

# Review of Maine Pharmacy Rules

An update of new rules adopted 12/11/2013

- ▶ This review is meant to highlight important changes and additions to the rules as adopted on 12/11/2013.
- ▶ We will cover the rules and changes that impact the practice of pharmacy on a day to day basis. We encourage everyone to read the rules frequently to familiarize yourself so that we all can avoid behavior that may be detrimental to our profession.

# Chapter 1

## New Definitions

- ▶ Some definitions have been deleted because they have become obsolete. Any reference to drug outlet is changed to pharmacy. *[Note: Not all Chapters were involved in the recent rule revisions and may still use the term “drug outlet.”]*
- ▶ **Affiliated** - the relationship between a hospital, nursing facility, or SNF.
- ▶ **Closed Shop Pharmacy**- purchase and dispense drugs to a limited patient population.
- ▶ **Direct Supervision**- activities performed by a technician or intern during the pharmacist’s short term absence from the workplace.

# Chapter 1 cont'd

- ▶ **Electronic prescription-** a prescription generated as an electronic data file.
- ▶ **Extended hospital pharmacy-** pharmacy owned and operated in a hospital licensed by DHHS and also licensed by the Board.
- ▶ **Non-Sterile Compounding Pharmacy-** Operating under USP 795 for non-sterile compounded products.

# Chapter 1 cont'd

- ▶ **Removal of pharmacy technician advanced designation.**
- ▶ **Retail Pharmacy**-closed shop, sterile compounding, extended hospital pharmacy, opioid treatment pharmacy, medical oxygen.
- ▶ **Sterile Compounding Pharmacy**- compounding pharmacy operating under USP 797.

# Chapter 4

- ▶ The Board encourages a pharmacist to voluntarily notify the Board of the pharmacist's commencement or cessation as employment as a pharmacist.

# Chapter 4-A

- ▶ Vaccine administration references the new law under Title 32.
- ▶ Treatment protocol-if there is a change, you have **20** calendar days to notify the Board of the effective date of the changes.
- ▶ The patient must be at least **18** years of age except for influenza vaccine when the patient must be at least **9** years of age.

# Chapter 4-A cont'd

- ▶ If operating a clinic for administration a one time approval of a written plan must be submitted to the Board at least 30 days prior to running the clinic. Any changes means that a new plan must be submitted.
- ▶ A pharmacy intern may administer vaccines under the direct supervision of a pharmacist that holds a certificate for administration and the intern has obtained the training required.



# Chapter 6

- ▶ Pharmacy student internship programs deleted and moved to a different chapter 6-A.

# Chapter 6-A

- ▶ Goes over all the new rules pertaining to student interns.
- ▶ Qualifications for licensure as an intern
- ▶ Who can be a preceptor to an intern-valid license and 2 years of experience.
- ▶ Non-traditional practice settings can count towards the 1500 hours required to sit for examination.

# Chapter 6-A cont'd

- ▶ Requirements of interns from foreign countries other than Canada.
- ▶ Need to notify the Board within 48 hours if intern is terminated for theft.

# Chapter 7

- ▶ License requirements of technicians and allowed duties of technicians.
  - ▶ Accepting original or renewal
  - ▶ Receipt of transferred prescription for non-controlled drug
  - ▶ Prescription data entry
  - ▶ Drug selection from inventory
  - ▶ Counting, packaging, and labeling

## Chapter 7 cont'd

- ▶ **All the previous duties are to be done solely at the discretion of the pharmacist on duty!**

# Chapter 7 cont'd

- ▶ A pharmacy technician in an institutional setting may perform duties as related to automated dispensing systems under the direct supervision of a pharmacist.
- ▶ **The technician ratio is repealed. The pharmacist and pharmacy are responsible for ensuring that the number of technicians on duty can be satisfactorily supervised!**

# Chapter 7 cont'd

- ▶ The pharmacist in charge is responsible to make sure each technician is licensed with the Board.
- ▶ The PIC must notify the Board within **10** days after commencement or cessation of employment of any pharmacy technician.
- ▶ In case of termination for theft there is a **7** day notice to the Board.

# Chapter 8

- ▶ Licensure of retail pharmacies.
- ▶ Repeal of minimum size requirement of a pharmacy.
- ▶ Other requirements that may be considered when issuing a retail pharmacy license.
- ▶ The pharmacy shall notify the Board when a pharmacist is terminated for drug related reasons or theft.
- ▶ Cosmetic changes to the pharmacy do not require Board approval.



# Chapter 13

- ▶ Operation of retail pharmacies.
- ▶ Pharmacies do not have to report to the Board when closing for holidays.
- ▶ The PIC must make sure that each pharmacist employed is licensed by the Board.
- ▶ Administrative procedures of licensing a PIC at more than one location if OTP, closed shop pharmacy, or sterile compounding pharmacy.

# Chapter 13 cont'd

- ▶ Compounding areas and storage areas must have alarms and cameras as of 7/1/2014.
- ▶ No separate license for non-sterile compounding.
- ▶ Records shall be kept of non-sterile compounded prescriptions.

# Chapter 18

- ▶ This chapter is repealed and covered by Chapter 37 for sterile compounding pharmacies.
- ▶ Non-sterile compounding is covered under Chapter 13, Section 7.

# Chapter 19

## Receipt and handling of prescription drug orders

- ▶ Technicians and interns are allowed to accept original or renewal drug orders as authorized by the pharmacist on duty.
- ▶ Establishes the ability to accept electronic prescriptions for controlled drugs.
- ▶ Acknowledges that a pharmacist has the right to not sell methamphetamine precursor drugs.

# Chapter 20

- ▶ Allows for hospitals to ask for a waiver from all the requirements of Automated Dispensing Systems if they can demonstrate all safety requirements can be achieved by alternate means.

# Chapter 23

- ▶ In disposing of controlled drugs, pharmacies shall comply with 21 CFR §1307.21 entitled “Procedure for Disposing of Controlled Substances” guidance from DEA. DEA has now issued new rules that should be followed.
- ▶ Disposal of non-controlled drugs should follow guidance of the US EPA.
- ▶ Pharmacist shall report any significant theft, loss, or unresolved inventory discrepancy of controlled drugs no later than 7 days after discovery.

# Chapter 23 cont'd

- ▶ What defines “significant”?
  - ▶ Quantity lost in relation to the type of business
  - ▶ Specific drugs lost
  - ▶ Can it be attributed to specific individuals or unique activities
  - ▶ Is it a pattern of losses over a specific time or are they random. What was done to resolve the losses?
  - ▶ Are these drugs that have high potential for diversion?

# Chapter 24

- ▶ Patient profiles shall be maintained for 5 years from date of last entry.
- ▶ Unless otherwise specified all other records must be kept for two (2) years.



# Chapter 25

- ▶ The obligation to counsel at OTP is satisfied as long as there is written information with each new prescription that includes a telephone number that can contact the pharmacist in charge.

# Chapter 29

- ▶ Incorporates by reference certain federal and state laws and regulations establishing practice standards and professional behavior.

# Chapter 30

- ▶ Unprofessional conduct now includes failure to notify the Board within 7 days when terminating a pharmacist for any drug related reason, including theft, abuse, adulteration, or diversion of drugs.
- ▶ Theft of non-drug merchandise.
- ▶ Theft of cash or credit/debit card data.

# Chapter 34

- ▶ Clarifies that a retail supplier of medical oxygen is licensed by the Board of Pharmacy.
- ▶ Discusses the application for licensure and what defines adverse Board actions.

# Chapter 35

- ▶ Defines what is an extended hospital pharmacy
- ▶ Coordinates with DHHS.
- ▶ Describes the authorized patient population that may be dispensed prescription medication from this facility.
- ▶ What information is required on the application for that pharmacy.

# Chapter 36

- ▶ Licensure of Opioid Treatment Programs.
- ▶ Reaffirms licensure by the Board of Pharmacy under Title 32.
- ▶ Also certified by US DHHS.
- ▶ Maine DHHS license.
- ▶ Discusses license application process.
- ▶ Pharmacist in Charge responsibilities, safety requirements, security requirements, record keeping requirements.

# Chapter 37

- ▶ Licensure of sterile compounding pharmacies.
- ▶ Application procedure.
- ▶ Barrier requirements.
- ▶ Security camera requirements.
- ▶ Operational requirements USP 797.
- ▶ This is in response to NECC tragedy!

# Chapter 38

- ▶ Licensure of closed shop pharmacies.
- ▶ The closed shop pharmacy may not be accessible to the public and there must be a physical separation if there are two separate types of pharmacies on the same premises. The records must also be kept separate.



# Questions from presentation

- ▶ What is meant by “direct supervision”?
- ▶ It is a mandatory requirement to notify the BoP of place of employment? True/False
- ▶ How old must a patient be in order to receive an immunization?
- ▶ Can a pharmacy intern administer vaccines? True/False
- ▶ A technician may accept an original Rx from a prescriber. True/False

Any Questions?

The slide features a white background with the text "Any Questions?" in a large, dark grey, sans-serif font. On the right side, there are several overlapping, semi-transparent green geometric shapes, including triangles and polygons, creating a modern, abstract design.