

State-Specific Controlled Substance Requirements

Updated 5/31/23

DEA Biennial Inventory:	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. PA follows DEA biennial inventory requirements
CE:	Veterinarians: 30 hours during the 24 months preceding the renewal date.
	 b) A maximum of 25% of the hours may be earned by taking individual study or written or computer-based correspondence courses for which third-party verification of satisfactory completion is provided. (d) Courses in office management or practice building may not be used to
	meet the 30-hour continuing education requirement.
	Veterinarian Technicians: minimum of 16 hours in the 24 months prior to license renewal.
	CE records must be saved for 5 years.
	No specific opioid CE requirements at this time.
	49 Pa. Code § 31.15(a-d) Continuing education
Compounding:	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
	PA Compounding: Veterinary compounding must be done either by a veterinarian or a compounding pharmacist who has received a prescription from the veterinarian. Compounded drugs are created on a case-by-case basis for a specific patient, and they are not created in bulk.



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§ 27.601. Compounding of preparations: The compounding of sterile and nonsterile preparations shall be done in accordance with section 503a of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 353a), Federal regulations promulgated thereunder, and the current version of the USP chapters governing compounding. § 27.605. Label information required.

The label affixed to or on the dispensing container of a compounded drug product dispensed by a pharmacy pursuant to a prescription or drug order must bear the information as required in § 27.18(d) (relating to standards of practice) and any additional information required by USP provisions pertaining to label information requirements.

§ 27.606. Compounding records.

Compounding records required by this chapter shall be retained as the original records and shall be readily available at the pharmacy for inspection and photocopying by agents of the Board or other authorized authorities for at least 2 years following the date of the record. Prescriptions for all products compounded at the pharmacy shall be maintained on file at the pharmacy as required under § 27.18(b) (relating to standards of practice).

PA State Board of Pharmacy Compounding Regulations

Dispensing:

"<u>Dispense</u>" or "dispensing" means the delivery or preparation of a prescription or non-prescription drug pursuant to the lawful order of a practitioner including packaging, labeling, or compounding necessary to prepare such item for that delivery for subsequent administration to or use by a patient or other individual entitled to receive the drug. (PA Controlled Substances, Drugs, Device, and Cosmetic Act of 1972, P.L. 233, No. 64., Section 2)

Packaging: (c) Prescription drugs dispensed by a veterinarian, other than drugs for food animals, shall be dispensed in child resistant packaging or in the manufacturer's original packaging, except when the client specifically requests other packaging.

- (d) Prescription drugs dispensed by a veterinarian shall be labeled with, at a minimum, the following information:
- (1) The name, address and telephone number of the prescribing veterinarian and the name and telephone number of the dispenser, if different.
 - (2) The brand or generic name of the drug.
 - (3) The potency and the quantity of the drug.
 - (4) The number of refills allowed, if any.
 - (5) Adequate directions for use, which shall include quantity of dose, frequency of administration or application, duration of administration or application, and route or method of administration or application.
 - (6) Any cautionary statement specified by the veterinarian or required by law.
 - (7) The name of the patient, if applicable.
 - (8) The date the drug was dispensed.
 - (9) The expiration date of the drug.

<u>Expiration</u>: (e) Veterinarians shall dispense or administer only drugs, including prescription drugs, that are within the expiration date specified by the manufacturer, and shall dispense or administer only drugs that will not expire within the prescribed treatment period.

Title 49, § 31.21, Principle 8 (2) (c-f)



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Diversion Reporting:	Reporting Suspected Aberrant Medication Dispensing
	Follow DEA reporting requirements for theft and significant loss.
Euthanasia:	Euthanasia may be performed by licensed veterinarians, certified veterinary technicians working under indirect supervision of a licensed veterinarian or a certified euthanasia technician Someone is qualified to be issued a euthanasia technician license if all of the following apply: "(i) [the person] meets the eligibility criteria established by the board which shall include knowledge of the Commonwealth's statutes and regulations relating to euthanasia; (ii) [the person] demonstrates adequate knowledge of the potential hazards and proper techniques to be used in administration of euthanasia drugs by satisfying all requirements of the board and at least one of the following: (A) [the person] successfully completes a euthanasia technician certification course, including at least 14 hours of instruction, which is approved by the board and
	administered by: (I) the National Animal Control Association; (II) the American Humane Association; (III) the Humane Society of the United States; (IV) the Pennsylvania Veterinary Medical Association; (V) the University of Pennsylvania School of Veterinary Medicine; (VI) the Federated Humane Societies of Pennsylvania; or (VII) any other courses approved by the board; (B) [the person] is a euthanasia technician registered or licensed under the laws of another state or territory of the United States which has requirements substantially similar to the requirements of this section and presents satisfactory proof to the board of being engaged in the practice of euthanasia for a period of at least one year out of the past five years; [or] (C) [the person] meets other requirements established by the board" (3 P.S. § 328.304(c)).
PA Prescription Drug Monitoring Program (PA PDMP):	Pennsylvania <u>veterinarians are specifically exempted from reporting</u> to the PA PDMP but they must register .
	As of January 1, 2017, licensed prescribers who are lawfully authorized to distribute, dispense, or administer a controlled substance in the Commonwealth <u>must register</u> with the PA PMDP: <u>PA PDMP Registration</u>
	Non-veterinary prescribers must query the PA PDMP each time a patient is prescribed an opioid drug product or benzodiazepine by the prescriber. Prescribers must continue to query the PA PDMP: 1. For each patient the first time the patient is prescribed a controlled substance by the prescriber for purposes of establishing a baseline and a thorough medical record; or 2. If a prescriber believes or has reason to believe, using sound clinical judgment, that a patient may be abusing or diverting drugs.
PA Veterinary Medical Professional License:	PA law requires veterinary practitioners working with controlled substances to have a valid DEA registration and Veterinary Medical Professional License for the State of Pennsylvania.



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	Renewal: veterinarians and veterinary technician licenses expire on November the
	30th of each even-numbered year. Renewal notices are mailed two to three months
	prior to this expiration date.
	The fee for veterinary technician license renewal in the state of Pennsylvania is \$100.
Ownership:	Non-veterinarians are prohibited from individually owning a veterinary practice or forming a for-profit corporation to provide veterinary medical services and directly receive the fee for these services that reside in states that prohibit non-veterinary ownership or majority veterinary ownership.
Power of Attorney Notarization:	A POA in Pennsylvania <u>must be dated, signed by the principal, witnessed by two adults, and notarized.</u> If the principal is not able to write, he or she may sign by making a mark (such as an "X") or by directing another person to sign on his or her behalf.
Prescriptions:	e-prescribing: Veterinarians are exempt from the requirement to use the electronic prescribing of controlled substances (EPCS) system that went into effect October 24, 2019. A veterinarian shall only prescribe prescription drugs to animals that are under the
	veterinarian's care. "Under the veterinarian's care" means that the veterinarian or one of the veterinarian's licensed associates has examined the animal or has made medically appropriate and timely visits to the premises where the animal is kept. Title 49, § 31.21, Principle 8 (2)(b)
	"Prescribe" means the issuance of a prescription by a duly licensed medical practitioner authorized by law to prescribe drugs. (See "prescription").
	" <u>Prescription</u> " means a written or oral order issued by a duly licensed medical practitioner in the course of his or her professional practice for a controlled substance which is dispensed for use by a consumer. PA. (Pharmacy Act, Section 2-8 added June 29, 2002, P.L.673, No.102)
Recordkeeping:	CS Records: two years per DEA requirements.
	Patient Records: PA requires patient records to be maintained for three years from the date that the patient was last treated by the veterinarian.
State CS's License:	Pennsylvania 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 Pennsylvania.
State Scheduled CS's:	<u>Xylazine</u> : As of June 3, 2023, xylazine was temporarily added to the list of schedule III drugs under Pennsylvania's Controlled Substance, Drug, Device, and Cosmetic Act. <u>Temporary scheduling of xylazine</u>
Supervision:	Direct veterinary supervision—A veterinarian has given either oral or written instructions to the certified veterinary technician, veterinary assistant, or other licensed professional as set forth in Principle 6(b) of § 31.21 (relating to Rules of Professional Conduct for Veterinarians), and the veterinarian is on the premises and is easily and quickly available to assist the certified veterinary technician, veterinary assistant or other licensed professional.
	Immediate veterinary supervision—A veterinarian is in visual and audible range to assist the veterinary assistant.



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	Indirect veterinary supervision—A veterinarian is not on the premises but is acquainted with the keeping and care of the animal by virtue of an examination of the animal or medically appropriate and timely visits to the premises where the animal is kept, and has given written or oral instructions to the certified veterinary technician for treatment of the animal patient.
Telemedicine:	No existing laws. Where telemedicine occurs is not defined.
Veterinary Client Patient Relationship (VCPR):	VCPR must be established in-person but VCPR can apply to any vet working at the same practice .
	Regulations Concerning Establishing a VCPR: " <u>Under the veterinarian's care</u> " means that the veterinarian or one of the veterinarian's licensed associates has examined the animal or has made medically appropriate and timely visits to the premises where the animal is kept (<u>49 Pa. Code § 31.21</u>).

Information and Resources

FEDERAL:

Drug Enforcement Administration, Philadelphia Division Wm. J. Green Fed. Bldg. 600 Arch Street, Room 10224 Philadelphia, PA 19106 Phone: (215) 861-3474

Harrisburg Resident Office 1001 Elmerton Avenue Harrisburg, PA 17110 Phone: (717) 221-2270

Local DEA Offices:

Allentown - (610) 770-0940

Harrisburg - (717) 221-2270

Pittsburgh - (412) 777-6940

Scranton - (570) 496-1020

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/



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STATE:

Pennsylvania Veterinary Licensing Board website:

 $\underline{https://www.dos.pa.gov/Professional Licensing/Boards Commissions/Veterinary Medicine/Pages/defaul}\\ \underline{t.aspx}$

Pennsylvania Pharmacy Board website:

https://www.dos.pa.gov/ProfessionalLicensing/BoardsCommissions/Pharmacy/Pages/default.aspx

Pennsylvania Law: http://www.pacodeandbulletin.gov/