

State-Specific Controlled Substance Requirements

Updated 6/26/23

Biennial Inventory (DEA):	 A physical inventory of all controlled substances on hand must be taken at least every two years. The biennial inventory may be taken on any date, which is within two years of the previous biennial or initial inventory. [21 CFR 1304.11] NOTE: Separate biennial inventories must be completed for schedule II and schedule III-V controlled substances. Biennials may be conducted more frequently than every two years. As a recommendation, conduct your DEA biennial inventory at the same time you conduct your annual inventory for the state. Biennial inventories must be conducted by the DEA registrant, or their designee who has been granted Power of Attorney, along with an authorized witness. Biennial inventories must indicate whether they are conducted at the start or close of business. Maine follows the same biennial inventory guidelines as the DEA.
CE:	 Veterinarian: 24 hours every 2 years All 24 hours can be obtained online. Of the 24 CE hours, at least 18 must be in medicine, surgery, diagnostics and other subjects relating to the hands-on clinical practice of veterinary medicine. No more than 6 CE hours can be in practice management and other non-clinical subjects relating to the practice of veterinary medicine. You may have to complete sexual harassment training in Maine. Click here to see if your employment status requires this type of training. Download Rule 02 285 Chapter 4 for board approved CE parameters. Controlled Substances Mandate - 1 CE hour must be on the administration, prescription and management of controlled substances, including benzodiazepine and opioid medications by any veterinarian who prescribes these substances per Title 32 Chapter 71-A Section 4878. Veterinarian Tech: CE recommended, but not required by state.
Compounding:	"8.2.10 Compounding of a controlled substance by a practitioner is permitted as long as the United States Pharmacopoeia (USP) 795 and 797 standards and guidelines are followed." 24 Del. Admin. Code § 8.0 Compounding is any manipulation of a drug beyond that stipulated on the drug label. Veterinary drugs should only be compounded based on a licensed veterinarian's prescription, and to meet the medical needs of a specific patient. Manipulation might include mixing, diluting, concentrating, flavoring, or changing a drug's dosage form. Examples of compounding include: • Mixing two injectable drugs in the same syringe • Creating an oral suspension from crushed tablets or an injectable solution • Adding flavoring to a commercially available drug • Creating a transdermal gel for a drug typically taken through other routes • Mixing two solutions for instilling into the ear ME Compounding: "Compounding: "Compounding" means the preparation, mixing, assembling, packaging or labeling of a drug or device by a pharmacist: A. For the pharmacist's patient for dispensing as the result of a practitioner's prescription drug order;



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- B. For the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing;
- C. In anticipation of prescription drug orders to be received by the pharmacist based on routine, regularly observed prescribing patterns for the pharmacist's patient; or
- D. For nonpatient-specific drugs for distribution to licensed veterinarians for veterinarian office use for nonfood-producing animals, as that term is defined in board rule.

"Compounding drugs for veterinarian office use" means the compounding of nonpatient-specific drugs for veterinarian office use according to the terms and conditions described in this chapter.

Limit on Use of Bulk Drug Substances. A pharmacist compounding drugs for veterinarian office use from bulk drug substances should first confirm that the bulk drug substances are on the List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals, available at https://www.fda.gov/animal-veterinary/animal-drug-compounding/list-bulk-drug-substances-compounding-office-stock-drugs-use-nonfood-producing-animals].

1. Required Information in Order:

Orders for a compounded drug for veterinarian office use shall contain, at a minimum, the following information:

- A. Name, address and telephone number of the licensed veterinarian;
- B. An acknowledgment, signed by the licensed veterinarian submitting the order, stating the veterinarian understands that the compounded drug is being provided for veterinarian office use and:
 - i. will only be dispensed or administered to nonfood-producing animals that are patients of the veterinarian with a valid veterinarian-client-patient relationship;
 - ii. will only be dispensed or administered for the treatment of emergency conditions, when, as determined by the prescribing veterinarian, urgent treatment is needed to avoid animal suffering or death and there is no timely access to a compounding pharmacy to compound and dispense the drug under a patient-specific prescription;
 - iii. the quantity dispensed by a prescribing veterinarian will not exceed a 120-hour supply; and
 - iv. iv. the prescribing veterinarian will provide instructions to owners to contact the prescribing veterinarian immediately if a compounded preparation has caused an adverse event or the owner suspects a defective drug product, and the veterinarian will report this information to the compounding pharmacy and the FDA Center for Veterinary Medicine.

A signature may either be original or electronic.

<u>Labeling requirements</u>. Compounding drugs for veterinarian office use shall be labeled in a conspicuous and legible manner, as appropriate for the size and attributes of the container. The label shall include:

- 1. Pharmacy name, address, and telephone number;
- Date of distribution;
- 3. Name, address, and telephone number of the licensed veterinarian who placed the order:
- 4. The name and strength of the compounded preparation or a list of the active ingredients and the strength of the active ingredients in the compounded preparation;
 - 5. The quantity of compounded preparations;
 - 6. Cautionary statements if appropriate for the drug;
 - 7. An appropriate beyond-use date as determined by the pharmacist in compliance with United States Pharmacopeia and the National Formulary (USP-NF) standards for pharmacy compounding; and,
 - 8. Text reprinted as follows:



	Notice: Compounded Preparation For Veterinarian Office Use Only. Intended only for dispensing and administration for nonfood-producing animals for the treatment of emergency conditions, when, as determined by the prescribing veterinarian, timely access to a compounding pharmacy is not available. Intended for dispensing or administration in a quantity not to exceed a 120- hour supply.
	Please contact the FDA Center for Veterinary Medicine immediately if a compounded preparation has caused an adverse event or if there is a suspected defective drug product involving these compounded preparations. ###
	Record-keeping requirements: The pharmacy compounding a drug pursuant to this chapter shall comply with all other laws and rules of the board concerning record-keeping. Any pharmacy compounding a drug pursuant to this chapter shall maintain an activity records of the distribution of the compounded drug to the veterinarian and have the ability to retrieve compounding and distribution records by both preparation and by specific veterinarian, if requested by the board or its agent.
	The board or its authorized agent may inspect and make copies of any and all records of shipment, purchase, compounding record activities, quality control, and sale of these items provided, however, that such inspection shall not extend to financial data or pricing data. Compounding for veterinary office use 32 M.R.S. § 13722(1) (B-2)
Dispensing:	" <u>Dispense</u> " or " <u>dispensing</u> " means the preparation and delivery of a prescription drug in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug pursuant to a lawful order of a practitioner. A licensed veterinarian may sell and dispense the written prescription of another licensed veterinarian with respect to any prescription or administration of a drug, medicine or nutritional substance on, for or to any animal (<u>32 M.R.S.A. § 4876</u>).
Diversion Reporting:	Theft/Loss Reporting: Theft or loss of prescription drugs must be reported to the board of pharmacy within 7 days after discovery of the theft, loss or inventory discrepancy. The report may be made via letter, facsimile transmission or email. Sending a copy of a submitted DEA Form 106 to the board also satisfies the reporting obligation for controlled substances.
	 Unresolved Inventory Discrepancy Reporting report an unresolved inventory discrepancy of prescription drugs to the board as follows: 1. For noncontrolled prescription drugs, unresolved inventory discrepancies that lead to the suspicion of theft must be reported to the board within 7 days after discovery. 2. For controlled substances, the following minimum quantities of unresolved inventory discrepancies must be reported: (1) Solid dosage forms (a) Three or more unreported shortages totaling 30 or more dosage units during the previous six months; or
	 (b) A total of 10 or more doses of the same drug regardless of strength or manufacturer. (2) Oral liquids (a) Three or more unreported shortages totaling 360 ml or more during the previous six months; or (b) A volume greater than 4 oz (120ml) of the same drug regardless of strength or manufacturer. (3) Injectable medications: (a) Three or more unreported shortages of the same drug; (b) More than one manufacturer original container;



	(c) More than 5 dosage units (i.e. ampoule or Tubex); or
	(d) For powders, more than 1 gram.
	(4) 10 10 10 10 10 10 10 10 10 10 10 10 10
	<u>Drug Loss Theft, Loss, Unresolved Discrepancy Form</u>
	Make sure to attach your official report to the form when submitting.
	Link to the rules published by the Secretary of State: www.maine.gov/professionallicensing
Euthanasia:	Euthanasia may be performed by licensed veterinarians and certified euthanasia technician
Ownership:	Non-veterinarian ownership is restricted.
Power of Attorney:	While Maine does not technically require you to get your POA notarized, notarization is very strongly recommended. Under Maine law, when you sign your POA in the presence of a notary public, your signature is presumed to be genuine—meaning your POA is more ironclad.
Prescribing:	"Prescription drug" or "legend drug" means a drug that: A. Under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements: (1) "Caution: Federal law prohibits dispensing without prescription."; or
	(2) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."; or
	B. Is required by an applicable federal or state law or rule to be dispensed on prescription only or is restricted to use by practitioners only.
	Written prescriptions: If the veterinarian is prescribing a medication for a patient, the doctor is required to provide the patient, upon request, with a written prescription.
	E-prescribing: mandated e-prescribing of all controlled substances containing opiates was enacted January 1, 2017.
PMP:	Veterinarians must register as prescribers with the Maine PMP.
	Veterinarian Requirements
	a. Veterinarians must check the Prescription Monitoring Program system in accordance with the terms described in <u>22 MRSA §7253(1)</u> . The following records must be checked:
	i. Records related to the individual seeking care for the animal;
	ii. If deemed appropriate by the prescriber, the records related to the owner of the animal, in the event the owner is not the individual seeking care for the animal.
	In order to fulfill the requirement to check the Prescription Monitoring Program system, the veterinarian must review the following information:
	 i. Aggregate Morphine Milligram Equivalent (MME) for the individual seeking care for the animal, or, if appropriate, the owner of the animal.
	ii. The number of prescribers currently prescribing controlled substances to the individual; andiii. The number of pharmacies currently filling prescriptions for controlled substances for the individual.
	In the event the prescribing veterinarian identifies concerns related to any of the following regarding the information found in the prescription monitoring program system, the veterinarian must contact
	 the PMP coordinator: Aggregate Morphine Milligram Equivalent for the individual seeking care for the animal, or, if appropriate, the owner of the animal.
	ii. The number of prescribers currently prescribing controlled substances to the individual; and



	iii. The number of pharmacies currently filling prescriptions for controlled substances for the
	individual.
	Register with the Maine PMP: https://maine.pmpaware.net/login
Recordkeeping:	Patient records: All patient records must be kept for a period of 7 years.
	Controlled substance records at least two years from the last entry
Poliof Sorvices Permit	Controlled substance records: at least two years from the last entry. "Relief veterinary service" means the practice of veterinary medicine in Maine on a temporary basis
Relief Services Permit	by a qualified veterinarian not licensed to practice in this State for the purpose of substituting for a Maine-licensed veterinarian at a specified location during the licensee's absence or period of incapacitation.
	Permit to perform relief veterinary service in Maine:
	The board may issue without examination a permit to perform relief veterinary service in this State to a qualified person who holds a doctorate degree in veterinary medicine from an approved veterinary medicine program that is recognized by the United States Department of Education and by the board or by rules of the board applicable to foreign educated graduates, and who holds a current license for the practice of veterinary medicine issued by another state, United States territory province of Canada or other jurisdiction. The board may establish, by rule, the application process.
	2. <u>Application</u> An applicant for a permit for performance of relief veterinary service must apply to the board. The application consists of the following items: <u>Veterinary Relief Permit Application</u> <u>Fee</u> : \$96
	A. A completed application form and the application fee required by Chapter 10, Section 4(40) of the rules of the Office of Licensing and Registration, entitled "Establishment of License Fees;" B. An official transcript of the applicant's degree of veterinary medicine from a school of veterinary medicine as described in Section 8(1) of this chapter; and C. Verification from all jurisdictions in which the applicant has at any time been licensed as a veterinarian.
	Term: The initial term of a permit issued under this subsection may not exceed 30 days. Extensions may be granted in the discretion of the board. The applicant shall pay the relief permit fee as set under section 4863-A.
	3. Extensions: Extensions to the 30-day term of the permit may be requested by submitting a written request to the board prior to the expiration date of the permit and by paying the required permit extension fee. 02-285-2 Me. Code R. § 8
State-Scheduled CS's:	N/A
State CS License:	Maine does not require DEA registrant practitioners to obtain a second state controlled substance license, just a DEA registration and an active Veterinary Medical Professional License to practice in Maine.
Supervision:	" <u>Direct supervision</u> " means any time when a supervisor is on the premises and is quickly and easily available.
	"Indirect supervision" means any time when a supervisor is not on the premises , but is available for consultation on patient care.



	" <u>Supervisor</u> " means a licensed veterinarian or, if the task being supervised warrants, a licensed
	veterinary technician.
	§4866. Duties of licensed veterinary technicians and veterinary assistants
	A veterinary assistant may, under the direct supervision of a licensed veterinarian or a licensed
	veterinary technician, perform duties of an animal health care nature excluding diagnosing, making
	prognoses, performing surgery or prescribing treatment.
	A licensed veterinary technician in the State may engage in the practice of veterinary technology
	on the basis of written or oral instruction of a veterinarian.
Telemedicine:	No existing law. Where telemedicine occurs is not defined.
Veterinary Professional	<u>Veterinarians</u>
License:	Veterinary License Application
	■ Fee: \$96 application fee and \$21 criminal background check fee
	Renewals: annually on September 30 th .
	• Fee: \$100
	September 30, 2023 is the next license renewal deadline in Maine.
	Veterinary License Renewal
	Veterinary Reinstatement Form
	For licenses that have expired 91 days up to two years from the date of expiration
	■ Fee: \$196
	Licensed Veterinary Technicians
	means a person who has completed a minimum of 2 years in a college program that is certified
	according to the standards adopted by the American Veterinary Medical Association's Committee
	on Veterinary Technician Education and Activities or an equivalent program, as determined by the
	board, and who has passed an examination for licensure prescribed by the board.
	VTNE Exam: You must contact American Association of Veterinary State Boards (AAVSB) directly in
	order to register for the VTNE examinations. Exam dates and application are available at their
	website at <u>www.aavsb.org</u> . Once you have taken and passed the VTNE exam, you may submit an
	application for licensure as a Veterinary Technician.
	Veterinary Technician Application
	• Fee: \$35
	Renewal: annually on September 30 th
	Veterinary Technician Online Renewal
	■ Fee: \$50
	Late Fees: A late fee of \$50.00 is assessed for licenses renewed after the license expiration date.
	Licenses may be renewed up to 90 days after the date of expiration upon payment of a late fee of
	\$50 in addition to the renewal fee. Any person who submits an application for renewal more than 90
	days after license expiration date is subject to all requirements governing new applicants and is
	required to reapply with original license application, documentation and fees.
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	Renewal reminders: are emailed to the email address on file at least 30 days prior to the license
	expiration date. It is the licensee's responsibility to keep the Board informed of current contact
	information and to see that the license is renewed absent the renewal application. Reminder
	includes licensee's access code which, along with license number, is required for online renewal.
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VCPR: VCPR must be established in-person and only applies to one veterinarian.

A veterinarian-client-patient relationship exists when a veterinarian:

- 1. Engaged by client. Has been engaged by the client;
- **2. Assumed responsibility.** Has assumed responsibility for making medical judgments regarding the health of the patient;
- 3. Knowledge of patient. Has sufficient knowledge of the patient to initiate a preliminary diagnosis of the medical condition of the patient and has personal knowledge of the keeping and care of the patient as a result of:
 - A. A timely examination of the patient by the veterinarian; or
- B. A medically appropriate and timely visit or visits by the veterinarian to the patient while that patient is under the care of the veterinarian's practice;
- **4. Follow-up evaluation.** Is readily available for follow-up evaluation or has arranged for veterinary emergency coverage and continuing care and treatment; and
- 5. Records. Maintains patient records.

A licensed veterinarian who in good faith engages in the practice of veterinary medicine by rendering or attempting to render emergency care to a patient when a client cannot be identified and a veterinarian-client- patient relationship is not established is not subject to any disciplinary sanctions authorized by Title 10, section 8003, subsection 5-A based solely upon the veterinarian's inability to establish a veterinarian-client-patient relationship (32 M.R.S.A. § 4877).

Information and Resources

FEDERAL:

Drug Enforcement Administration, New England Division 15 New Sudbury St, Room E-400 Boston, MA 02203

Phone: (617) 557-2100

Local DEA Offices

• Portland (207) 780-3331

Federal Law: <u>www.deadiversion.usdoj.gov</u> Controlled Substances Act: 21 USC 801 – 904

Code of Federal Regulations: 21 CFR Part 1300 – 1399

NDC drug: www.fda.gov/Drugs/DevelopmentApprovalProcess/UCM070829
Diversion Control Division: https://www.deadiversion.usdoj.gov/schedules/

STATE:

Maine Board of Veterinary Medicine website:

https://www.maine.gov/pfr/professionallicensing/professions/board-veterinary-medicine

Maine Board of Pharmacy website:

https://www.maine.gov/pfr/professionallicensing/professions/board-pharmacy