THE PHARMACY PATIENT’S RIGHT TO CARE

The Pharmacists Society of the State of New York
2019 LEGISLATIVE AGENDA

PSSNY
Pharmacists Society of the State of New York, Inc.
THE PHARMACY PATIENT’S RIGHT TO CARE
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 27,000 licensed pharmacists in New York State. PSSNY’s mission is to serve New York pharmacists and the profession of pharmacy with advocacy and resources to improve patient care and public health.

Pharmacists are the second most trusted profession according to a 2017 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 they serve. It is critical to public health that access to local pharmacists and access to appropriate medication at an affordable price be protected.

Impact of Pharmacy Benefit Managers
Recent vertical integrations between pharmacy benefit managers and health insurers (CVS Health/Aetna Inc., Express Scripts/Cigna) raise several questions regarding the impact on patient access to local pharmacies, network adequacy, formulary construction, and medication costs.

A recent Council of Economic Advisers, Reforming Biopharmaceutical Pricing at Home and Abroad, found that just three pharmacy benefit managers (PBMs) account for 85% of the market. This significant market dominance allows pharmacy benefit managers to exercise undue market leverage and generate outsized profits for themselves. As a result, community pharmacies have very little negotiating power and are routinely forced to accept take-it-or-leave-it contracts to be part of the PBM’s pharmacy network. In some cases, even if a pharmacy is willing to accept onerous contract terms, the PBM will simply exclude pharmacies from their networks altogether, limiting patient access and choice.

In addition, PBMs structure pharmacy benefits in ways that direct or incentivize patients into certain pharmacies. For example, as of January 1, 2019, CVS Caremark forced patients on maintenance medications into a 90-day supply that would only be covered if it was dispensed by a CVS retail pharmacy or CVS mail order pharmacy. Any patient choosing another option (quantity or pharmacy) is required to cover the full cost out-of-pocket.

Any entity that controls the healthcare benefit as well as the prescription drug benefit will inevitably give patients less control over choice, access and costs, and therefore must be regulated.

The Pharmacists Society of the State of New York proposes the following agenda to optimize the practice environment of pharmacists with concurrent benefits to patients and the quality of patient care. These objectives will help assure consistent access to safe, timely healthcare for our communities.

License and Regulate PBMs
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.

Recent reports and ongoing investigations suggest that PBMs have played a significant role in escalating drug prices by demanding higher and higher rebates in exchange for formulary placement. By regulating PBMs, 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.

2 CVS Caremark letter to patients regarding maintenance medications dated September 27, 2018
Millions of Americans lack adequate access to primary healthcare and this provider shortfall is only expected to widen as our population ages. Over the next two decades, the number of Medicare enrollees is expected to grow from roughly 50 million to over 80 million. 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. 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 2016 State of the State Address, it is estimated that over 2.7 million New Yorkers would lose health coverage if the PPACA is repealed. Although it has not been completely repealed, the individual mandate penalty has been eliminated as of January 1, 2019, and is one of a number of factors that will impact individual coverage in the coming years. 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.

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

In the fall of 2017, a major pharmacy benefit manager (PBM) drastically reduced reimbursement on generic medications that threatened the viability of community pharmacies and their ability to maintain inventory. Through its unprecedented and unilateral decision to underpay pharmacy providers, the PBM recklessly and needlessly put the health of patients in jeopardy. For no reason other than its desire for profit, the PBM created patient access problems without regard for how its actions would affect the clinical and financial wellbeing of patients. During this crisis, the PBM blatantly disregarded the MAC appeals law and pharmacies struggled to hold them accountable. While progress and improvements have been made, providers have not been able to recoup the lost dollars and amendments are needed to strengthen provisions of current law so 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 healthcare provided by local community pharmacists; 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 supply prescription medications promptly and provide reliable access to a local pharmacist.

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Expand Immunization Authority for Pharmacists

The New York State Public Health and Health Planning Council is updating its *Prevention Agenda 2013-2018: New York State’s Health Improvement Plan* for the next six years. The Committee has updated the vision for the Prevention Agenda and committed to maintaining the current priorities to improve the health of New Yorkers in five priority areas and to reduce health disparities for racial, ethnic, disabled and low socioeconomic groups, as well as other populations who experience these care gaps. Focus Area 2 of the blueprint targets preventing vaccine-preventable diseases, including:

- Decreasing the burden of pertussis disease;
- Decreasing the burden of influenza disease;
- Increasing the number of providers who offer pneumococcal vaccine to adults;
- Decreasing the burden of disease caused by human papillomavirus; and
- Increasing 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 influenza 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 14,000 pharmacists have completed the additional requirements to become certified.

In 2018, interns were given the authority to immunize under the supervision of a certified pharmacist and the pharmacists’ authority was expanded to allow vaccination of children aged 2 and older for influenza.

**Remove Sunsets and Add All CDC-Recommended Vaccines for Adults**

The right to Pharmacists’ authority to administer immunizations sunsets July 1, 2020. If this is not addressed this session, pharmacists will be unable to order vaccines for the 2020 influenza season. To support the Department of Health’s plan to increase access to immunizations, the following should be implemented:

- Authorize pharmacists to administer all Centers for Disease Control and Prevention (CDC) recommended adult immunizations;
- Remove 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
- Make the statute permanent.

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Comprehensive Medication Management

As healthcare becomes increasingly patient-centered, there is a new focus on measuring the quality of care. Many quality standards involve the appropriate use of medications and their effectiveness in terms of therapeutic outcomes. Pharmacists are uniquely qualified in this regard and well positioned in community pharmacies throughout the state. In the Medicaid program, Comprehensive Medication Management (CMM) is an official Health Department recommendation as a component of Medicaid Redesign. CMM is a medication management service provided by a qualified pharmacist pursuant to a written protocol from a physician who is treating a patient for a chronic disease or diseases. Such a physician would have the option of referring a patient for CMM services when the physician determines that the patient has not met the clinical goals of therapy, is at risk for hospitalization, or would otherwise benefit from additional support in the appropriate use of prescribed medications.

These amendments to the public health law and education law:
- Specify pharmacists’ qualifications to enter into CMM protocol agreements;
- Authorize physicians to enter into voluntary CMM protocol agreements with qualified pharmacists and to refer patients they are treating;
- Authorize qualified pharmacists to enter into voluntary CMM protocol agreements and to implement the terms of the agreements by serving as a lawful agent of the physician; and
- Describe the limitations of written protocol agreements.

Patients who receive additional support from a pharmacist in the appropriate use of prescribed medications achieve positive clinical results and are on a path to maintain quality of life with chronic disease.

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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 non-invasive 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 blood glucose levels and cholesterol levels; and
- Screen for the presence of drugs.

Laws in most states permit pharmacists to perform FDA-approved CLIA-waived tests consistent with manufacturer’s test instructions.

Patients would benefit from a bill that would:
- Add pharmacists to the list of licensed healthcare providers performing routine CLIA-waived tests; and
- Authorize the Commissioner of Health to develop the list of CLIA-waived tests available from qualified pharmacists.

Expanded patient access to CLIA-waived tests would improve the management of patient outcomes by delivering important health status information in a timely manner.

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 the establishment of 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 operating policies and procedures; licensure verification; a survey of a facility’s operations; and screening through the NABP Clearinghouse.7

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 electronic 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.

These layers of regulations have 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.

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.

CONCLUSION

The Pharmacists Society of the State of New York’s mission is to improve patient care and overall public health. The Pharmacy Patient's Right to Care will provide the New York pharmacy patient sustainable access to medications, vaccinations, and counseling – all provided by trusted pharmacists at an affordable cost.

As healthcare delivery is transformed, it is critical that state laws keep pace to ensure that patients continue to have access to care and medications in the best possible environment. To this end, PSSNY’s other areas of interest include, but are not limited to:

- Recognition of Pharmacy Technicians
- Telepharmacy
- Medication Synchronization
- Authorizing pharmacists to administer injectable medications that treat mental health and substance abuse disorders
- Pharmacogenomics
- Patient consent for medication delivery
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