance claims. Over time, that role has expanded to include managing formularies, designing drug benefit plans, negotiating prices and manufacturers' rebates, providing drug utilization reviews and creating and maintaining pharmacy networks. While the role of the PBM has expanded, oversight and regulation of these middlemen have not.

Pharmacists have long experienced the inappropriate business practices of PBMs such as improper audits, unfair, inconsistent and non-transparent reimbursement rates, and improper use of patient information — which have fueled the recent growth and profits of PBMs on the backs of taxpayers, patients and community pharmacies at the expense of patient choice and privacy. The net result is a lack of access for patients to their local pharmacy and healthcare providers and the critical services that they provide.⁸

Recent reports and ongoing investigations suggest that PBMs have played a significant role in escalating drug prices by demanding higher and higher rebates for formulary placement. By redefining PBMs as fiduciaries, their profit motive would be limited and drug price inflation could come under better control.

Regulating the business practices of the intermediaries in the drug supply chain will have an impact on drug pricing for the patient, and the payor, i.e., state and local governments, self-insured unions and employers, health plans, as well as, provide protection from unfair practices for community pharmacies.

⁷ Cuomo, A. “Governor Cuomo Presents 33rd Proposal of the 2017 State of the State: Protect New Yorkers from Soaring Prescription Drug Prices through a Groundbreaking Three-Pronged Approach”. 2017. Web. 12 Jan. 2017. <<https://www.governor.ny.gov/news/governor-cuomo-presents-33rd-proposal-2017-state-state-protect-new-yorkers-soaring-prescription>>.

⁸ Wiesner, D. “Time to stop inappropriate PBM business practices.” The Hill. N.p., 2016. Web. 13 Jan. 2017. <<http://thehill.com/blogs/congress-blog/healthcare/321635-time-to-stop-inappropriate-pbm-business-practices->>>

PROTECT THE SAFETY OF PATIENTS

The safety of pharmacy patients is paramount. Considerable state and federal laws and regulations ensure the security and safety of medications from the point of manufacture to the ultimate user, the patient. In November of 2013, the United States Food and Drug Administration (FDA) began implementation of the Drug Supply Chain Security Act (DSCSA) — a ten-year plan that will result in an electronic, interoperable system to identify and trace prescription drugs as they are distributed in the United States. Included in the program are controls such as a national pharmaceutical track and trace system and establishing national standards for licensing of prescription drug wholesale distributors and third-party logistics providers.

In addition, in New York, the State Board of Pharmacy licenses and oversees the continuing education requirements of pharmacists; regulates entities that manufacture, distribute and dispense prescription drugs and prescription devices (i.e. manufacturers, wholesalers, repackers and pharmacies.) Many wholesale distributors in New York State are also Verified-Accredited Wholesale Distributors (VAWD) accredited by the National Association of Boards of Pharmacy (NABP). To become VAWD-accredited, facilities must undergo a criteria compliance review, which includes: a rigorous review of their operating policies and procedures; licensure verification; a survey of a facility's operations; and screening through the NABP Clearinghouse.⁹

New York State has implemented several measures of its own to ensure the public's safety including I-STOP legislation which introduced the Prescription Monitoring Program (PMP) Registry and mandatory e-prescribing. New York State also requires pharmacies to track sales of over-the-counter (OTC) cold and allergy medications containing precursors to the illegal drug, methamphetamine.

The multitude of regulations has developed as the safety needs of the patient and community have evolved. The bills outlined here add another level of protection for New York State pharmacy patients.

⁹ NABP. "VAWD: Contributing to a Safe Wholesale Distribution Supply Chain." National Association of Boards of Pharmacy. N.p., 2016. Web. 19 Dec. 2016. <<https://nabp.pharmacy/programs/vawd/>>.

Strengthen Patient Protections Against Mandatory Mail Order for Prescription Drugs

Despite the passage of a No Mandatory Mail Order Insurance law in 2012, patients are still being forced into mandatory mail programs when they express a clear preference to obtain their prescriptions from a local pharmacy with the added benefit of direct access to a NYS-licensed pharmacist for consultation, advice and support.

Many of the most vulnerable patients report that their medications arrive damaged, lack the required refrigeration or do not arrive at all. They experience difficulty accessing counseling, suffer from decreased privacy, or delays in starting prescription drug regimens. While mail order may work for some patients, it doesn't work for all.

More important to some patients, wellness centers, hospitals, clinics and physician offices are increasingly developing close collaborations with pharmacists in community pharmacies, creating patient-centered care teams with benefits for both the clinicians and their patients. Pharmacists are easy to reach in non-threatening environments. They respond to time sensitive demands, provide special packaging, ensure that products are handled safely and offer timely support and guidance to patients with challenging medical conditions.

State laws should protect patient choice and allow patients who are managing chronic medical conditions to maintain optimal levels of health. Such laws maintain quality of life for individuals and benefit society by helping to control healthcare costs.

Recognize Registered and Certified Pharmacy Technicians

New York is one of only four states that do not require the individuals who are directly assisting licensed pharmacists in the dispensing of prescription drugs to be identified and regulated by state authorities. As a matter of public safety, the individuals behind the pharmacy counter who are not licensed pharmacists but who, under the supervision of the pharmacist, are authorized to modify prescription records and also have access to prescription drugs should be under the direct disciplinary authority of the Office of Professional Discipline at the NYS Education Department. Official recognition of pharmacy technicians is an important step toward preventing diversion and theft, thereby improving the security of the drug supply and inventory in the state's pharmacies.

Recognizing pharmacy technicians for their importance in the handling of prescription drugs under the supervision of licensed pharmacists is a key aspect of protecting public health and safety.

CONCLUSION

The Pharmacists Society of the State of New York's mission is to improve patient care and the overall public health of the communities they serve. The Pharmacy Patient's Right to Care will provide the New York pharmacy patient sustainable access to medications, vaccinations, and counseling in a timely, convenient manner and at an affordable cost.



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