

State-Specific Controlled Substance Requirements

# Updated 5/31/23

<ul> <li>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] NOTE:</li> <li>Separate biennial inventories must be completed for schedule II and schedule III-V controlled substances.</li> <li>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.</li> <li>Biennial inventories must be conducted by the DEA registrant, or their designee who has been granted Power of Attorney, along with an authorized witness.</li> <li>Biennial inventories must indicate whether they are conducted at the start or close of business.</li> </ul>
Rhode Island follows DEA requirements for biennial inventory
Veterinarian: 24 hours, every 2 years         General medicine topics: 20 hours on professional practice of veterinary         medicine         Management topics: 4 hours allowed         Online and home study: 4 hours allowed         Veterinarian Tech: Not required by state, however, if certified by the RIVTA, 12         hours required every 2 years.         General medicine topics: 12 hours if approved by national, state, or local associations         Other: College courses allowed (one class=3 CE hours)
Rhode Island does not currently require specific controlled substance CE
Evidence of completion of CE courses must be maintained for the preceding <b>two years.</b>
<ul> <li><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:         <ul> <li>Mixing two injectable drugs in the same syringe</li> <li>Creating an oral suspension from crushed tablets or an injectable solution</li> <li>Adding flavoring to a commercially available drug</li> <li>Creating a transdermal gel for a drug typically taken through other routes</li> <li>Mixing two solutions for instilling into the ear</li> </ul> </li> </ul>



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	" <u>Compounding</u> " means the act of combining two (2) or more ingredients as a result of a practitioner's prescription or medication order occurring in the course of professional practice based upon the individual needs of a patient and a relationship between the practitioner, patient, and pharmacist. Compounding does not mean the routine preparation, mixing, or assembling of drug products that are essentially copies of a commercially available product. Compounding shall only occur in the pharmacy where the drug or device is dispensed to the patient or caregiver and includes the preparation of drugs or devices in anticipation of prescription orders based upon routine, regularly observed prescribing patterns. R.I. Gen. Laws § 5-19.1-2(d)
	" <u>Manufacturer</u> " means a person engaged in the production, preparation, propagation, <b>compounding</b> , or processing of a drug or other substance or the packaging or repackaging of the substance, or the labeling or re-labeling of the commercial container of that substance, but does not include the activities of a veterinarian or pharmacist who, as an incident to the administration or dispensing of the substance in the course of professional practice, prepares, compounds, packages, or labels the substance. <b>COMPOUNDING FOR OFFICE USE IS PROHIBITED IN RI.</b>
Dispensing:	A " <u>dispenser</u> " is identified as a practitioner who delivers a controlled substance to an ultimate user or their representative by, or pursuant to the lawful order of, a practitioner, including the packaging, labeling, or compounding necessary to prepare the substance for delivery.
	Veterinary drugs dispensed by a veterinarian shall comply with the requirements of <u>section 21-31.1-8 of the Rhode Island General Laws</u> , as amended, except for the prescription number.
	Label of dispensed veterinary drugs. – Every veterinary drug dispensed pursuant to a prescription shall bear a label containing the name and address of the dispenser, prescription number, date of filling, name of the veterinarian, species of patient, name and strength of drug, amount dispensed, directions for use, withdrawal time, and cautionary statements, if any, appropriate for the prescription. Labels of veterinary drugs dispensed by a veterinarian shall comply with this section except for the prescription number.
Diversion Reporting:	Follow DEA reporting guidelines and inform local law enforcement.
Euthanasia:	Euthanasia may be performed by licensed veterinarians or an agent of a veterinarian.
Rhode Island PDMP:	The RI PDMP monitors the prescribing and dispensing of Schedule II–V controlled substances and opioid antagonists including, but not limited to, naloxone.
	PDMP enrollment is required for prescribers and dispensers; however, the use of the PDMP is required for only prescribers. Veterinarians have access to animal owner's prescription history.
	All dispensers_of Schedule II–V controlled substance prescriptions are required to collect and report their dispensing information.
	Rhode Island requires Opioid Antagonists PMP reporting as well.



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	Account Registration page: <u>https://pmpclearinghouse.net/registrations/new</u>
Ownership:	Non-veterinarian practice ownership is allowed but a licensed veterinarian is required to be on the clinics veterinary premise permit as the responsible licensee for the clinic.
Power of Attorney Notarization:	If the power of attorney is granted to a person other than an attorney, certified public accountant, or licensed public accountant, or enrolled agent, it must be witnessed or notarized below. $\frac{22-4.10-2}{2}$
Prescribing:	<u>E-prescribing</u> : Rhode Island passed SB 546 in 2017 which requires e-Prescribing of all controlled substances went into effect January 1, 2020. <b>Prescribers, such as</b> <b>veterinarians are issued a permanent waiver.</b> " <u>Prescription</u> " means an order from a veterinarian to a pharmacist authorizing the dispensing of a prescription veterinary drug to a client for use on or in a patient.
	Any veterinarian licensed in the state of Rhode Island who writes a prescription for an animal patient shall provide a copy of that prescription to the owner of the animal patient, upon request of the owner, for the purpose of filling the prescription with a licensed pharmacy. <u>216-RICR- 40-05-14.9</u> .
	<ul> <li>(2) The distribution of a prescription veterinary drug to, or its possession by, any person other than the following: <ul> <li>(i) A person holding a permit required by § 21-31.1-4(a).</li> <li>(ii) A veterinarian's client or his or her agent, provided that the drug is dispensed by or on the prescription of the veterinarian as the relationship is defined in § 21-31.1-2(13).</li> <li>(3) The failure to keep records on distribution and receipt of veterinary drugs as required by § 21-31.1-7.</li> <li>(4) The use of a code or euphemism on records, required by § 21-31.1-7, which causes the true nature of a veterinary drug to be concealed.</li> <li>(5) The failure to permit entry or inspection and collection of samples as authorized by § 21-31.1-11, or to produce for examination the records required to be kept by § 21-31.1-7.</li> <li>(6) The extra-label use of a veterinary drug by any person except as provided by § 21-31.1-12.</li> <li>(7) The removal or other authorized disposition of a drug while under detention as provided by § 21-31.1-15.</li> <li>(8) The failure to have a valid permit posted as described in § 21-31.1-1-4(d).</li> <li>(21 R.I. Gen. Laws Ann. § 21-31.1-13 (West)) Statute</li> </ul> The extra-label use of any veterinary drug in or on a food-producing animal by any person other than a veterinarian or a person working under the control of a veterinarian is a prohibited act. Extra-label use of these drugs by or on the order of a veterinarian is not prohibited provided all the following conditions are met: <ul> <li>(1) A careful medical diagnosis is made by the veterinarian within the context</li> </ul></li></ul>
	of a valid veterinarian-client/patient relationship. (2) A determination is made by the veterinarian that there is no marketed drug specifically labeled to treat the condition diagnosed, or that drug therapy as



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	recommended by the labeling has been found clinically ineffective in the animal(s) to be treated.
	(3) Procedures are instituted to assure that the identity of the treated animal is
	carefully maintained.
	(4) A significantly extended time period is assigned for drug withdrawal prior to
	marketing meat, milk, or eggs; steps are taken to assure that the recommended withdrawal times are met; and no illegal residues occur as determined by the
	U.S. FDA or other federal agency which may have jurisdiction, e.g. USDA, EPA.
	(21 R.I. Gen. Laws Ann. § 21-31.1-12
Recordkeeping:	Controlled Substance Records: Records required by this chapter shall be
	maintained for not less than two (2) years after distribution of the drug has been
	completed. <u>R.I. Gen. Laws § 21-31.1-10</u>
	Patient Records: <b>5 years</b> from last visit, or, for deceased patients/3 years from
	the date of death.
Veterinary Professional License:	Renewals: or before the <b>first day of March of each two-year (2) period</b> .
	On or before the first day of March of each two-year period, the Department
	shall mail an application for renewal of license to every person to whom a
	license has been issued or renewed during the current licensure period. Every
	person so licensed who desires to renew his or her license shall file with the
	Department such renewal application duly executed, together with a renewal
	fee as set forth in the Fee Structure for Licensing, Laboratory and Administrative
	Services Provided by the Department of Health (Part 10-05-2 of this Title) on or before the thirty-first day of March of each even year.
	Renewal Info
Supervision:	
	(5) The nursing care to animals in the establishment or facilities of a registered
	veterinarian under his or her general supervision, direction, and control by the
	employees of the veterinarian or the activities of a person assisting a
	veterinarian during the course of any procedure or treatment.
	R.I. Gen. Laws § 5-25-7
State Scheduled CS's:	<u>Xylazine</u> : on March 21, 2023, <u>HB 5922<sup>19</sup> and <u>SB 738<sup>20</sup></u> were introduced seeking to</u>
	designate xylazine HCL as a schedule V controlled substance. The bills are still in process and have not yet been signed into law.
	process and have not yer been signed into idw.
State CS License:	Rhode Island does require DEA registrant practitioners to obtain a second state
	controlled substance license, prior to a DEA registration and an active
	Veterinary Medical Professional License to practice in Rhode Island.
Telemedicine:	No existing laws. Where telemedicine occurs is not defined.
VCPR:	VCPR must be established in-person and only applies to one veterinarian.
	(6) "Veterinarian/client/patient relationship" means a relationship where all of
	the following conditions have been met:
	(i) The veterinarian has assumed the responsibility for making medical
	judgments regarding the health of the animal or animals and the need for
	medical treatment, and the client has agreed to follow the instructions of the
	veterinarian.
	(ii) The veterinarian has sufficient knowledge of the animal or animals to
	initiate at least a general or preliminary (e.g. tentative) diagnosis of the
	medical condition of the animal or animals. This means that the veterinarian



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<ul> <li>has recently seen and is personally acquainted with the keeping and care of the animal or animals, and/or by medically appropriate and timely visits to the premises where the animal or animals are kept.</li> <li>(iii) The veterinarian is readily available for follow-up in cases of adverse reactions or failure of the regimen of therapy.</li> <li>(iv) The veterinarian maintains records, which document patient visits, diagnosis, treatment, and other relevant information.</li> </ul>
5-25-2. Definitions

### **Information and Resources**

#### FEDERAL:

Drug Enforcement Administration, New England Division 15 New Sudbury Street, Room E-400 Boston, MA 02203 Phone: (617) 557-2100

### Local DEA Offices

Providence - (401) 732-2550

Federal Law: <u>www.deadiversion.usdoj.gov</u> Controlled Substances Act: <u>21 USC 801 – 904</u> Code of Federal Regulations: <u>21 CFR Part 1300 – 1399</u> NDC drug: <u>www.fda.gov/Drugs/DevelopmentApprovalProcess/UCM070829</u> Diversion Control Division: <u>https://www.deadiversion.usdoj.gov/schedules/</u>

### STATE:

Rhode Island Board of Veterinary Medicine website: <u>https://health.ri.gov/licenses/detail.php?id=247</u> Rhode Island Board of Pharmacy website: <u>https://health.ri.gov/licenses/detail.php?id=275</u>