

## State-Specific Controlled Substance Requirements Checklist

#### Updated 6/24/23

Biennial Inventory (DEA):	<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]</li> <li>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 annual inventory for the state.</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> </ul>
	Biennial inventories must indicate whether they are conducted at the start or close of business.
Annual Inventory (NE):	<ul> <li>Annual inventory must be submitted to the NE Department of Health and Human Services Division of Public Health Licensure Unit. To submit your annual controlled substances inventory you can either:</li> <li>1. Mail a copy to the address listed in the pharmacy contact information; OR</li> <li>2. Submit a scanned copy to <u>dhhs.medicaloffice@nebraska.gov</u></li> </ul>
	<ul> <li>The original annual controlled substance inventory must be maintained at the facility. A registrant whose inventory fails to comply with these requirements shall be guilty of a Class IV misdemeanor. Each registrant manufacturing, distributing, storing, or dispensing controlled substances in Schedules I, II, III, IV, or V of section 28-405 of the Statutes Relating to Pharmacy shall prepare an annual inventory of each controlled substance in his or her possession. Such inventory shall:</li> <li>Be taken within one year after the previous annual inventory date</li> <li>Contain such information as shall be required by the Board of Pharmacy</li> <li>Be copied and such copy forwarded to the Department within 30 days after completion</li> <li>Be maintained at the location listed on the registration for a period of five years</li> <li>Contain the name, address, and Drug Enforcement Administration number of the registrant, the date and time of day the inventory was completed, and the signature of the person responsible for taking the inventory</li> <li>List the exact count or measure of all controlled substances listed in Schedules I, II, III, IV, and V of section 28-405; and</li> </ul>
	<ul> <li>Be maintained in permanent, read-only format separating the inventory for controlled substances listed in Schedules I and II of section 28-405 from the inventory for controlled substances listed in Schedules III, IV, and V of section 28-405</li> </ul>
CE:	Veterinarian: 32 hours every 2 years – Nebraska Accepts 8 hours of Online CE Courses 32 hours every 2 years General medicine topics: 32 hours if approved by national, state, and local associations Management topics: 8 hours allowed Formal meetings: allowed
	Veterinary Technicians: 16 hours every 2 years – Nebraska Accepts 4 hours of Online General medicine topics: 16 hours required and must be approved by national, state, or local associations Management: 4 hours allowed Other: Formal presentations allowed



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	All hours can be completed online.
	New 2022 Continuing Competency Requirement for veterinarians who prescribe controlled substances: 3 hours of the 32 hours of CE are required to be on the subject of opioids and .5 hours of the 3 hours are required to be on the subject of the PDMP (Prescription Drug Monitoring Program).
	Records must be maintained for a period of <b>four years</b> and copies may be requested by the Board for audit verification purposes. Please do not send records to the Board unless requested for an audit.
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." <u>24 Del. Admin.</u> Code § 8.0
	<ul> <li><u>Compounding</u> 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:</li> <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>
	NE Compounding: Compounding means the preparation of components into a drug product (1) as the result of a practitioner's medical order or initiative occurring in the course of practice based upon the relationship between the practitioner, patient, and pharmacist or (2) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding includes the preparation of drugs or devices in anticipation of receiving medical orders based upon routine, regularly observed prescribing patterns.
	It is only legal to compound a medication if there is not a commercially FDA approved drug available. Using a trusted, reputable compounding pharmacy is extremely important because as your veterinarian we are liable for unsafe compounded medications not the pharmacy.
Dispensing:	<u>Dispense</u> or <u>dispensing</u> means interpreting, evaluating, and implementing a medical order, including preparing and delivering a drug or device to a patient or caregiver in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.
	Dispensing includes (a) dispensing incident to practice, (b) dispensing pursuant to a delegated dispensing permit, (c) dispensing pursuant to a medical order, and (d) any transfer of a prescription drug or device to a patient or caregiver other than by administering. <u>Nebraska Revised Statute 38-2817</u>
	You cannot dispense without a valid VCPR.
	(1) Except as otherwise provided in this section or section 28-412 or when administered directly by a practitioner to an ultimate user, a controlled substance listed in Schedule II of section 28-405 shall not be dispensed without a prescription from a practitioner authorized to prescribe.
	Beginning January 1, 2022, all such prescriptions shall be subject to section 38-1,146, except that all such prescriptions issued by a practitioner who is a dentist shall be subject to section 38-1,146



## State-Specific Controlled Substance Requirements Checklist

	Beginning January 1, 2024, no prescription for a controlled substance listed in Schedule II of section 28-405 shall be filled more than six months from the date of issuance. A prescription for a controlled
	substance listed in Schedule II of section 28-405 shall not be refilled.
	(3)(a) In emergency situations, a controlled substance listed in Schedule II of section 28-405 may be dispensed pursuant to an oral prescription reduced to writing in accordance with subsection (2) of this section, except for the prescribing practitioner's signature, and bearing the word " <b>emergency</b> ".
	(b) For purposes of this section, <u>emergency situation</u> means a situation in which a prescribing practitioner determines that (i) immediate administration of the controlled substance is necessary for proper treatment of the patient, (ii) no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance listed in Schedule II of section 28-405, and (iii) it is not reasonably possible for the prescribing practitioner to provide a signed, written or electronic prescription to be presented to the person dispensing the controlled substance prior to dispensing.
	Nebraska Revised Statute 28-414
Diversion Reporting:	<ul> <li>In addition to submitting a completed 106 form to the DEA, please provide a copy of the completed DEA 106 form to:</li> <li>Diversion Captain, NE State Patrol Headquarters, PO Box 94907, Lincoln, NE 68509-4907</li> <li>Division of Investigations, NE Department of Health &amp; Human Services, PO Box 94722, Lincoln, NE 68509</li> <li>Division of Public Health, Licensure Unit ATTN: Pharmacy, PO Box 94986, Lincoln, NE 68509-</li> </ul>
Euthanasia:	4986 Euthanasia may be performed by:
Lomanasia.	<ul> <li>Licensed veterinarians</li> <li>Licensed veterinarian technician under the direction, supervision and control of a veterinarian provided the veterinarian makes a physical examination of the patient treated</li> <li>Commercial Dog Breeder</li> <li>Commercial Dog and Cat Operator</li> </ul>
Ownership:	Non-veterinary ownership is allowed, but a licensed veterinarian is required to be on the premises permit as the responsible licensee responsible for the clinic.
Power of Attorney:	A power of attorney under the Nebraska Uniform Power of Attorney Act is not valid unless it is acknowledged before a notary public or other individual authorized by law to take acknowledgments.
Prescribing:	Prescription means an order, formula, or recipe issued in any form of oral, written, electronic, or other means of transmission by a practitioner licensed under the Uniform Credentialing Act.
	For purposes of this section, <u>prescriber</u> means a health care practitioner authorized to prescribe controlled substances in the practice for which credentialed under the Uniform Credentialing Act.
	<ul> <li>A prescription for controlled substances listed in Schedule II of section 28-405 must contain the following information prior to being filled by a pharmacist or dispensing practitioner:</li> <li>(a) Patient's name and address,</li> <li>(b) name of the drug, device, or biological,</li> <li>(c) strength of the drug or biological, if applicable,</li> <li>(d) dosage form of the drug or biological,</li> <li>(e) quantity of the drug, device, or biological prescribed,</li> <li>(f) directions for use,</li> <li>(g) date of issuance,</li> <li>(h) prescribing practitioner's name and address, and</li> </ul>



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(i) Drug Enforcement Administration number of the prescribing practitioner.
If the prescription is a written paper prescription, the paper prescription must contain the prescribing practitioner's manual signature. If the prescription is an electronic prescription, the electronic prescription must contain all of the elements in subdivisions (a) through (i) of this subsection, must be digitally signed, and must be transmitted to and received by the pharmacy electronically to meet all of the requirements of the Controlled Substances Act, 21 U.S.C. 801 et seq., as it existed on January 1, 2014, pertaining to electronic prescribing of controlled substances. Nebraska Revised Statute 28-414
<u>E-prescribing:</u> <b>veterinarians are exempt</b> from the January 1, 2022 e-prescribing mandate. <u>Nebraska Revised Statute 38-1,146</u>
<ul> <li>Nebraska requires pharmacies and other dispensers to submit information on all dispensed prescriptions daily to provide a comprehensive medication history to improve patient safety.</li> <li>Submission of ALL controlled substances (C2-C5 only) dispensed to a veterinarian patient (non- human) in the state or to an address in the state.</li> <li>Dispensers are required to provide data daily in a standardized format or may provide zero reports if no medications were dispensed that met the required criteria.</li> </ul>
Data is encouraged to be provided as close to real-time as possible.
If you do not dispense any controlled substances to veterinary patients, you may apply to DHHS for an exemption <u>here</u> .
Nebraska PDMP RxGov User's Guide
Patient records: All records, except records for boarding kennels, shall be kept and maintained for a period of three (3) years, unless the Director requests, in writing, that they be maintained for a longer period, for the purpose of investigation. 23 Neb. Admin. Code, ch. 18, § 010
Controlled substance records: Each registrant manufacturing, distributing, or dispensing controlled substances in Schedule I, II, III, IV, or V of section 28-405 shall keep and maintain a complete and accurate record of all stocks of such controlled substances on hand. Such records shall be maintained for <b>five years</b> .
N/A
Nebraska <b>does not</b> require a state CS's license.
<u>Supervisor</u> means a licensed veterinarian or licensed veterinary technician as required by statute or rule or regulation for the particular delegated task being performed by a veterinary technician or unlicensed assistant.
Direct supervision means that the supervisor is on the premises and is available to the veterinary technician or unlicensed assistant who is treating the animal and the animal has been examined by a veterinarian at such times as acceptable veterinary practice requires consistent with the particular delegated animal health care task.
Immediate supervision means that the supervisor is on the premises and is in direct eyesight and hearing range of the animal and the veterinary technician or unlicensed assistant who is treating the animal and the animal has been examined by a veterinarian at such times as acceptable veterinary practice requires consistent with the particular delegated animal health care task.



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Telemedicine:	Indirect supervision means that the supervisor is not on the premises but is easily accessible and has given written or oral instructions for treatment of the animal and the animal has been examined by a veterinarian at such times as acceptable veterinary practice requires consistent with the particular delegated animal health care task. No existing laws.
Veterinary Professional License:	Renew <b>annually</b> . Licenses expire April 1 of every even year, regardless of when the license is issued.
VCPR:	<ul> <li>VCPR must be established in-person and only applies to one veterinarian.</li> <li><u>Veterinarian-client-patient relationship</u> means that: <ul> <li>(1) The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the animal and the need for medical treatment, and the client has agreed to follow the veterinarian's instructions;</li> <li>(2) The veterinarian has sufficient knowledge of the animal to initiate at least a general or preliminary diagnosis of the medical condition of the animal. This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal by virtue of an examination of the animal or by medically appropriate and timely visits to the premises where the animal is kept; and</li> <li>(3) The veterinarian is readily available or has arranged for emergency coverage and for followup evaluation in the event of adverse reactions or the failure of the treatment regimen.</li> </ul> </li> </ul>

### **Information and Resources**

#### FEDERAL:

Drug Enforcement Administration, Omaha Division 7300 World Communications Drive Omaha, NE 68122 Phone: ((402) 965-3600

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:

Nebraska Veterinary Medical Association website: <u>https://nvma.org</u> Nebraska Board of Pharmacy website: <u>https://www.board-of-pharmacy.com/nebraska-board-of-pharmacy/</u>