



Massachusetts

State-Specific Controlled Substance Requirements

updated 5/31/23

Biennial Inventory (DEA):	<p>A physical inventory of all controlled substances on hand must be taken at least every <u>two years</u>. 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]</p> <p>NOTE:</p> <ul style="list-style-type: none"> • 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 state biennial inventory. • Biennial inventories must be conducted by the DEA registrant, or their designee who has been granted Power of Attorney, along with an authorized witness. <p>Biennial inventories must indicate whether they are conducted at the start or close of business.</p>
Biennial Inventory (MA):	<p>A new inventory of all stocks of controlled substances in Schedules II through V must be taken every <u>two years</u>.</p> <p>(a) On the day of the year on which the initial inventory was taken;</p> <p>(b) On the registrant's regular physical inventory date, if any, which is nearest to and does not vary by more than six months from the biennial date and which would otherwise apply; or</p> <p>(c) Any other fixed date which does not vary by more than six months from the biennial date which would otherwise apply.</p> <p>(4) A registrant who elects to take his or her biennial inventory on his or her regular general physical inventory date or another fixed date, shall inform the Commissioner of this election and of the date on which he or she will take his biennial inventory upon request.</p> <p>105 Mass. Reg. 700.006</p>
CE:	<p>Veterinarians: Licensed Veterinarians are required to complete a minimum of 15 continuing education credits per calendar year to renew a license. All credits can be obtained online but at least 9 must be "interactive" (instruction occurs live in real time and interaction occurs between the instructor and licensee). 6 online credits can be "non-interactive" (pre-recorded for home study).</p> <p>Keep CE certificates and records for 4 years.</p> <p>Vet Techs: 12 CE hours per year via MVTA – Accepts 12 hours of Online CE Courses. Accepts RACE Approved Courses and MVTA Approved Courses.</p> <p>https://www.massvta.org/ce-guidelines</p> <p>MA does not require completion of any CEs specific to controlled substances.</p>
Compounding:	<p><u>Compounding</u> is <u>any manipulation</u> 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:</p> <ul style="list-style-type: none"> • Mixing two injectable drugs in the same syringe • Creating an oral suspension from crushed tablets or an injectable



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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

MA Compounding: (a) "Compounded drug", a drug formulation distributed from a pharmacy that has been prepared, mixed or assembled for use on or for a companion animal to meet the unique medical need of a companion animal as determined by the prescribing veterinarian including, but not limited to, the removal of a dye for medical reasons, a change in strength, the addition of a flavor or a change in dosage, form or delivery mechanism.

(b) A veterinarian may dispense a compounded drug to a companion animal if:

- (i) the companion animal is a patient within a valid veterinarian-client-patient relationship, as defined in the principles of veterinary medical ethics established by the American Veterinary Medical Association;
- (ii) the quantity dispensed does not exceed a 120 hour supply;
- (iii) the compounded drug is for the treatment of an emergency condition;

and

- (iv) timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian.

(c) Pharmacists shall label all compounded products for companion animals distributed to a veterinarian for further distribution or sale and shall include:

- (i) the name and strength of the compounded medication or list of the active ingredients and strengths;
- (ii) the facility's control number;
- (iii) an appropriate beyond-use date as determined by the pharmacist in compliance with the United States Pharmacopeia and the National Formulary standards for pharmacy compounding;
- (iv) the name and address of the pharmacy; and
- (v) the quantity.

[Section 58A1/2](#)

[Section 58A1/2: Dispensing of compounded drugs to companion animals by veterinarians](#)

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Compounded e-kits: The Massachusetts Board of Registration in Pharmacy (Board) and the Drug Control Program (DCP) adopted a policy regarding the provision of emergency medication kits ("e-kits") containing compounded medications for use in veterinary office practices. This policy only applies to compounded drugs intended for animal use by a licensed veterinarian and allows the veterinarian to address immediate medical needs, pain, and suffering in a timely manner when FDA-approved products are not available or appropriate for veterinary administration or there is not time to have a patient specific prescription filled by a compounding pharmacy.

In accordance with applicable state and federal laws and regulations, a pharmacy may provide an emergency kit ("e-kit") containing limited quantities of compounded medications to a licensed veterinarian for the purpose of direct administration or dispensing in emergency situations, providing the following conditions are satisfied:

1. The veterinarian must have a valid (MCSR).
2. The pharmacy must maintain a written agreement with the veterinary office that identifies the specific medications (formulary) to be contained in the e-kit. The agreement and formulary must be reviewed and renewed at least annually.
3. The e-kit may only contain compounded schedule VI controlled substances.
4. The medications contained in the e-kit remain the pharmacy's responsibility and part of the pharmacy's inventory until such time as the veterinarian provides a patient specific prescription to the pharmacy.
5. The pharmacy must ensure the e-kit is properly stored and secured. An Automated Dispensing Device (ADD) may be used to secure medications in accordance with Joint Policy 2019-02: Automated Dispensing Device Use. Adopted: 10/3/19 Page 1 of 2
6. The pharmacy must obtain a patient-specific prescription for each medication removed from the e-kit within 7 days of the medication's removal.
7. Compounded emergency medications must be prepared to meet the unique medical needs of an animal (e.g. xylitol-free, increased concentration, etc.).
8. The veterinarian may dispense up to a 120 hour emergency supply from the e-kit only if timely access to a compounding pharmacy is not possible.
9. At least once every 10 days, the pharmacist must inspect, restock, and reconcile prescriptions for any medications dispensed from the e-kit.

Loss: 10. The pharmacy must report any drug loss in accordance with Board Policy 2018-05: Requirements and Procedures for Reporting Theft or Loss of Controlled Substances.



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	<p><u>Labeling:</u> Pharmacists are responsible for the proper labeling of each medication in an e-kit. The label of each compounded product must contain the following elements:</p> <ol style="list-style-type: none"> 1. Generic name and strength 2. Quantity 3. Date of preparation 4. Lot number 5. Beyond-use-date(BUD) 6. Storage, handling, and any other cautionary information 7. Name, address, and telephone number of the pharmacy 8. A statement indicating that the product is a sterile or non-sterile compounded drug preparation
<p>Dispensing:</p>	<p>Massachusetts defines “<u>dispenser</u>” as a practitioner who dispenses, including veterinarians in the definition of “practitioner” or “dispenser”.</p> <p>(1) A licensee shall dispense or prescribe drugs and medications in accordance with 247 CMR: Board of Registration in Pharmacy and only for specific animals and for specific medical problems. When treating groups of animals, a licensee shall judiciously dispense or prescribe drugs and medications on a per client basis only for specific medical problems and only in accordance with 256 CMR 7.01 (2)(e).</p> <p>(2) A licensee shall provide prescription information to an off-site pharmacy or a written prescription to the client if requested. The prescription may be written or transmitted by any electronic means at the discretion of the prescribing licensee and in accordance with M.G.L. c. 94C.</p> <p>(3) In the event of an emergency situation a veterinarian who does not have a veterinarian-client patient relationship may dispense a prescription or drug for the immediate treatment of the patient when necessary to save life or relieve suffering provided that the quantity prescribed and dispensed is limited to the amount needed for the immediate treatment of the patient during the emergency period.</p> <p>(4) A non-prescribing veterinarian may dispense a prescription veterinary diet for the treatment of a patient without establishing a veterinary client patient relationship only upon receiving the authorization of the prescribing licensed veterinarian.</p> <p>256 Mass. Reg. 5.02</p> <p>Section 9.04 - Requirements for Dispensing and Refilling Prescriptions</p>
<p>Diversion Reporting:</p>	<p>Within <u>24 hours of discovery</u>, fax a Drug Incident Report Form to the DPH Drug Control Program at (617) 753-8083. Report in writing within one business day of discovery to DEA, preferably by submitting the DEA Form 106 online.</p> <p>You must immediately report it to the MA Drug Control Program (DCP). You must then follow it up in writing within 7 days of the incident.</p> <p>MA Controlled Substance Loss Reporting</p> <p><u>MA definition of loss:</u> The Department considers the loss of one unit of medication to be significant enough to warrant a report of such loss. Such thefts or losses may be part of a pattern within a facility or among several area institutions. Please consult with the Boston Field Office of the Drug Enforcement Administration for further guidelines on reporting thefts or loss of controlled substances to federal agencies.</p>



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	<p>https://www.mass.gov/service-details/requirements-for-reporting-a-loss-of-controlled-substances</p>
Euthanasia:	<p>Euthanasia may be performed by licensed veterinarians and animal control officers in a manner deemed acceptable by the AVMA Guidelines on Euthanasia (AVMA Guidelines for the Euthanasia of Animals: 2020 Edition).</p>
Facility classification:	<p>Hospital DEA registration only applies to human medicine.</p> <p><u>Hospital</u> means any institution, however named, whether conducted for charity or for profit, which is advertised, announced, established or maintained for the purpose of caring for persons admitted thereto for diagnosis, medical, surgical or restorative treatment which is rendered within said institution.</p> <p>A registered hospital means those registered with AHA. An institution may be registered by AHA as a hospital if it is accredited as a hospital by the Joint Commission on Accreditation of Healthcare Organizations or is certified as a provider of acute services under Title 18 of the Social Security Act and has provided AHA with documents verifying the accreditation or certification.</p>
Inspections (BOV):	<p>The Board of Veterinary Medicine conducts impromptu inspections.</p> <p>There is an automatic \$500.00 fine to turn away a state veterinary inspector.</p>
Massachusetts Prescription Monitoring Program (MassPAT):	<p><u>Veterinarians are excluded from using MassPAT</u>, including all reporting and use requirements unless the facility has an on-site licensed pharmacy in which case you are required to register with and use MassPAT.</p> <p>Naloxone must be reported to MassPAT. Pharmacies have the option to report naloxone dispensing in daily submissions in lieu of submitting an annual report of naloxone doses dispensed (M.G.L. c. 94C Section 19B) The submission of naloxone dispensation data to the PMP is for data collection purposes only and will not appear on a patient's PMP profile.</p> <p>Massachusetts has added Gabapentin to the list of drugs that must be reported to the Prescription Monitoring Program MassPAT. <u>This does not apply to veterinarians, unless you are also running a pharmacy dispensing Gabapentin.</u></p> <p>https://www.mass.gov/doc/pmp-data-submission-dispenser-guide-version-40-0/download</p> <p><u>If a veterinarian dispenses at the animal clinic or hospital instead of sending the prescription to a retail pharmacy they are exempt from reporting to MassPAT.</u></p>
MCSR (State Controlled Substance License):	<p>In MA all substances are considered controlled and MA veterinarians must register with MCSR before registering with the DEA.</p> <p><u>Renewal:</u> Each individual vet in MA must have his/her own MCSR which shall be renewed annually as well as a DEA registration for schedule II-VI.</p> <p>https://www.mass.gov/mcsr-for-individuals</p> <p>If a practitioner does not plan on registering to use DEA-scheduled CS's and only plans to work with MA schedule VI CS's they only need to obtain an MCSR.</p>



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	Do not publicly display your MSCR or DEA Registration.
Ownership:	<p>In Massachusetts, non-veterinarians can own practices but it depends on the legal business structure of a veterinary practice. Professional corporations under MGL 156A must be owned by licensed professionals. Other forms of business, such as a sole proprietorship or a partnership, do not require that owners be licensed veterinarians.</p> <p>Per the Board of Registration in Veterinary Medicine guidelines on practice - 256 CMR 5.06 - "In those facilities/practices which are not owned by a licensed veterinarian, the owner(s) shall appoint a licensed veterinarian as the Veterinary Medical Director." If in doubt, we advise you seek the opinion of an attorney versed in corporate law in the Commonwealth.</p>
Prescribing:	<p>Section 18: Issuance of prescription by practitioner or physician</p> <p>A MA veterinary clinic cannot act as a drug supplier by filling prescriptions for other veterinarians to use.</p> <p><u>E-prescribing:</u> Veterinarians are exempt from e-prescribing regulations. CLICK HERE for the exemption language (page 2 under Exceptions):</p> <ol style="list-style-type: none"> Prescriptions issued by veterinarians. This exception is available to all licensed veterinarians with a Massachusetts Controlled Substance Registration (MCSR). <p>At the request of a client an MA veterinarian shall provide prescription to the pharmacy of choice. A licensee shall provide prescription information to an off-site pharmacy or a written prescription to the client if requested. The prescription may be written or transmitted by any electronic means at the discretion of the prescribing licensee and in accordance with M.G.L. c. 94C.</p> <p>Prescriptions for schedule II -V drugs require a DEA number but not for schedule VI medications. https://www.mass.gov/policy-advisory/board-policies-and-guidelines-veterinary-medicine</p> <p><u>Tramadol:</u> The prescription for Tramadol, as a controlled substance, may only be issued by an individual practitioner who is either registered with the DEA or exempt from registration. 21 CFR 1306.03. Tramadol prescriptions may be filled up to six months after the date prescribed, and may be refilled up to five times within six months after the date on which such prescription was issued. 21 U.S.C. 829(b); 21 CFR 1306.22 (a)and (e); see also 21 CFR 1306.23 (b)and (c).</p> <p><u>Limitations:</u> there are no dosage unit limitations for prescriptions for schedule III, IV, or V controlled substances unless the controlled substance is prescribed for administration to an ultimate user who is institutionalized. 21 CFR 1306.24(c)</p>
Power of Attorney Notarization:	Massachusetts law does not technically require a POA to be notarized; however, signing a POA in the presence of a notary public is very strongly recommended.
Radiation License:	A radiation license is required for new x-ray machines. You must have a Shielding Design Package sent to you (if you call the RCP they will send it out). This package will let you know what needs to be submitted, which includes how the x-ray machine will



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	<p>be built in the facility. An inspection will then be done to make sure everything is safe and the machine was built according to what was submitted. There is also a fee involved in this process. (Learn more on the Mass Radiation Control website or contact 617-242-3053 (RadiationControl@massmail.state.ma.us).</p>
<p>Recordkeeping:</p>	<p><u>Controlled substance records:</u> (B)Time for Keeping Records. A registrant shall keep for at least two years from the date of preparation, every report, inventory and record he or she is required to keep by 105 CMR 700.000." 105 Mass. Reg. 700.006</p> <p><u>Patient Records:</u> MA requires patient records to be kept 4 years from the last contact with the animal, even if the animal is deceased.</p> <p>(4)<u>Records for Schedule VI.</u> A registered individual practitioner, including an optometrist, who dispenses, other than by prescribing and administering, Schedule VI sample medications shall maintain a record, which may be kept in the patient's medical record, of the following information:</p> <ul style="list-style-type: none"> (a) the name, dosage and strength of the substance dispensed; (b) the volume of units dispensed; (c) the date of the dispensing; and (d) the name and address of the person to whom the medication was dispensed. <p>105 Mass. Reg. 700.006</p>
<p>Relief DVMS:</p>	<p><u>Proof of licensing:</u> (1) Each veterinarian engaged in practice shall have all current required licenses, certificates and permits on display. This includes a copy of the license certificate to practice veterinary medicine in the Commonwealth, and any applicable certifications by AVMA specialty boards.</p> <p>(2) <u>Each licensee practicing at a location where the display of certificates is not possible or practical shall have on his or her person a license card as proof that his or her license is current.</u></p> <p>In Massachusetts, most people who work or provide services are considered employees under the law. There is a 3-part test for an employer who wants to treat someone as an independent contractor whereby you have to show that the work: 1) is done without the direction and control of the employer; and 2) is performed outside the usual course of the employer's business; and 3) is done by someone who has their own, independent business or trade doing that kind of work. Relief veterinarians generally perform the same work in the normal course of business as would the person they are filling in for, and so generally speaking, should be treated as an employee under the law. Read more HERE.</p>
<p>State Schedule CS's:</p>	<p>Xylazine and gabapentin are currently classified as a schedule XI in Massachusetts according to MGL 94C Section 3.</p> <p>In MA all substances are considered controlled. Each individual vet in MA must have his/her own MCSR and DEA registration for schedule II - VI, as the state doesn't register animal/veterinary practices/hospitals.</p> <p>Massachusetts considers all prescriptions not listed as a federally scheduled II-V controlled substance a <u>schedule VI</u> drug in the state. This is a special Massachusetts schedule (MGL 94C, 105 CMR 720.002). MGL 94C Section 3 states: "SCHEDULE VI.— (A) The substance is a prescription drug; and (B) Said prescription drug has not been included in Schedules I through V." In short, this states that Schedule VI substances are any "normal" prescriptions that are not considered controlled substances in other states. Some examples of drugs that would fit into Schedule VI are antibiotics and</p>



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	<p>"maintenance meds," such as penicillin, azithromycin, metoprolol, simvastatin, lisinopril, gabapentin, levothyroxine, metformin, etc. https://malegislature.gov/laws/generallaws/parti/titlexv/chapter94c/section3</p> <p>In inventory and storage, state-scheduled controlled substances must be separate from federally controlled substances.</p>
<p>Supervision:</p>	<p>All professional activities of a physician assistant must be supervised by a supervising physician licensed by the Massachusetts Board of Registration in Medicine pursuant to 243 CMR 2.08:</p> <p>A "supervising physician", for purposes of 263 CMR 5.04, shall mean a physician who holds an unrestricted full license issued by the Massachusetts Board of Registration in Medicine.</p> <p>(2) A supervising physician may use a physician assistant to assist him or her in the process of gathering data necessary to make decisions and institute patient care plans. A physician assistant shall not, however, supplant a licensed physician as the principal medical decision-maker.</p> <p>(3) A supervising physician shall afford supervision adequate to ensure all of the following:</p> <p>(a) The physician assistant practices medicine in accordance with accepted standards of medical practice. 263 CMR 5.04(1) does not require the physical presence of the supervising physician in every situation in which a physician assistant renders medical services.</p> <p>(b) The physician assistant, except in life-threatening emergencies where no licensed physician is available, informs each patient that he or she is a physician assistant and that he or she renders medical services only under the supervision of a licensed physician.</p> <p>(c) The physician assistant wears a name tag which identifies him or her as a physician assistant.</p> <p>(d) The supervising physician reviews diagnostic and treatment information, as agreed upon by the supervising physician and the physician assistant, in a timely manner consistent with the patient's medical condition.</p> <p>(e) On follow-up care, hospital visits, nursing home visits, attending the chronically ill at home, and in similar circumstances in which the supervising physician has established a therapeutic regimen or other written protocol, the physician assistant checks and records a patient's progress and reports the patient's progress to the supervising physician. Supervision is adequate under 263 CMR 5.04(3)(e) if it permits a physician assistant who encounters a new problem not covered by a written protocol or which exceeds established parameters to initiate a new patient care plan and consult with the supervising physician.</p> <p>(f) In an emergency, the physician assistant renders emergency medical services necessary to avoid disability or death of an injured person until a licensed physician arrives.</p> <p>(g) When a supervising physician is unable or unavailable to be the principal medical decision-maker, another licensed physician must be designated to assume temporary supervisory responsibilities with respect to the physician assistant. The name and scope of responsibility of the physician providing such temporary supervision must be readily ascertainable from records kept in the ordinary course of business which are available to patients. The supervising physician(s) of record is</p>



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	<p>ultimately responsible for ensuring that each task performed by a physician assistant is properly supervised.</p> <p>263 Mass. Reg. 5.04</p> <p>Microchipping pets is a veterinary procedure that should only be performed by a licensed veterinarian or under supervision of a licensed veterinarian. Read more HERE.</p>
Telemedicine:	<p>No existing laws. Where telemedicine occurs is not defined.</p> <p>The Board of Registration does permit the use of telemedicine when appropriate only after a VCPR is first established. Read the full policy HERE.</p>
Veterinary Client Patient Relationship (VCPR):	<p>VCPR must be established in-person but VCPR can apply to any vet working at the same practice.</p> <p>A VCPR exists when:</p> <ol style="list-style-type: none"> a. The Veterinarian has assumed the responsibility for making clinical judgments regarding the health of the patient and the client has agreed to follow the Veterinarian's instructions; b. The Veterinarian has sufficient knowledge of the patient to initiate at least a general or preliminary diagnosis of the medical condition of the patient This means that the Veterinarian and/or his or her Veterinary Practice is acquainted with the keeping and care of the patient by virtue of a timely examination of the patient by the Veterinarian and/or his or her Veterinary Practice, or medically appropriate and timely visits by the Veterinarian and/or his or her Veterinary Practice to the operation where the patient is managed; and The Veterinarian is readily available for follow-up evaluation or has arranged for the following: veterinary emergency coverage and continuing care and treatment. c. The VCPR shall extend to associate Veterinarians within the same practice. (256 CMR. 2.01) <p>A licensee shall dispense or prescribe controlled substances only in the course of his or her professional practice after establishing a genuine veterinarian-client patient relationship (256 CMR 7.01).</p>
Veterinary Medical Director:	<p>All Veterinary Facilities, including but not limited to, Emergency Service Veterinary Facilities, and Mobile Clinics are required to appoint a Veterinary Medical Director, as defined in 256 CMR 2.01: Veterinary Medical Director.</p>

Information and Resources

FEDERAL:

Drug Enforcement Administration, New England Division
 15 Sudbury St, Boston, MA 02203
 Phone: (617) 557-2100



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Local DEA Offices:

- Cape Cod - (508) 996-4805
- New Bedford - (508) 996-4805
- Springfield - (413) 306-6920

Federal Law: www.deadiversion.usdoj.gov

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:

Massachusetts Veterinary Licensing Board website: <https://www.mass.gov/orgs/board-of-registration-in-veterinary-medicine>

Massachusetts Pharmacy Board website: <https://www.mass.gov/orgs/board-of-registration-in-pharmacy>

Massachusetts Law: <https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter94C>