**02-392**

**BOARD OF PHARMACY**

Maine Administrative Procedure Act

2015 - 2016 Regulatory Agenda

AGENCY UMBRELLA-UNIT NUMBER: **02-392**

AGENCY NAME: Department of Professional & Financial Regulation, Office of Professional and Occupational Regulation, **Board of Pharmacy**

**CONTACT PERSON:** Geraldine L. Betts, Board Administrator, 35 State House Station, Augusta, ME 04333, Tel. (207) 624-8625. E-mail: Geraldine.L.Betts@Maine.gov .

**EMERGENCY RULES ADOPTED SINCE THE LAST REGULATORY AGENDA:** None

**EXPECTED 2015-2016 RULE-MAKING ACTIVITY:** Rule-making activity is currently underway to adopt rules for collaborative drug therapy management pursuant to 2013 Public Law Chapter 308. In addition, the Board is expected to review rules overall to ensure compliance with current laws and to update rules by addressing outdated references, providing clarification of certain rules as may be necessary, and setting licensing standards and requirements and operating standards for newly identified types of retail pharmacies. Review may include, but is not limited to, the following:

* License requirements and operation of various pharmaceutical facilities, including but not limited to: wholesale distributors; manufacturers; rural health centers; free clinics; mail order prescription pharmacies; mail order contact lenses; retail pharmacies; self-service customer kiosks in retail pharmacies; and various types of retail pharmacy facilities such as opiate treatment centers, compounding/sterile facilities, prescription medical oxygen facilities, prescription devices, long term care facilities, nuclear facilities, closed door or limited demographic facilities, central filling and consultant focus on medication regimen reviews, remote verification, and other facilities consistent with Title 32 Chapter 117;
* Requirements for licensing of pharmacists, and pharmacist practice duties and responsibilities;
* Licensee continuing education requirements, sponsors of continuing education courses and programs, and professional practice conduct;
* Pharmacy technician license requirements and defining permitted practice areas and practice that is not permissible, pharmacy student interns, preceptor qualifications, and internship requirements for individuals who were foreign educated;
* Internet pharmacies;
* Certification requirements and practice requirements for administration of drugs and immunizations by pharmacists;
* Receipt, handling and security of prescription drug orders, automated pharmacy systems, central fill processing centers, and electronic prescribing;
* Registration requirements, and duties and responsibilities of a pharmacist in charge;
* Accounting for prescription drugs, inventory management, reporting and action on drug loss, and controls and record keeping requirements;
* Requirements for patient counseling to ensure that recipients of prescription drugs are informed on taking the medication dispensed;
* Requirements for the destruction and disposing of certain prescription drugs;
* Unregistered facilities;
* Pharmacist and pharmacy involvement in emergency preparedness and disaster situations; and
* The 126th Maine Legislature enacted several laws that may require the Board to review current rules for consistency and to implement new rules as required:

**Public Law Chapter 6** - Allows the administration of vaccines licensed by U.S. Food and Drug Administration that are outside the guidelines recommended by the U.S. Center for Disease Control and Prevention Advisory Committee on Immunization Practices to a person 18 years of age or older according to a valid Rx when the person has an existing primary care physician or other existing relationship with a nurse practitioner or an authorized practitioner in this State if the prescription specifically states that the vaccine is medically necessary.

**Public Law Chapter 105** - Replaces references to a licensee’s “substance use disorder” with “misuse of alcohol, drugs or other substances” that may result in endangering patients as grounds for discipline within the Maine Health Security Act and within the provision of the health care practitioner licensing laws dealing with grounds for discipline.

**Public Law Chapter 308** - Expands the scope of practice for a pharmacist to include collaborative drug therapy management in accordance with a collaborative practice agreement and treatment protocol. The Board will adopt rules to implement this law and to establish record-keeping and documentation procedures and reporting requirements, and allowing for electronic filings.

Outdated or duplicative rules that may exist in 10 MRS, Part 9, Chapter 901 and rules established by the Office of Professional and Occupational Regulation as authorized by 10 MRS §8003 will be updated or repealed.

**CHAPTER 1**: Definitions

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13723

PURPOSE: This chapter defines certain specialized terms used throughout all rules adopted by the board.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 2**: Advisory Rulings

STATUTORY AUTHORITY: 5 MRS §§ 8051, 9001(4)

PURPOSE: This chapter provides for the discretionary issuance of advisory rulings by the board.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 3**: Applicability of Rules to Unregistered Facilities

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1)(D), 13723

PURPOSE: This chapter provides for the applicability of the board’s rules to the facilities identified in 32 MRS §13721(1)(D)

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 4**: Licensure of Pharmacists

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1), 13723, 13732, 13733, 13734

PURPOSE: This chapter sets forth the application procedure for persons applying for licensure as a pharmacist pursuant to 32 MRS §§ 13732 and 13733

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 4-A**: Administration of Drugs and Immunizations

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13723, 13831, 13832, 13833, 13834(1), 13835

PURPOSE: This chapter sets forth minimum requirements for treatment protocols, administration and recordkeeping requirements, and standards for the operation of drug administration clinics.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 5**: Continuing Pharmacy Education

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13723, 13735

PURPOSE: This chapter implements the requirement in 32 MRS §13735 that each pharmacist complete 15 hours of continuing pharmacy education annually as a condition of license renewal.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 6-A**: Pharmacy Student Internship Programs

STATUTORY AUTHORITY: 32 MRS. §§ 13720, 13721(1)(G), 13723, 13732(3), 13834(1)

PURPOSE: This chapter sets forth requirements of the pharmacy student internship required for licensure by Chapter 4, Section 1(4)(B) of the board's rules.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 7**: Licensure and Employment of Pharmacy Technicians

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(I)(H), 13723

PURPOSE: This chapter sets forth the qualifications, permissible duties and supervision responsibilities of the pharmacist in charge with respect to licensed pharmacy technicians.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 8**: Licensure of Retail Drug Outlets

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1)(E), 13722(1)(B), 13723, 13751, 13752, 13752-A, 13753

PURPOSE: This chapter sets forth licensure requirements for retain drug outlets.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 9**: Registration of Rural Health Centers

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1)(E), 13723, 13751, 13762, 13763, 13764

PURPOSE: This chapter sets forth registration requirements for rural health centers.

ANTICIPATED SCHEDULE: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 10**: Registration of Free Clinics

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1)(E), 13723, 13751, 13752, 13752-A, 13753

PURPOSE: This chapter sets forth registration requirements for free clinics.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 11**: Registration of Mail Order Prescription Pharmacies and Licensure of Mail Order Contact Lens Suppliers

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1)(E), 13721(2), 13723, 13751, 13752, 13752-A, 13753

PURPOSE: This chapter sets forth registration requirements for mail order prescription pharmacies and license requirements for mail order contact lens suppliers. This chapter also contains enforcement provisions unique to these two types of drug outlet.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 12**: Licensure of Manufacturers and Wholesalers

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1)(E), 13723, 13751, 13758

PURPOSE: This chapter sets forth license requirements for wholesalers, also known as wholesale pharmacies or wholesale drug distributors, and manufacturers.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 13**: Operation of Retail Pharmacies

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1), 13722, 13723, 13751

PURPOSE: This chapter sets forth operation requirements for retail pharmacies licensed by the board.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 14**: Pharmacy Services at Rural Health Centers

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1), 13722, 13723, 13762, 13763, 13764

PURPOSE: This chapter sets forth requirements for the pharmacy services provided by rural health centers licensed by the board.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 15**: Operation of Free Clinics

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1), 13722, 13723

PURPOSE: This chapter sets forth requirements for the operation of free clinics licensed by the board.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 16**: Operation of Wholesalers and Manufacturers

STATUTORY AUTHORITY FOR ADOPTION: 32 MRS §§ 13720, 13721(1), 13722, 13723, 13751(3), 13758

PURPOSE: This chapter sets forth operational requirements for wholesale drug distributors, including wholesalers and manufacturers.

ANTICIPATED SCHEDULE: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 17**: Operation of Nuclear Drug Outlets

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1), 13722, 13723

PURPOSE: This chapter incorporates by reference rules of the Maine Radiation Control Program applicable to nuclear drug outlets.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 19**: Receipt and Handling of Prescription Drug Orders

STATUTORY AUTHORITY: 22 MRS.A §2681(6); 32 MRS §§ 13720, 13721(1), 13722, 13723, 13781, 13785, 13786-A, 13794, 13795

PURPOSE: This chapter sets forth requirements for creating, transmitting, filling and transferring prescription drug orders.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 20**: Automated Pharmacy Systems

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1), 13722(1)(B-1), 13723, 13751(3)

PURPOSE: This chapter sets forth requirements for automated pharmacy systems.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 20-A**: Self-Service Customer Kiosks

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1), 13722(1)(B-1), 13723, 13751(3)

PURPOSE: This chapter sets forth requirements for self-service customer kiosks.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year.

AFFECTED PARTIES: Retail pharmacists, retail pharmacies, the general public

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 21**: Central Prescription Processing

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1), 13722, 13723, 13784, 13785, 13794

PURPOSE: This chapter sets forth requirements for central prescription processing.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 22**: Sale of Schedule V Controlled Substances

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1), 13722(1)(E), 13723

PURPOSE: This chapter sets forth requirements for the sale of Schedule V controlled substances.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 23**: Accounting for Prescription Drugs

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1), 13722, 13723

PURPOSE: This chapter sets forth requirements relating to maintenance of a perpetual inventory, disposal of drugs, and reporting the loss of controlled substances.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 24**: Retention of Records by Pharmacies

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1), 13722(1)(B-1), 13723(7), 13785

PURPOSE: This chapter sets forth record retention requirements for pharmacies.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 25**: Patient Counseling

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1), 13722, 13723, 13784

PURPOSE: This chapter sets forth the pharmacist’s obligation to counsel patients.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 26**: Generic Substitutions

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1), 13722, 13723, 13781

PURPOSE: This chapter defines and outlines the use of generic and therapeutically equivalent drugs by pharmacists.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 27:** Possession and Administration of Noncontrolled Prescription Drugs by Nurses

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1), 13722, 13723, 13810

PURPOSE: This chapter defines the conditions under which nurses can possess and administer noncontrolled prescription drugs. This chapter, including the chapter title, will be amended to include new rules on the possession, dispensing and administration of certain noncontrolled drugs and substances to certified midwives.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 28**: Enforcement and Disciplinary Procedures

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1)(F), 13722, 13723, 13741

PURPOSE: This chapter sets forth a licensee’s right to appeal certain board actions and specifies the enforcement and disciplinary procedures used by the board.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 29**: Violations of State or Federal Law or Rule; Other Standards

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1)(F), 13722, 13723, 13742-A(1)(C)

PURPOSE: This chapter recognizes certain state and federal statutes and rules and certain chapters of the U.S. Pharmacopeia as having established standards of professional behavior, the violation of which constitutes unprofessional conduct pursuant to 32 MRS §13742-A(1)(C).

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 30**: Unprofessional Conduct

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1)(F), 13722, 13723, 13742-A(1)(C)

PURPOSE: This chapter establishes standards of professional behavior, the violation of which constitutes unprofessional conduct pursuant to 32 MRS §13742-A(1)(C)

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 31**: Practice of Fraud or Deceit

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1)(F), 13722, 13723, 13741, 13742(2)(A)

PURPOSE: For purposes of 32 MRS §13742(2)(A), the practice of fraud or deceit includes, but is not limited to, the conduct described in this chapter.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 32**: Issuance of Citations

STATUTORY AUTHORITY: 10 MRS §8003-E; 32 MRS §§ 13720, 13721(1)(F), 13722, 13723

PURPOSE: This chapter lists the violations for which a citation may be issued, describes the licensee’s right to request a hearing, and describes the time and manner in which the fine must be paid or a hearing requested.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 33**: Access to Certain Medications by Certified Midwives

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13722, 13723, 13811, 13812

PURPOSE: This chapter implements PL 2007, c. 669 by: (a) regulating the sale of certain noncontrolled drugs and substances to certified midwives, (b) regulating the purchase and administration of certain noncontrolled drugs and substances by certified midwives, and (c) requiring certified midwives to record and report their purchase and administration of certain noncontrolled drugs and substances.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 34**: Licensure of Retail Suppliers of Medical Oxygen

STATUTORY AUTHORITY: 22 MRS §2681(6); 32 MRS §§ 13720, 13721(1)(E), 13722(1)(B), 13723, 13751(3), 13752, 13752‑A, 13753(1)(D)

PURPOSE: This chapter establishes a limited type of retail pharmacy license for retail suppliers of medical oxygen.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Retail suppliers of medical oxygen and prescription devices

CONSENSUS-BASED RULE DEVELOPMENT: Not Contemplated

**CHAPTER 35**: Licensure of Extended Hospital Pharmacies

STATUTORY AUTHORITY: 22 MRS §2681(6); 32 MRS §§ 13720, 13721(1)(E), 13722(1)(B), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

PURPOSE: This chapter provides for the licensure of extended hospital pharmacies.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary

AFFECTED PARTIES: Licensees, residents of long term care facilities that are wholly owned by the hospital in which the extended hospital pharmacy is located.

CONSENSUS-BASED RULE DEVELOPMENT: Not contemplated

**CHAPTER 36:** Licensure of Opioid Treatment Programs

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1)(E), 13722(1)(B), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

PURPOSE: This chapter provides for the licensure of opioid treatment programs.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary

AFFECTED PARTIES: Licensees, general public

**CHAPTER 37:** Licensure of Sterile Compounding Pharmacies

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1)(E), 13722(1)(B), 13723,

13751(3), 13752, 13752-A, 13753(1)(D)

PURPOSE: This chapter provides for the licensure of sterile compounding pharmacies.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary

AFFECTED PARTIES: Licensees, general public

**CHAPTER 38**: Licensure of Closed-Shop Pharmacies

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1)(E), 13722(1)(B), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

PURPOSE: This chapter provides for the licensure of closed-shop pharmacies.

ANTICIPATED SCHEDULE FOR ADOPTION: Within one year, if necessary.

AFFECTED PARTIES: Licensees, residents of long term care facilities and other institutions

**CHAPTER 39**: Collaborative Drug Therapy Management *(new)*

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13846

PURPOSE: This chapter is a new joint rule being proposed by the Board of Licensure in Medicine and the Board of Pharmacy for purposes of establishing safe and effective collaborative practice agreements, treatment protocols, and documentation and reporting requirements between a pharmacist and a practitioner.

ANTICIPATED SCHEDULE FOR ADOPTION: In progress. Adoption is anticipated in early 2016.

AFFECTED PARTIES: Licensees of the Maine Boards of Pharmacy and Medicine.