NEW YORK CHAPTER OF THE AMERICAN SOCIETY OF CONSULTANT PHARMACISTS

LEGISLATIVE ISSUES IN NYS AFFECTING PHARMACY
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Objectives

At the completion of this program, the participant will be able to:

- Describe the 2017 NYS budget proposal and the potential impact on pharmacies and pharmacists in New York State;
- Describe the status of pharmacist immunizers and the proposed changes to expand the program to add all CDC recommended vaccines for adults and allow pharmacy interns to immunize;
- Discuss the current regulations for automated dispensing systems in NY and the January 2017 letter from PNE;
- Discuss the proposed legislation to register and/or certify technicians in NYS and how it may impact pharmacy workflow.

Legislative issues in NYS affecting pharmacy

- Medicaid reimbursement proposed 2017
- Comprehensive Medication Management (CMM)
- Expand immunization authority for pharmacists
- Simple Lab Tests – CLIA Waived Testing
- E-prescribing waiver for LTC
- Automated Dispensing Systems in NY
- Controlled Substance Fact Sheet
- Recognize registered and certified pharmacy technicians
- Medication synchronization
- Improve the appeals process for Medicaid cost reimbursement for generic drugs
- Fair pharmacy audits
- Patient Protection from Clawbacks
- PBM Registration and Licensure
Proposed new Fee For Service (FFS) payment formula:
- Professional Fee: $10
- National Average Drug Acquisition Cost (NADAC) for brands and generics
- For brand drugs without NADAC, lower of Wholesale Acquisition Cost (WAC) \( \times 3.3\% \) or Usual & Customary Price (U&C)
- For generics without NADAC, lower of WAC \( \times 17.5\% \), Federal Upper Limits (FUL), State Maximum Allowable Costs (SMAC) or U&C
- Co-pays: Reduced to $2.50 for Brands
- OTC’s: Covered if the product is on the CMS list

**MEDICAID BUDGET 2017**

As of March 17th, both houses have rejected the DOH’s proposal, but do not agree on the replacement details. The Assembly retains the $10 dispensing fee and the Senate has proposed a $12 dispensing fee, neither of which is sustainable for pharmacies and patients will lose critical access to medications.

**GOVERNOR’S BUDGET PROPOSAL 2017**

**COMPREHENSIVE MEDICATION MANAGEMENT (CMM)**

- Amends Public Health Law
- Authorizes a qualified pharmacist to modify a patient’s drug regimen following a specific written protocol from the patient’s physician.
- A qualified pharmacist must have completed an ACPE-approved course.
- This proposal was included as an official policy recommendation of the Value-Based WorkGroup. It allows community pharmacists to collaborate with MDs to manage selected patients.
- CMM was included in the Governor’s budget as the request of the DOH to advance the Medicaid reform agenda (Delivery System Reform Incentive Payment known as DSRIP).
COMPREHENSIVE MEDICATION MANAGEMENT (CMM)

UPDATE:
- NYASCP Prepares a Letter of Support for CMM
- Letter of Support sent to Assembly & Senate Chairs of Health & Higher Ed Committees on March 10th
- The language for this proposal was dropped in both the Senate and Assembly budgets. It will likely show up as a stand-alone bill after the budget has been negotiated and we will have another opportunity to work towards passage.

SIMPLE LAB TESTS

- FDA-approved CLIA-waived tests (Clinical Laboratory Improvement Amendments from 1988) must be administered according to manufacturer’s test instructions.
- New York considers any site where CLIA-waived tests are administered, to be a laboratory that is supervised by a qualified Medical Director.
- The Bill proposes:
  - Authorize a licensed pharmacist to qualify as a laboratory director
  - 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

Examples of 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
EXPAND IMMUNIZATION AUTHORITY FOR PHARMACISTS

- 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 to increase adult access to immunizations, the following should be implemented:

- Remove Sunsets and Add All Centers for Disease Control (CDC) Recommended Vaccines for Adults
- Authorize pharmacists to administer all (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
- Make the statute permanent

EXPAND IMMUNIZATION AUTHORITY FOR PHARMACISTS

- 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 underserved areas
- Provides an additional resource for immunizations during a declared emergency
Mandatory Electronic Prescribing

- Effective until 10/31/2017

The Department further acknowledges that, while many nursing homes/residential health care facilities have adopted electronic prescribing, there remain some facilities in which electronic prescribing may not be currently possible due to technological or economic issues or other exceptional circumstances, including a heavy reliance upon oral communications with the prescriber and pharmacy.

I hereby continue to waive from the requirements of electronic prescribing:

1. a practitioner prescribing a controlled or non-controlled substance either through an Official New York State Prescription form or an oral prescription communicated to a pharmacist serving as a vendor of pharmaceutical services, by an agent who is a health care practitioner, for patients in nursing homes and residential health care facilities as defined by PHL § 2801; and
2. a pharmacist serving as a vendor of pharmaceutical services dispensing a controlled or non-controlled substance through an Official New York State Prescription form or an oral prescription communicated by an agent who is a health care practitioner, for patients in nursing homes and residential health care facilities as defined by PHL § 2801.

Automated Dispensing Systems

- On January 13, 2017, BNE issues letter to Class 11 Pharmacy Licensees
- ADS units at Residential Health Care Facilities are approved for emergency medication kits use only.
Controlled Substance Fact Sheet & CMS Opioid Limits

- Pharmacies are required to provide a Controlled Substance Fact Sheet issued by DOH at the time of dispensing.
- Does this apply to pharmacies servicing LTC/RHCF?

From OASAS (Sara Osborne) on January 23, 2017, "We have opined that this requirement does not apply where the pharmacy does not directly dispense the medication to the patient."

From BNE Website:

**Opioid Treatment Guidelines and Other Information for Healthcare Professionals and Patients**

* CDC
  - CDC Guidelines for Prescribing Opioids
  - CDC Guidelines for Prescribing Opioids in the Management of Chronic Pain
  - CDC Opioid Guideline

* ASDH
  - ASDH Guideline for Opioid Prescribing

* BNE
  - BNE Guidelines

**Information for Patients**
- Information regarding prescription opioids, avoiding painkillers, factors, medication and other conditions can be found at the following.
- ASDH Opioid Treatment Guideline

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**FACILITATE SYNCHRONIZATION OF MEDICATION REFILLS**

**What is medication synchronization?**

- Voluntary program initiated by Pharmacists.
- Refills are coordinated to be due the same day each month.

**Legislation would:**
- Require insurers to reimburse pharmacies for an initial partially filled prescription and to prorate the co-payment based on the days' supply.
- Require insurers to pay the 1st professional dispensing fee because the required record-keeping, consultation and associated services are the same regardless of the quantity of medication dispensed.
IMPROVE THE APPEALS PROCESS FOR BELOW-COST REIMBURSMENT FOR GENERICS

- Pharmacy Benefit Managers (PBM’s) are largely unregulated middlemen that manage pharmacy networks.
- In March 2016, a new state law gave local pharmacies a mechanism for recovering amounts due when reimbursement from PBM’s

When state law allows pharmacies to have a mechanism to resolve below cost payments from PBM’s, it:
- 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 pharmacy
- Promotes pharmacy services of consistent quality and reliability

ESTABLISH RULES FOR FAIR PHARMACY AUDITS

- Pharmacists' valuable time is best spent taking care of their patients
- Pharmacy audits can take a considerable amount of time preparing for the audit, during the audit, and collecting information after the audit
- While pharmacy audits are not necessarily abusive, establishing a law that sets ground rules for all pharmacy audits would deter abuse
What is a clawback?
- PBMs take back a portion of the patient copayment from the pharmacy after the PBM determines what it will actually pay for the drug.
- 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.

Patient Protection from Clawbacks

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

PBM Registration and Licensure

- Requires registration by June 1, 2017 with a $1000 fee
- Licensure by January 1, 2019 - $1000 penalty first violation, $2500 penalty for each subsequent violation
PROTECT THE SAFETY OF PATIENTS

AMMO – Anti-Mandatory Mail Order

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.

State laws should:
- Strengthen patient protections against mandatory mail order
- Protect patient's choice

TECHNICIANS – registration & certification
current bills A4841(Englebright)/S1883 (Grifo)

- Would amend the education law by adding new section 6805-a.
- Any individual employed in a pharmacy who directly assists the licensed pharmacist to dispense prescriptions shall be a registered or certified pharmacy technician. This provision shall not apply to individuals employed by a pharmacy who are not directly assisting the licensed pharmacist such as clerks who assist patients picking up prescriptions at point of sale or delivery personnel.

In 2016:
- As of 5-16-16, a4841 referred to higher education committee
- As of 6-8-16, s1883 reported & committed to rules

PHARMACY TECHNICIANS 2016 BILL

- Registered pharmacy technician: Any individual employed in a pharmacy who (a) directly assists the licensed pharmacist to dispense prescriptions or (b) has authority to add or to modify prescription records maintained in the pharmacy computer system and who in addition has access to prescription drugs shall be a registered pharmacy technician.
- A registered pharmacy technician shall fulfill the following requirements:
  - Application: file an application with the department.
  - Education: have received an education including, at a minimum, a high school or a general equivalency diploma (GED) or who is enrolled in a course of study leading toward a high school or general equivalency diploma.
  - Age: be at least seventeen years of age.
  - Character: be of good moral character as determined by the department, which shall include a criminal background check that indicates that the applicant has no drug-related felony convictions and if the applicant has such a conviction, no certificate under article twenty-three of the corrections law has been issued concomitantly or subsequently to the applicant having such conviction.
Fee: Pay a triennial registration fee established in regulation by the board. Such fee shall be maintained in a dedicated fund to support the regulation of the professions by the department.

As a condition of employment as a registered pharmacy technician, an individual shall have a current valid registration as a pharmacy technician issued by the department or shall have completed the application process. Such individual shall provide evidence of registration or evidence that the application has been received by the department.

An individual employed in a pharmacy, as of the effective date of this section, who directly assists licensed pharmacists in dispensing prescriptions and who meets the qualifications set forth in this section for registered technicians with the exception of having a high school or general equivalency diploma who submits evidence verified by his or her employer of a minimum of five years of employment in good standing with the employer may be eligible for a waiver approved by the department in consultation with the state board of pharmacy, upon good cause shown as determined by the department, from the educational requirements herein.

Certified pharmacy technician. Any individual employed in a pharmacy located within a facility licensed in accordance with the provisions of article 28 of the public health law or who is employed by a facility that is engaged in the compounding or preparation of drugs on behalf of facilities licensed in accordance with the provisions of article 28 of the public health law and who (a) directly assists licensed pharmacists in dispensing prescriptions or medication orders, (b) who has authority to add to or modify prescription records maintained in the pharmacy computer system and who in addition has access to prescription drugs and is a certified pharmacy technician. An individual assisting in the compounding of medications under the direct supervision of a licensed pharmacist shall be a certified pharmacy technician in any authorized setting, including, but not limited to, facilities authorized pursuant to section 6831 of this chapter.

A certified pharmacy technician shall fulfill the following requirements:

Application: File an application with the department.

Education: Have received an education, including (i) high school or a general equivalency diploma and (ii) have completed requirements necessary to qualify for and maintain current valid certification status, including continuing education requirements as may apply, from a nationally accredited independent certifying body including but not limited to the Pharmacy Technician Certification Board (PTCB) and the Institute for the Certification of Pharmacy Technicians (ExCPT) or other nationally accredited independent certifying body as may be satisfactory to the department and approved in accordance with the regulations of the commissioner.
PHARMACY TECHNICIAN BILL 2016

- **Age:** be at least eighteen years of age.
- **Character:** be of good moral character as determined by the department which shall include a criminal background check that indicates that the applicant has no drug-related felony convictions and if the applicant has such a conviction, no certificate under article twenty-three of the corrections law has been issued concurrently or subsequently to the applicant having such conviction; and
- **Fee:** pay a triennial registration fee established in regulation by the board. Such fee shall be maintained in a dedicated fund to support the regulation of the professions by the department.

As a condition of employment as a certified pharmacy technician, an individual shall have a current valid certification issued by the department or shall have completed the application process. Such individual shall provide evidence of certification or evidence that the application for certification has been received by the department.

A registered pharmacy technician directly assisting licensed pharmacists to dispense prescriptions who, as of the effective date of this section, is employed in a pharmacy located within a facility licensed in accordance with article 28 of the public health law and who submits evidence, verified by his or her employer, of a minimum of five years of employment within the previous eight years as a pharmacy technician in good standing and who attempted but did not successfully complete the requirements necessary to qualify for certification in accordance with this section may continue to be employed in such pharmacy or facility without being certified in accordance with these provisions, provided that such registered pharmacy technician shall not be permitted to assist in the compounding of medications.

Legislative Issues in NYS Affecting Pharmacy

Acknowledgments:
- PSNY – 2017 Legislative Agenda – “The Pharmacy Patient’s Right to Care”
- Capital Public Affairs – Elizabeth Lasky – PSNY Lobbyist
- Millram Group LLC – PSNY Lobbyists
- DOH Letter issued March 2, 2017
- BNE Website

Illustrations By Andrew Flynn RPh – ACPHS Pharmacy Practice Department
Pharmacy Lobby Day
April 25, 2017
The Egg, Albany, NY

Join us on April 25th to advocate with members, associates and students for the pharmacy patient’s right to care.

Register at PSSNY.ORG