Annual List of Rulemaking Activity
Rules Adopted January 1, 2023 to December 31, 2023
Prepared by the Secretary of State pursuant to 5 MRS §8053-A(5)

Agency name:	Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, **Board of Pharmacy**
Umbrella-Unit:	**02-392**
Statutory authority:	32 M.R.S. §§ 13721(1)(E) and 13751(3)
Chapter number/title:	**Ch. 1,** Definitions; **Ch. 13,** Operation of Retail Pharmacies; **Ch. 25,** Patient Counseling; **Ch. 36,** Licensure of Opioid Treatment Programs (repeal)
Filing number:	**2023-218 to 2023-221**
Effective date:	11/4/2023
Type of rule:	Routine Technical
Emergency rule:	No

Principal reason or purpose for rule:
The rulemaking would repeal Board of Pharmacy rules that establish licensure of and otherwise regulate Opioid Treatment Programs. Opioid Treatment Programs are already regulated at both the federal and state level – certified by the United States Department of Health and Human Services, Substance Abuse and Mental Health Services Administration and licensed by the Maine Department of Health and Human Services, Division of Licensing and Regulatory Services.

Basis statement:
This rulemaking involves a complete repeal of Chapter 36: Licensure of Opioid Treatment Programs and removes other rule chapter references to opioid treatment programs as a category of pharmacy requiring licensure by the Board of Pharmacy. The requirement of Board of Pharmacy licensure for opioid treatment programs is being removed to reduce overlapping regulatory requirements for these programs which are also regulated by other federal and state agencies, specifically the United States Department of Health and Human Services, Substance Abuse Mental Health Services Administration (SAMHSA), the United States Drug Enforcement Administration (DEA), and the Maine Department of Health and Human Services, Division of Licensing and Regulatory Services.

Fiscal impact of rule:
Expected to be minimal

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Agency name:	Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, **Board of Pharmacy**
Umbrella-Unit:	**02-392**
Statutory authority:	32 M.R.S. §§ 13720, 13723, 13831, 13832, 13833, 13834(1), 13835
Chapter number/title:	**Ch. 4-A,** Administration of Drugs and Vaccines
Filing number:	**2023-068**
Effective date:	5/15/2023
Type of rule:	Routine Technical
Emergency rule:	No

Principal reason or purpose for rule:
Chapter 4-A – This chapter sets forth minimum requirements for treatment protocols, administration and recordkeeping requirements, and standards for the administration of drugs and vaccines and the operation of drugs and vaccine administration clinics.

Basis statement:
The Notice of Proposed Rulemaking was published on November 9, 2022, and a public hearing was held on December 1, 2022. The public comment period ended on December 11, 2022, at 5:00 p.m. (EST). The following is a summary of the comments collected from the public hearing verbally and written comments submitted.

This proposed rule is in response to Public Law 2021 Chapter 271 (L.D. 1293 An Act To Improve Access to Certain Injectable Medications Approved by the Federal Food and Drug Administration). This chapter sets forth minimum requirements for treatment protocols, administration and recordkeeping requirements, and standards for the administration of drugs and vaccines and the operation of drugs and vaccine administration clinics. This chapter eliminates the requirement for submission of a vaccine administration treatment protocol and Board approval and requires pharmacies to maintain a protocol on the premises and to make the protocol available to the Board or an agent of the Board upon request. This chapter outlines the requirements for administration of drug clinics and the one-time approval by the Board for a drug administration clinic.

Fiscal impact of rule:
None

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Agency name:	Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, **Board of Pharmacy**
Umbrella-Unit:	**02-392**
Statutory authority:	32 M.R.S. §§ 13751, 13792(2)
Chapter number/title:	**Ch. 41,** Sales of Nonprescription Drugs Through Vending Machine Outlets
Filing number:	**2023-069**
Effective date:	5/15/2023
Type of rule:	Routine Technical
Emergency rule:	No

Principal reason or purpose for rule:
This chapter sets forth requirements for licensing, management, and safe operation of vending machine outlets.

Basis statement:
The Notice of Proposed Rulemaking was published on November 9, 2022, and a public hearing was held on December 1, 2022. The public comment period ended on December 11, 2022, at 5:00 p.m. (EST). The following is a summary of the comments collected from the public hearing verbally and written comments submitted.

This proposed rule is in response to Public Law 2019 Chapter 454 (L.D. 37 An Act To Allow for the Sale of Nonprescription Drugs through Vending Machines). This chapter sets forth requirements for licensing, management, and safe operation of vending machine outlets for the sale of nonprescription drugs through vending machines.

Fiscal impact of rule:
None

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Agency name:	Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, **Board of Pharmacy**
Umbrella-Unit:	**02-392**
Statutory authority:	32 M.R.S. §§ 13720, 13723, 13722(1)(B-2)
Chapter number/title:	**Ch. 42,** Compounding Drugs for Veterinary Office Use
Filing number:	**2023-070**
Effective date:	5/15/2023
Type of rule:	Routine Technical
Emergency rule:	No

Principal reason or purpose for rule:
This chapter establishes the terms and conditions for compounding drugs for veterinarian office use pursuant to 32 M.R.S. § 13722(1)(B-2). This chapter was developed in consultation with the Maine State Board of Veterinary Medicine.

Basis statement:
The Notice of Proposed Rulemaking was published on November 9, 2022, and a public hearing was held on December 1, 2022. The public comment period ended on December 11, 2022, at 5:00 p.m. (EST). The following is a summary of the comments collected from the public hearing verbally and written comments submitted.

This proposed rule is in response to Public Law 2021 Chapter 289 (L.D. 4 An Act To Amend the Maine Pharmacy Act). This chapter establishes the terms and conditions for compounding of animal drugs for nonfood-producing animals and nonpatient-specific use in veterinary offices. This chapter was developed in consultation with the Maine State Board of Veterinary Medicine.

Fiscal impact of rule:
None