OBJECTIVES

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

- 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.
- Describe the Bill for Comprehensive Medication Management (A8664) and how it may affect pharmacists.
- Discuss the proposed legislation to register and certify technicians in NYS and how it may impact pharmacy workflow.
- Describe the Bill A8661 which would authorize pharmacists to administer injectable drugs that treat mental health and substance abuse disorders.
- Explain the Drug Take Back Law.

PRE-TEST QUESTION #1

Pharmacists ability to immunize will sunset on which of the following dates?

A. 7/1/2019
B. 1/1/2020
C. 7/1/2020
D. 1/1/2021
PRE-TEST QUESTION #2
As part of the new Drug Take Back law, all of the following will be required to take back unused medications from the public EXCEPT:

A. Independent pharmacies
B. Chain pharmacies of 10 or more stores
C. Pharmacy franchises
D. Mail order pharmacies
E. All of the above will be required to take back medications

PRE-TEST QUESTION #3
In the Pharmacy Technician Bill, what is the minimum age for a person to become a registered technician?

A. 16
B. 17
C. 18
D. 15 with working papers

PRE-TEST QUESTION #4
All of the following are components of the CMM bill EXCEPT:

A. Includes any licensed pharmacist in NY
B. Includes any licensed physician in NY
C. Must follow a specific written protocol between physician and pharmacist
D. All of the above are valid components of the bill
Legislative issues in NYS affecting pharmacy

- COMPREHENSIVE MEDICATION MANAGEMENT (CMM)
- EXPAND IMMUNIZATION AUTHORITY FOR PHARMACISTS
- AUTHORIZE PHARMACISTS TO INJECT MEDICATIONS FOR TREATMENT OF MENTAL HEALTH AND SUBSTANCE ABUSE
- RECOGNIZE REGISTERED AND CERTIFIED PHARMACY TECHNICIANS
- MEDICATION SYNCHRONIZATION
- DRUG DISPOSAL in NY
- FAIR PHARMACY AUDITS
- PROTECTION FROM CLAWBACKS & GAG CLAUSES
- ELECTRONIC PRESCRIPTIONS IN LTC UPDATE
- GABAPENTIN - A NEW DRUG CLASS IN NY?

What Made It – Ability for RPhs to Immunize Children 2+ for flu and Sunset Extension

- Pharmacists may immunize children aged 2-18 for flu
- Need standing order specifically for pediatric vaccination/anaphylaxis. This must be issued by a physician or nurse practitioner in your county or an adjacent county. (Same as adult rule.)
- MUST report within 14 days of administration for immunizations for 19 yrs old and younger.
- No consent or opt out for reporting for this age group.
- New York City – report to Citywide Immunization Registry (CIR).
- All others – report to New York State Immunization Information System (NYSIIS).
- Pharmacists will be required to post informational materials to be developed by the Commissioners of Health and Education.
- Immunizer must be certified in pediatric CPR.
- Immunization of children is permitted, NOT required.

Ability for RPhs to Immune Children 2 and Older for Flu

- Need standing order specifically for pediatric vaccination/anaphylaxis. This must be issued by a physician or nurse practitioner in your county or an adjacent county. (Same as adult rule.)
- MUST report within 14 days of administration for immunizations for 19 yrs old and younger.
- No consent or opt out for reporting for this age group.
- New York City – report to Citywide Immunization Registry (CIR).
- All others – report to New York State Immunization Information System (NYSIIS).
- Pharmacists will be required to post informational materials to be developed by the Commissioners of Health and Education.
- Immunizer must be certified in pediatric CPR.
- Immunization of children is permitted, NOT required.
Adult Immunizations
- New sunset for adult immunization bill is July 1, 2020.
- All aspects of adult immunization bill remain in place.
- Need non-patient specific standing order from a physician or nurse practitioner in your county or an adjacent county for each type of vaccine.
- MUST now report vaccination to patient’s primary care provider (PCP) electronically or via fax.
- Continue to report to CIR or NYSISS for patients aged 19+ with patient consent.
- Discuss patient cost of receiving the vaccine at the pharmacy.
- Discuss option to receive vaccine from PCP and importance of having a PCP.
- Vaccinate in a private area.
- Post the most current ACIP recommended adult immunization schedule.
- All vaccines administered via non-patient specific order must follow ACIP guidelines.

Immunization Potpourri
- All non-patient specific standing orders must include orders for medications required for emergency treatment of anaphylaxis resulting from the immunization.
- Vaccine Information Sheet (VIS) must be given with every vaccination.
- Commissioner of Health has the authority to issue a state-wide non-patient specific order in the event of an influenza outbreak or threat.

What Didn’t Make It
PHARMACIST IMMUNIZERS
- Remove sunsets and add all Centers for Disease Control (CDC) recommended vaccines for adults.
- Authorize pharmacists to administer all (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.
- Makes the statute permanent.
What Didn’t Make It

COMPREHENSIVE MEDICATION MANAGEMENT (CMM)

BACKGROUND:

➢ Originally introduced as part of Gov. Cuomo’s 2017 Budget.
➢ In July 2017, DOH Commissioner Zucker asked Pharmacists from PSSNY, NY Chain Assoc to join in roundtable discussion on Community Pharmacy Programs and Interventions to Better Assist Seniors and those with Disabilities in Managing Pharmacy & Other Medical Needs and Navigating Health Care System.
➢ WHY? To prevent hospitalizations for patients that have co-morbid chronic conditions such as diabetes and asthma.

COMPREHENSIVE MEDICATION MANAGEMENT (CMM) A8664-A McDonald/SS7682 LaValle

➢ Amends Public Health Law and Pharmacy Practice section of Education Law to allow written protocol agreements between ‘qualified’ pharmacists and physicians.
➢ Authorizes the pharmacist to be an agent of the MD for prescriptions specifically authorized in the written protocol.
➢ Completely voluntary between the patient, physician and pharmacist.

UPDATE: No movement on this Bill – sponsor is engaging with MSSNY.

What Didn’t Make It

PHARMACY TECHNICIANS BILL

S5584-A (Griffo)/A4611-A (Engelbright)

➢ Pharmacy technicians are individuals who directly assist licensed pharmacists.
➢ Current law refers to pharmacy technicians as "unlicensed persons."
➢ This bill replaces the term with the titles of "registered pharmacy technician" and "certified pharmacy technician," strengthening the Education Department’s jurisdiction over these individuals.
➢ One year after this legislation is enacted into law, every pharmacy technician in New York will be SED-registered or certified.
➢ The legislation defines pharmacy technicians as individuals who have access to prescription drugs and are either directly assisting a licensed pharmacist or have authority to add to or modify prescription records.
PHARMACY TECHNICIANS

Requirements for a registered pharmacy technician are:

- Be at least seventeen years of age;
- Meet good moral character standards established by the Department including a disclosure, under penalty of perjury, of convictions under penal law;
- At a minimum, have completed high school or earned a general equivalency diploma (GED), or be currently enrolled in a course of study leading graduation;
- The legislation authorizes the Education Department to issue registrations to experienced individuals who may not have met the education requirement but who are in good standing with their employer and have been employed as a pharmacy technician for at least five years, including at least eighteen consecutive months with the same employer.

PHARMACY TECHNICIAN BILL

Requirements for a certified pharmacy technician are:

- Meet requirements for registered pharmacy technicians;
- Be at least eighteen years of age; and
- Have completed certified pharmacy technician requirements from a national certifying body acceptable to the department;
- Any technician directly assisting a pharmacist to compound medications in any practice setting must be certified based on the pharmacy mathematics and compounding skills associated with certification.

NYASCP joins FSSNY, NYSCHP, Chain Pharmacy Assoc NY, NY-ACCP Memo of Support for the Technician Bill.


What’s Next – Interns as Immunizers
Authorize Pharmacy Interns to Immunize Adults

Authorizes pharmacy interns who have 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.

- Interns As Immunizers (A-2857-D/S-1043-D) has passed both the Senate and the Assembly last week!
- The next step to becoming a law is the Governor’s signature.
- Interns cannot immunize until the Bill is signed into Law by the Governor before 12/31/18.

What’s Next

Drug Take Back Act

- Program entirely paid for by drug manufacturers
- Pharmacies that have 10 or more stores must provide one of the following for “qualified” medications:
  - ON-SITE COLLECTION, DROPBOX, OR RECEPTACLE MEETING FEDERAL STANDARDS
  - MAIL-BACK COLLECTION BY PREPAID ENVELOPES AS AUTHORIZED BY FEDERAL LAW AND REGULATION OR
  - OTHER FEDERAL DRUG ENFORCEMENT AGENCY APPROVED METHODS OF COLLECTION.

Passed by Senate and Assembly

The next step to becoming a law is the Governor’s signature before 12/31/18.

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.
- Feb 2017, BNE updates their ADS Checklist (Appendix D)
- Nov 2017, NYASCP meets with BNE & BOP to discuss 24 hour lockout and continuous dosing requirements noted in Jan 2017 letter from BNE.
- Jan 2018, NY-ASCP sends “ask” letter to BNE and BOP.
- Follow up emails sent to BNE & BOP (see pdf attachment for updates).
Law of Interest

New York Opioid Stewardship Act
- Purpose: to help battle the opioid crisis
- Requires manufacturers, distributors and importers to report transactions of opioids going back to 1/1/2017.
- BNE will calculate the morphine milligram equivalents from each entity and issue an invoice to each going back to 1/1/2017.
- First payment due 1/1/2019.

Bill of Interest - GABAPENTIN
A10321 McDonald / S8145 Hannon
- Amends Public Health Law to establish a new Schedule VI in NY to authorize the PMP to monitor prescribing and use of gabapentin
- CAN NY RE-CLASSIFY GABAPENTIN as Schedule VI rather than create a new schedule?
- Assemblyman McDonald said when tramadol was rescheduled there were access issues. Wanted it in PMP, but not affecting access

Update: ASSEMBLY: Codes
SENATE: Health Committee

Patient Protection from Gag Clauses & Clawbacks
A8781 Rosenthal/S6940 Hannon
- What is a clawback?
- PBM’s take back a portion of the patient copayment from the pharmacy after the PBM determines what it will actually pay for the drug
- The passage of the New York State Budget resulted in the addition of several laws affecting pharmacy practice as it pertains to PBM contracts. This was the result of a concentrated effort by PSSNY.
- A change to the NY Public Health Law means that gag clauses and clawbacks are now prohibited.
- Pharmacists can now discuss price options with patients
- Less expensive therapeutic equivalents can be discussed
- Alternatives to copays can be offered (including discount cards)
The 2018 New York State budget includes requirements regarding the audit of pharmacy records by PBM’s. These requirements became effective April 1, 2018.

**TIMELINE REQUIREMENTS – ON-SITE AUDIT**
- 15 days prior written notice to pharmacy with delivery confirmation to PBM
- No audits in first 3 days of any calendar month
- Preliminary report to pharmacy within 45 days after audit
- Pharmacy then has 45 days to address discrepancies
- Final report from PBM due within 60 days of the initial report
- PBM must consider reasonable requests for deadline extension from a pharmacy requiring additional time to gather supporting documentation.

**AUDIT PARAMETERS**
- Audit limited to 100 prescriptions (except in fraud cases)
- Can only audit Rx for 2 years after claim submission
- Written notice must include Rx numbers. Last 2 digits may be omitted.
- Payment cannot be denied for unintentional clerical errors that do not result in financial burden, provided the Rx is filled correctly (patient, drug, dose, quantity).
- See PSSNY Website for more detail (www.pssny.org)

**Other Bills of Interest**
- License and regulate PBMs (A10985 Gottfried/S3934 Rivera)
- Strengthen current MAC appeal law (S5623 Hannon/A4717-A Rosenthal)
- Remove barriers in NYS Insurance law that still allow mandatory mail order (S1743 Golden/A3179 Joyner)
- Medication Synchronization in Commercial Insurance (S5195-B Lanza/A4306-B Quat)
- Medication Synchronization in Medicaid (S5622-A Hannon/A7492-A Gottfried)
Other Bills of Interest

- Authorize partial fills of controlled substance prescriptions at the patient's request (S8342 Hannon/A10392-A McDonald)
- Authorize pharmacists to perform CLIA-waived tests (S8960 Griffio)
- Add hepatitis A and B to the list of vaccines available from pharmacists (A9073-A Gottfried/S321-A Robach)

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Acknowledgments and References

PSSNY – 2018 Legislative Agenda – “The Pharmacy Patient’s Right to Care”
Capital Public Affairs – Elizabeth Loary – PSSNY Lobbyist
MIRram Group LLC – PSSNY Lobbyists
BNE Website
NYSED.GOV Website
NYSDEC website www.dec.ny.gov/chemical/108213.shtml
PSSNY Website - www.pssny.org
New York State Pharmacists Century II, Volume 92, Issue 4 – 2018 August
Andy Flynn, RPh– ACPHG – slide enhancements

Questions