

State-Specific Controlled Substance Requirements

Updated 6/20/23

Annual IL Inventory:	Every licensee shall conduct an <u>annual inventory</u> that includes an actual count of drugs on hand for all Schedule II controlled substances and an approximate count for all Schedule III, IV and V controlled substances. The inventory shall be <u>maintained for a period of no less than five (5) years</u> . III. Admin. Code tit. 77, § 3100.360(c)
DEA Biennial Inventory:	 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: 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.
CE:	 Veterinarian: Each person who applies for renewal of a license as a veterinarian is required to complete 40 hours of continuing education (CE) relevant to the practice of veterinary medicine and surgery during the prerenewal period. A prerenewal period is the 24 months preceding the expiration date of the license. A renewal applicant is not required to comply with CE requirements for the first renewal. CE credit hours used to satisfy the CE requirements of another state may be applied to fulfillment of the CE requirements of the State of Illinois if the CE required by the other state is consistent with the CE requirements set forth in this Section. CE credit hours used to satisfy this requirement may be achieved through self-study courses offered by an approved provider.
	Legislation passed in <u>August 2018 (SB 2777</u>) requires all controlled substance providers, including veterinarians, to obtain 3 hours of continuing education on safe opioid prescribing. All veterinarians must obtain 3 hours of Safe Opioid Prescribing CE by January 2021. These 3 hours can be counted toward the total CE hours required for license renewal. The licensees shall maintain their CE records for <u>4 years</u> . <u>Title 68 Section 1500.25</u>
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.</u> Admin. Code § 8.0 <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: 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
	" <u>Compounding</u> " means the preparation and mixing of components, excluding flavorings, (1) as the
	result of a prescriber's prescription drug order or initiative based on the prescriber-patient-
	pharmacist relationship in the course of professional practice or (2) for the purpose of, or 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 prescription drug orders
	based on routine, regularly observed dispensing patterns. Commercially available products may
	be compounded for dispensing to individual patients only if both of the following conditions are
	met: (i) the commercial product is not reasonably available from normal distribution channels in a
	timely manner to meet the patient's needs and (ii) the prescribing practitioner has requested that
	the drug be compounded. (720 ILCS 570/)(d-10) Illinois Controlled Substances Act.
	III. Admin. Code tit. 68, § 1330.640 - Pharmaceutical Compounding Standards:
	All pharmaceutical compounding standards, both sterile and nonsterile, shall be governed by the
	USP-NF (USP 41-NF 36), as set forth in the United States Pharmacopoeia (USP), 41st Revision and the
	National Formulary, 36 th Edition, Compounding Compendium, with the exception of USP Chapter
	<800> as it pertains to the handling of hazardous drugs in health care settings. Beginning May 1,
	2019, all pharmaceutical compounding standards, both sterile and nonsterile, shall be governed
	by the USP-NF (USP 42-NF 37), as set forth in the 2019 edition of the USP Compounding
	Compendium, with the exception of USP Chapter <800> as it pertains to the handling of hazardous
	drugs in health care settings.
	a) <u>A pharmacy may only dispense compounded drugs pursuant to a valid patient-specific</u>
	prescription, except as provided in this Section.
	b) " <u>Office use</u> " means the administration of a non-patient specific compounded drug to a patient
	by a practitioner in the practitioner's office or by the practitioner in a health care facility or
	treatment setting. "Office use" does not include a pharmacy's delivery of a compounded drug to a
	prescribing practitioner's office pursuant to a valid patient-specific prescription.
	c) Sterile compounding for office use is prohibited unless the pharmacy is in full compliance with 21
	USC 353b, including becoming registered as an outsourcing facility and licensed as a wholesale
	drug distributor pursuant to the Wholesale Drug Distribution Licensing Act [225 ILCS 120]. However,
	a sterile compounded drug may be delivered to the prescribing practitioner's office for
	administration pursuant to a valid patient-specific prescription.
	d) A pharmacist may dispense and deliver a reasonable quantity of a nonsterile compounded
	drug to a practitioner for office use by the practitioner in accordance with this Section, provided:
	1) The quantity of compounded drug does not exceed the amount a practitioner anticipates
	may be used in the practitioner's office before the expiration of the beyond use date of the
	drug;
	2) The quantity of compounded drug is reasonable considering the intended use of the
	compounded drug and the nature of the practitioner's practice;
	3) The quantity of compounded drug for any practitioner, and all practitioners as a whole, is not
	greater than an amount the pharmacy is capable of compounding in compliance with
	pharmaceutical standards for identity, strength, quality and purity of the compounded drug
	that are consistent with United States Pharmacopoeia guidelines;
1	4) The pharmacy maintains readily retrievable records of all compounded drugs ordered by
	practitioners for office use. The records must be maintained for a minimum of 5 years and shall
	include:
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	A) The name, address and phone number of the practitioner ordering the compounded drug
	for office use and the date of the order;
	B) The name, strength, quantity and dosage form of the compounded drug provided, including
	the number of containers and quantity in each;
	C) The date the drug was compounded;D) The date the compounded drug was provided to the practitioner; and
	E) The lot number and beyond-use date. Label: 5) The pharmacy affixes a label to any compounded drug that is provided for office use. The
	label shall include:
	A) The name, address and phone number of the compounding pharmacy;
	B) The name, strength and dosage form of the compounded drug and a list of active
	ingredients and strengths. If the number of active ingredients would prohibit proper labeling,
	then the pharmacist shall provide to the practitioner a complete list of the active ingredients
	and strengths (including those on the label);
	C) The pharmacy's lot number and beyond-use date;
	D) The quantity or amount in the container;
	E) The appropriate ancillary instructions, such as storage instructions, cautionary statements, or
	hazardous drug warning labels when appropriate; and
	F) The statement "For Office Use Only - Not for Resale".
	e) All pharmacies that compound drugs must maintain, at a minimum, the following standards and
	equipment:
	1) A separate storage area for materials used in compounding;
	2) Scales or measuring devices with sufficient accuracy for the products to be compounded;
	3) An area of the pharmacy used exclusively for compounding;
	4) A logbook or record keeping system to track each compounded drug, which must include
	the lot number, expiration date of components used, and beyond-use date of compounded
	drug. This applies to each nonsterile compounded drug and each sterile compounded drug
	with a beyond-use date greater than 24 hours;
	5) The current edition of the USP Compounding Compendium. This publication may be in
	electronic format and/or available via the internet;
	6) If engaged in veterinary drug compounding, "Plumb's Veterinary Drug Handbook" or any
	other similar publication approved by the Division;
	7) Consumable materials, as appropriate to the pharmacy services provided at that specific
	pharmacy, including but not limited to: filter paper, powder papers, empty capsules, ointment
	jars, bottles, vials, safety closures, powder boxes, labels and distilled water;
	8) Drug Distribution and Control
	A) Patient Profile or Medication Record System. A pharmacy generated patient profile or
	medication record system shall be maintained, in addition to the prescription file. The patient
	profile or medication record system shall contain, at a minimum:
	i) Patient's name;
	ii) Date of birth or age;
	iii) Gender;
	iv) Compounded sterile drugs dispensed;
	v) Date dispensed, if off site;
	vi) Date compounded;
	vii) Drug content and quantity;
	viii) Patient directions, if drug is administered off site;
	ix) Other drugs or supplements the patient is receiving, if provided by the patient or his or her
	agent; and
	x) Known drug sensitivities and allergies to drugs and foods.



	B) <u>Labeling</u> . Each compounded drug dispensed to patients shall be labeled with the following information, using a permanent label:
	i) Name, address and telephone number of the licensed pharmacy, if not used within the
	facility;
	ii) Date dispensed and identifying number, if used off site;
	iii) Patient's name and room number, if applicable;
	iv) Name of each drug component, strength, amount and dosage form;
	v) Directions for use and/or infusion rate, if used off site;
	vi) Prescriber's name, if used off site;
	vii) Required controlled substances transfer warnings, when applicable;
	viii) Beyond-use date, and time if appropriate;
	ix) If used offsite, identity of compounding and dispensing pharmacist or other authorized individual; and
	x) Auxiliary label with storage requirements, if applicable.
	C) In addition to labeling requirements on the Pharmacy Practice Act [225 ILCS 85] and this Part,
	compounded drugs dispensed to patients shall have on the label or an auxiliary label the
	following: 'This prescription was specifically compounded in our pharmacy for you at the direction
	of your prescriber."
	D) The pharmacist-in-charge shall ensure that records are maintained for 5 years, are readily
	retrievable and in a format that provides enforcement agents an accurate and comprehensive
	method of monitoring distribution via an audit trail. The records shall include at least the following
	information:
	i) Purchase records; and
	ii) Patient profile or medication;
	g) Notwithstanding any other provision of this Section, a pharmacy may compound a reasonable
	quantity of sterile and nonsterile drug products for office use by a veterinarian.
Diversion Reporting:	DEA: DEA: Any theft or significant loss of a controlled substance must be reported in writing to the
	field division office of the DEA within one business day of the discovery of such loss or theft. Completion of a DEA 106 form regarding the loss or theft is also required.
	IL: In every instance that a licensee is required by <u>21 CFR 1301.76</u> to file with the DEA a Report of
	Theft or Loss of Controlled Substances (Form 106), a copy shall be sent to the IDFPR within one
	business day after submission to the DEA, along with the printed name of the person who signed
	the form. Failure to do so may result in discipline of the licensee. This information should be sent to
	the Drug Compliance Unit of the Division. <u>TITLE 77, CHAPTER XV: Section 3100.360(e)</u>
Euthanasia:	Por the ISV/MA non-veteringright are not able to perform outbenessis in Illingia. The only eventions
	Per the ISVMA, non-veterinarians are not able to perform euthanasia in Illinois. The only exceptions
	would be the certified euthanasia techs and an emergency situation likely overseen by IL Dept of Ag.
	Ag. Illinois Admin Rules on Humane Euthanasia Act:
	https://www.ilga.gov/commission/jcar/admincode/068/06801248sections.html
	Animals cannot be transported beyond State lines for the sole purpose of euthanasia unless the
	euthanasia is performed by a licensed veterinarian in a manner that is consistent with subsection
	(a) (510 ILCS 72/57(c)).
Illinois Prescription	Veterinarians are <u>exempt</u> from the IL PMP requirements.
Monitoring Program (IL PMP):	
	720 ILCS 570/314.5(C-5): a licensed veterinarian shall be exempt from registration and prohibited
	from accessing patient information in the Prescription Monitoring Program. Licensed veterinarians
	that are existing registrants shall be removed from the Prescription Monitoring Program.



IL State Veterinary License:	An Illinois controlled substances registration is a prerequisite for a DEA registration. The address on your Illinois controlled substances registration must be exactly the same address as your DEA registration. It is obtained through the Illinois Department of Professional Regulation (ILDPR) <u>Renewal</u> : Renew every <u>two years</u> through the IDFPR. <u>Fee</u> : \$100 <u>Inactive/expired</u> : (e) Any veterinarian or certified veterinary technician requesting restoration from inactive or expired status shall be required to complete the continuing education requirements for a single license or certificate renewal period, pursuant to rule, and pay the current renewal fee to restore his or her license or certification as provided in this Act. (f) Any licensee whose license is in inactive, expired, or suspended status shall not practice veterinary medicine and surgery in this State. (Source: <u>P.A. 98-339, eff. 12-31-13</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:	To have a valid <u>POA in Illinois</u> , you must sign the POA in the presence a notary public and at least one witness. The notary public cannot act as the witness.
Prescriptions:	On 1/1/23 a new law went into effect in Illinois requiring all controlled substance prescribers to issue prescriptions electronically. <u>This does not mean email</u> . This requirement is for all prescriptions classified as Schedule II, III, IV, or V. The only exemption to this requirement is if a prescriber issues 25 prescriptions or less in 12 months. The Illinois Department of Financial and Professional Regulation (IDFPR) has the authority to allow for additional exemptions and has not announced any exemptions at this time. As communicated by ISVMA on 6/20/23: Illinois veterinarians were to be exempted, no one objects, but the bill did not pass and the licensing department has decided to not write rules. IL veterinarians have no way of sending electronic scripts from veterinary practice software to our retail pharmacies. As a result, ISVMA is going to run a bill exempting the profession. Details will be forthcoming as things progress. Options for e-prescribing: https://iprescribe.app.link/iaWzi0Z1Pnb?_ga=2.110549635.725253530.1678451298-2041940787.1678451298 and https://mdtoolbox.com/eprescribe-controlled-substances.aspx Section 19.2 of the Veterinary Medicine and Surgery Practice Act of 2004, 225 ILCS 115/19.2: Sec. 19.2. <u>Patient requests for prescriptions</u> . A veterinarian shall honor a client's request for a prescription in lieu of dispensing a drug when a veterinarian-client-patient relationship exists and the veterinarian has determined that the drug is medically necessary. If you are asked to approve a prescription, you should do so only if the prescription is medically appropriate for the patient and you have a valid veterinarian-client-patient relationship. The decision as to whether a prescription drug should be used for a patient is made by you – the veterinarian – and not a pharmacy.



	<u>Containers</u> : Controlled substances must be marked and sealed as required under the Illinois Controlled Substance Act and its rules, and be placed in a plain outer container or securely wrapped in plain paper. Prescription medicines, the inner container must be labeled to show the name and address of the pharmacy or practitioner dispensing the prescription.
Recordkeeping:	<u>Illinois Controlled Substance Act</u> <u>CS & Patient records</u> : The Illinois Veterinary Licensing and Disciplinary Board requires you to keep records for a minimum of <u>five years</u> following the last treatment or examination. Records also need to be readily retrievable.
Relief Veterinarians:	The Illinois Department of Financial and Professional Regulation has indicated that relief veterinarians <u>may not</u> use their private Controlled Substance License to purchase medications for use in another clinic.
	Should a veterinary clinic run out of a medication, only a doctor with a controlled substance license registered at that location may legally purchase controlled substances for the clinic.
	In extraordinary circumstances a veterinarian should apply for a controlled substance license with the IDFPR, the cost is \$5.00 per Illinois licenses and the Department will work with the veterinarian in an effort to expedite the process.
State Scheduled CS's:	<u>Xylazine</u> : On February 9, 2023, <u>SB2089</u> was introduced to make xylazine a schedule I under the Illinois Controlled Substance Act with penalties for the knowing manufacture, delivery, or possession with intent to manufacture or deliver the drug. <i>Legislation is currently pending</i> On February 17, 2023, <u>HB 3873</u> was proposed to schedule xylazine as a schedule II controlled substance. <i>Legislation is currently pending</i>
State CS's License:	Illinois requires a separate state controlled substance license prior to obtaining a DEA registration.
Supervision:	" <u>Direct supervision</u> " means the supervising veterinarian is readily available on the premises where the animal is being treated. " <u>Immediate supervision</u> " means the supervising veterinarian is in the immediate area, within audible and visual range of the animal patient and the person treating the patient.
	" <u>Indirect supervision</u> " means the supervising veterinarian need not be on the premises, but has given either written or oral instructions for the treatment of the animal and is available by telephone or other form of communication.
	" <u>Supervising veterinarian</u> " means a veterinarian who assumes responsibility for the professional care given to an animal by a person working under his or her direction in either an immediate, direct, or indirect supervision arrangement. The supervising veterinarian must have examined the animal at such time as acceptable veterinary medical practices requires, consistent with the particular delegated animal health care task.
Telemedicine:	"VCPR" does not mean a relationship solely based on telephonic or other electronic communications. (225 ILCS 115/3)
Veterinary Client Patient Relationship (VCPR):	" <u>VCPR</u> " does not mean a relationship solely based on telephonic or other electronic communications. (225 ILCS 115/3)
	Sec. 5.5. Practice outside veterinarian-client-patient relationship prohibited. No person may practice veterinary medicine in the State except within the context of a veterinarian-client-patient relationship. (Source: <u>P.A. 96-1322, eff. 7-27-10.)</u>



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 <u>Veterinarian-client-patient relationship</u>" means that all of the following conditions have been met: (1) The veterinarian has assumed the responsibility for making clinical judgments regarding the health of an animal and the need for medical treatment and the client, owner, or other caretaker has agreed to follow the instructions of the veterinarian; (2) There is sufficient knowledge of an animal by the veterinarian 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, or the veterinarian with the prior relationship to provide reasonable and appropriate medical care if he or she is unavailable; and (3) The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the treatment regimen or, if unavailable, has designated another available
veterinarian who has access to the animal patient's records to provide reasonable and appropriate medical care.

Information and Resources

FEDERAL:

Drug Enforcement Administration, Chicago Division 230 S. Dearborn Street, Suite. 1200 Chicago, IL 60604-1745 Phone: (312) 353-7875

Local DEA Offices:

- Rockford (815) 987-4494
- Springfield (217) 585-2750

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:

Illinois Veterinary Licensing Board website: <u>https://www.idfpr.com/profs/vet.asp</u> Illinois Pharmacy Board website: <u>https://www.idfpr.com/profs/pharm.asp</u> Illinois Law: <u>http://www.ilga.gov/legislation/ilcs/ilcs5.asp?ActID=1941&ChapterID=53</u>