NEW YORK CHAPTER OF THE AMERICAN SOCIETY OF CONSULTANT PHARMACISTS

Legislative & Regulatory Issues Affecting Pharmacy in NY – Update October 2019

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LEARNING OBJECTIVES

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

- Explain how the State budget affects the practice of pharmacy in NY and the process for how a Bill becomes a Law in NY.
- 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 proposed legislation to register and or certify technicians in NYS and how it may impact pharmacy workflow.
- Discuss the current regulations in NY for automated dispensing systems and proposed statute change needed to Education Law.
- Discuss the current regulation in NY for disposal of controlled substances in LTCF and how this may change with new “sewer ban” that started in August 2019.
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

In NYS, current law allows Automated Dispensing Machines (ADM) to contain this number of controlled medications and non-controlled medications?

A. Max of 10 controlled drugs, 25 non-controlled oral drugs
B. Max of 7 non-injectable controlled drugs, unlimited non-controlled drugs
C. Unlimited number of both controlled drugs and non-controlled drugs.
D. Max of 10 controlled drugs, unlimited non-controlled drugs
E. None of the above
PRE-TEST QUESTION #3

As of today, New York State Certified Technicians can reconstitute antibiotic suspensions under the supervision of a NYS licensed Pharmacist?

A. TRUE
B. FALSE
PRE-TEST QUESTION #4

PHARMACISTS IN NYS CAN LEGALLY VACCINATE ADULTS FOR ALL THE FOLLOWING EXCEPT:

A. Measles
B. Pneumococcal
C. Tdap
D. All of the above may be administered by a pharmacist in NY.
Legislative & Regulatory issues in NYS affecting pharmacy

AUTOMATED DISPENSING SYSTEMS IN NY
RECOGNIZE REGISTERED AND CERTIFIED PHARMACY TECHNICIANS
EXPAND IMMUNIZATION AUTHORITY FOR PHARMACISTS
AUTHORIZE PHARMACISTS TO INJECT MEDICATIONS FOR TREATMENT OF MENTAL HEALTH AND SUBSTANCE ABUSE
CLIA WAIVED TESTING BY PHARMACISTS
DRUG TAKE BACK
DRUG DISPOSAL in NY
GABAPENTIN – A NEW DRUG CLASS IN NY?
The Legislative Process in NY

- Legislature is in session January – June
- January – March 31 focus is on the State budget
- April 1 – June is called End-of-session with focus on bills without a fiscal impact
The Budget Process in NY

- Starts in September with Governor's goals/initiatives communicated to the State agencies
- Governor’s Budget is released in January
- The Senate and Assembly analyze the Governor’s budget
- Budget Hearings inform the legislature of the Governor’s plans and the public’s reactions
- Senate and Assembly each develop their own budgets in early March
- The Senate, Assembly and Governor negotiate a final budget
- All 3 budgets will be negotiated into one common budget
- By law, it must be a balanced budget
- Must be in place by April 1
End-of-session – After Budget Passes

- Senate and Assembly consider legislation that does not have a fiscal impact.
- Policy issues that did not survive budget negotiations can now be introduced as individual bills.
- Approximately 15,000 bills are introduced each session.
- Average of 1,000 bills are passed by the Senate and Assembly.
- Every type of legislation is considered: scope of practice, environmental, infrastructure, labor, etc.
Where to find Pharmacy Laws, Rules and Regulations

Pharmacy law is housed in State Education Law

- Article 137, Section 6800
- Commissioner’s Regulations
- Part 52.29 and Part 63
- Regents Rules
- Parts 24, 28 and 29
- Laws and Regulations Specific to Pharmacy:
  http://www.op.nysed.gov/prof/pharm/pharmlaw.htm
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 June 4th requesting update.
- Nov 2018 – Met with BNE, NYS DOH NH Surveillance, NYSHFA, Leading Age, BOP
- **Legislative Change Needed in Education Law**
AN ACT to amend Section 1. Subdivision 1 of section 6802 of the education law, in relation to permitting pharmacies to store prescribed medications in automated dispensing machines

“A PHARMACY REGISTERED BY THE DEPARTMENT, AND BASED UPON A CONTRACTUAL ARRANGEMENT WITH A NURSING HOME OR RESIDENTIAL HEALTH CARE FACILITY AS DEFINED IN SECTION TWENTY-EIGHT HUNDRED ONE OF THE PUBLIC HEALTH LAW, MAY STORE PRESCRIBED MEDICATIONS AT SUCH FACILITY IN AN AUTOMATED DISPENSING MACHINE AND DISPENSE SUCH MEDICATIONS FOR THE SOLE USE OF THE FACILITY'S RESIDENTS.”
June 10, 2019

Attention NY-ASCP Members: **WE NEED YOU TO TAKE ACTION NOW!!!**
**THE LEGISLATIVE SESSION ENDS NEXT WEEK!!**

The Senate Bill S.6011 has advanced to its third reading and is on the Senate calendar ready to be voted on.

The Assembly Bill A.7806 has been referred to the High Education Committee and Assemblywoman Glick is the Chair of this committee.

**WE NEED YOU TO CONTACT ASSEMBLYWOMAN GLICK AND ASK HER TO ADD A.7806 TO THE NEXT HIGHER EDUCATION COMMITTEE MEETING AGENDA.**

**UPDATE:** Did not make it to either floor for a vote due to SED questions. NYSHFA having good dialogue with SED, but original BILL may need to be amended.
Permissibility of Stocking Multi-Dose Liquid Products in the eKit

Nothing in DEA’s Statement of Policy titled Controlled Substances in Emergency Kits for Long Term Care Facilities (45 Fed. Reg. 24128) restricts any particular formulation of a controlled substance from being placed in an EKit. Therefore, a liquid multi-dose formulation of a controlled substance may be placed in an EKit if the appropriate state agency or regulatory authority permits.

BNE response to inquiry: refer to 415.18 related to ekits

Prescription Requirements to Remove Medication from the eKit

DEA clarified that while verbal CII prescriptions issued pursuant to 21 CFR 1306.11(d) may be used to dispense a controlled substance from the EKit, it is not the only condition that would allow for the removal of a medication from the EKit. The letter indicates the prescription needs to be in compliance with 21 CFR 1306.11 or 21 CFR 1306.21 (the requirements of a prescription for CII and CIII-CVs).

NY?? BNE concurs with DEA
ASCP DEA UPDATE

"Splitting" a Prescription between the eKit (initial doses) and the Pharmacy (subsequent doses)

In the letter, the agency writes, "DEA has reviewed the information the ASCP has provided and is in agreement with the ASCP that the [practice of authorizing the initial doses of a medication from the eKit and sending the remaining doses from the pharmacy] does not conflict with the CSA or its implementing regulations, and may contribute toward good patient care."

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NY???
Ability for RPhs to Immunize Children 2 and Older for Flu

- Pharmacists may immunize children aged 2-18 for flu signed into Law 2018.
- 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 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**.
- Need non-patient specific standing order from a physician or nurse 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.
- A certified pharmacist who meets the requirements of this section shall be authorized to administer to patients 18 years of age or older, immunizing agents to prevent **influenza, pneumococcal, acute herpes zoster, meningococcal, tetanus, diphtheria or pertussis disease**, pursuant to a patient specific order or a non-patient specific order.

**For 2019:**  
S.5727 May/ A. 6511 Paulin

- Remove Sunsets and Add All Centers for Disease Control (CDC) Recommended Vaccines for Adults.
- Authorize pharmacists to administer **ALL** (CDC) recommended adult immunizations.
Authorize Pharmacy Interns to Immunize Adults
A2857 McDonald/S1043 Funke

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

* The Bill was signed into Law by the Governor on 12/7/18*

Interns may now submit applications for Immunization Certification

College deans or appropriate faculty officials will need to attest to completion of the required training

Once SBOP enters the intern into the system, a "U" certification will appear the next day on the License Verification Search website and the intern will receive an updated permit in the mail.

Be sure to add interns to any standing orders you have and update the physician/nurse practitioner authorization signatures accordingly.
The Bill defines the practice of registered technicians in Article 28 facilities ONLY.

- Allows the registered techs to assist in compounding activities.
- Increases the ratio of unlicensed persons to pharmacists from 2:1 to 4:1.
- Adds 2 registered technicians to the NYS Board of Pharmacy.
- Has not yet been called for by the Governors office.
SAFE DRUG DISPOSAL of CONTROLLED SUBSTANCES

https://www.health.ny.gov/professionals/narcotic/safe_disposal/

Safe Disposal of Unused Controlled Substances by Consumers

The Drug Enforcement Administration (DEA) has revised its regulations to expand the options available to collect controlled substances from ultimate users for purpose of disposal, including: take-back events, mail-back programs and collection receptacle locations.

Recent New York State (NYS) legislation, Chapter 379 of the Laws of 2015 (S. 3687/A. 8082), removed the requirement that the Commissioner of Health must designate pharmacies as disposal sites and added that disposal shall be operated by law enforcement agencies, pharmacies, “and other Federal Drug Enforcement Administration authorized collectors.” This legislation also removed the requirement that the Commissioner of Health make regulations in consultation with the Commissioner of Education to allow for entities to participate in expanded activities under federal rule.

Accordingly, the NYS Department of Health, Bureau of Narcotic Enforcement authorizes all activities allowed under the federal DEA’s Disposal of Controlled Substances Final Rule. Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with and on-site pharmacy and retail pharmacies may apply directly to the DEA for registration as a "Collector". For more information, click on the following links:

- Drug Disposal Information (usdoj.gov)
- National Prescription Drug Take Back Day: The National Prescription Drug Take Back Day occurs twice a year. Once in the spring and once in the fall. If you are a long-term healthcare facility that wishes to participate in the Federal DEA’s National Prescription Drug Take Back Day, please email your request to bredestruction@health.ny.gov.

Please note: current NYS Regulations under 10 NYCRR 80.51 related to surrender and disposal of controlled substances remain in effect.

- Guidance for Long-Term Care Facilities (LTCF) and Other Class 3A Institutional Dispenser, Limited Facilities (Class 3A Licensees) (PDF)
- Guidance for Law Enforcement Agencies Seeking to Collect and Dispose of Prescription Controlled Substances
  - Law Enforcement Collection Guidelines for the Surrender and Safe Disposal of Prescription Controlled Substances (PDF)
  - New York State Medication Drop Box Program Participation Memo (PDF)
  - New York State Medication Drop Box Program Statement of Agreement (PDF)
- Medication Drop Boxes by County
- Reverse Distributor List (Surrender to Independent Companies)
- Request for Approval of Disposal/Destruction of Controlled Substances (Important Note: Class 3A facilities only. DEA Registrants must see Reverse Distributor List or DEA Website)
- Guideline for "Waste" Disposal System Use (PDF)
SAFE DRUG DISPOSAL of CONTROLLED SUBSTANCES

https://www.health.ny.gov/professionals/narcotic/safe_disposal/

Request for Approval of Disposal/Destruction of Controlled Substances

- Instructions for Disposal/Destruction of Controlled Substances (PDF, 48KB, 2pg.)
- Request for Approval of Disposal/Destruction of Controlled Substances (DOH-2340) (PDF, 34KB, 1pg.)
- Controlled Substance Inventory Form (DOH-168) (PDF, 38KB, 1pg.)
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

Signed into Law by Gov Cuomo
DRUG TAKE BACK PROGRAM IN NEW YORK STATE

https://www.health.ny.gov/professionals/narcotic/drug_take_back.htm

Important Notice - Action Required by July 5, 2019

Important Notice to Manufacturers and Organizations Intending to Submit a Proposal to Operate a Drug Take Back Program in New York State

Pursuant to Chapter 120 Laws of 2018, the New York State Drug Take Back Act (DTB) mandates that manufacturers establish, fund, and manage a New York State approved drug take back program(s) for the safe collection and disposal of unused covered drugs. Pharmacies of ten or more establishments within NYS and non-resident pharmacies that provide covered drugs to NYS residents by mail must implement such programs by providing consumers with a pre-approved method(s) of collection and disposal, free of charge to the consumer and pharmacy.

Chapter 120 Laws of 2018 states:

- DTB takes effect on January 1, 2019.
- On or before February 5, 2019, wholesalers must provide a list to the Department of Health (DOH) of manufacturers that produce covered drugs sold in New York State.
- On or before July 5, 2019, manufacturers or organizations contracted by manufacturers must submit drug take back program proposals to DOH.
- DOH, in conjunction with the Department of Environmental Conservation (DEC), will approve or deny proposed drug take back programs within 60 days of receipt.
  - If program proposal is not approved, the applicant has 30 days to submit an amended proposal.
  - If the subsequent proposal is rejected, the manufacturer(s) shall be out of compliance with DTB.

More Information:

- Drug Take Back Act Notification Letter to Wholesalers – February 2019 (PDF)
- Chapter 120 Laws of 2018 – Drug Take Back Act (PDF)
- Wholesaler Data Submission – File specifications (PDF)
- Drug Take Back Act Overview (PDF)
Bill of Interest - **GABAPENTIN**

**A.3823 McDonald / S.3906 Rivera**

- 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

Currently in Senate Health Committee and Assembly Codes
COMPREHENSIVE MEDICATION MANAGEMENT (CMM)
A3849 McDonald/S5296 Breslin

2019:

- 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 2019:

Currently in Assembly Higher Ed Committee
License and Regulate PBMs (A2836-A/S6531) - PASSED

- Creates PBM oversight to both the Health Department and the Department of Financial Services (DFS).
- Requires PBMs to register with DFS by April 1, 2020 and to be licensed by January 1, 2021 in order to operate in New York;
- Requires PBMs to eliminate conflicts of interest, deceptive and anti-competitive practices, conduct fair audits and process claims fairly;
- Requires PBMs to disclose contract terms (including rebates and pharmacy dispensing fees) under penalty of perjury;
- Prohibits PBMs from imposing accreditation or certification requirements on network pharmacies that go beyond state laws or regulations;
- Requires PBMS to respond to all questions and inquiries promptly and under penalty of perjury; and
- Gives any patient or pharmacy harmed by the actions of a PBM to sue the PBM.
Other Bills of Interest

- Medication Synchronization in **Commercial Insurance**
  (S4078 Breslin/A3009 Quart) - PASSED

- Medication Synchronization in **Medicaid** (S3118A Hoylman/A2785A Gottfried) - PASSED

- Authorize partial-fills of controlled substance prescriptions at the patient’s request (S1813 Rivera/A3918 McDonald) - PASSED

- Authorize pharmacists to perform CLIA-waived tests (S5092 Rivera / A3867 McDonald)

- Extends the exemption from ERx mandate for prescriptions ordered for NH residents. Extends waiver to March 2021. (S4183 Rivera/A01034-A Gottfried)
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Acknowledgments and References

PSSNY – 2019 Legislative Agenda – “The Pharmacy Patient’s Right to Care”
MIIRram Group LLC – PSSNY Lobbyists
RM&S - NY Chain Assoc Lobbyists
BNE Website
NYSED.GOV Website
NYS DEC website www.dec.ny.gov.chemical/108213.html
PSSNY Website - www.pssny.org
NYS Assembly website
NYS Senate website
ASCP DEA Update – ASCP Website
New York State Pharmacist Century II, Volume 92, Issue 4 ~ 2018 August
Andy Flynn, RPh– ACPHS – slide enhancements
Questions