

State-Specific Controlled Substance Requirements

Updated 6/21/23

Inventory (DEA):	 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. [2] 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.
Biennial Inventory (CA):	You must compile an inventory reconciliation report of all federal <u>Schedule II controlled substances at least</u> every three months. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the
	biennial inventory was taken no more than three months from the last inventory. <u>California Code of</u> <u>Regulations, title 16, section 1715.65 (c)</u>
CE:	<u>Veterinarians</u> : must complete 36 units (36 hours) during each two-year license renewal cycle. <u>Registered Veterinary Technicians</u> : must complete 20 units (20 hours) of CE during each two-year license renewal cycle. CE hours must be earned two years prior to your license expiration date. For example, if your license expires on January 31, 2022, you can accrue CE hours earned between February 1, 2020 and January 31, 2022. <u>CE courses</u> <u>taken outside of your renewal window cannot count towards license renewal.</u>
	Beginning on January 1, 2018, in order to renew a veterinarian license, a licensee must complete a minimum of one credit hour of continuing education on the judicious use of medically important antimicrobial drugs every four years.
	If you do not complete CE by your license expiration date, you may renew as inactive or wait to renew until you have completed the hours. Waiting to renew your license until you have completed the CE hours will result in your license expiring and becoming delinquent. <u>Licensees with an inactive or delinquent status must cease practice until such time as they complete the 36 hours of approved CE.</u> It is ILLEGAL to practice veterinary medicine in California with an inactive or expired license.
	Exemptions: <u>Veterinarians and RVTs are not required to obtain CE for their first license renewal</u> [<u>California BPC</u> , <u>section 4846.5(d)</u> for veterinarians and <u>CCR, Title 16, Section 2086.1(d)</u> for RVTs].
	Veterinarians are exempt from the CE requirement starting June 27, 2023, for all DEA-registered practitioners to complete opioid CEs.
	Licensees are required to retain course completion certificates for a period of four years pursuant to the <u>CCR</u> <u>Title 16, Sections 2085.9(b)</u> for veterinarians and <u>2086.8(a)</u> for RVTs.
	https://cvma.net/wp-content/uploads/2020/09/Continuing-Education-FAQ.pdf



Compounding:	 <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>CA Compounding</u> : regulations allow compounding in "veterinary premises," which is broadly defined elsewhere in statute and regulation. A definition of "veterinary premise" should be included to guard against the establishment of a single person "clinic" becoming a front for a commercial compounding operation.
	A veterinarian may only practice veterinary medicine, including drug compounding for prescribing, dispensing, and administering medication for animal patients, from a veterinary premises registered with the Board. (BPC § 4853.) The term "veterinary premises" is defined in statute. (<u>BPC § 4853, subd. (b).</u>) The regulations do not authorize a veterinarian to compound drug preparations in, or from a location that is not registered or identified and declared as associated with, a registered veterinary premises.
	https://www.vmb.ca.gov/meetings/materials/20201022_23_mm9g.pdf
CURES:	As of 1/1/22, all data reporters that submit prescription dispensation data to www.aaicures.com were required to register with the Bamboo Health PMP Clearinghouse. Effective 2/9/22, all reporting must be made through the PMP Clearinghouse system.
	Mandatory use does not apply to veterinarians.
	<u>Registering</u> is the only requirement for veterinarians <u>unless</u> you dispense controlled substances to clients.
	If a veterinarian dispenses controlled substances, <u>California Health and Safety Code section 11165(d)</u> requires that a dispensation report be submitted to CURES within <u>seven days</u> . Online submission is the only form of submission.
	CURES 2.0 users are required to renew their accounts on an annual basis. Users receive renewal notifications on the renewal date and 30 days after the user's one-year renewal date.
	Each controlled substance security prescription form used for prescribing on or after that date must include a unique serialized number in an approved format (<u>Health & Safety Code, § 11162.1, subdivision (a)(15)</u>).
	No person shall prescribe a controlled substance on or after that date, nor fill, compound, or dispense a prescription for a controlled substance written on or after that date, without this security feature (<u>Health &</u> <u>Safety Code, § 11164, subdivision (a)</u>).
CA Veterinary	Renew <u>every two years.</u>
Medical Professional License:	Temporary licenses are available for a one year period: <u>https://www.vmb.ca.gov/applicants/rec_forms.shtml</u>



Destruction (Waste):	Pharmaceutical waste generated in California must be destroyed by incineration.
	The MWMA section 117747 defines pharmaceutical as a prescription or over-the-counter human or veterinary drug not regulated pursuant to the Resource Conservation and Recovery Act (RCRA) or the Radiation Control Law.
	Pharmaceutical wastes classified by the DEA as "controlled substances" must be disposed of in compliance with DEA requirements and are not exempt from RCRA hazardous waste or medical waste requirements.
	Under no circumstances should any waste medication – including controlled substance waste – be disposed of down the drain or into solid or biohazardous waste.
	Controlled substance pharmaceutical waste must be managed according to MWMA requirements. These requirements include the waste being labeled with the words "Incineration Only" and disposed of within one year on a waste tracking document .
	Pharmaceutical waste is to be separated from other medical waste, placed in a container labeled with the words "HIGH HEAT" or "INCINERATION ONLY" and incinerated at a permitted medical waste treatment facility.
	https://www.sandiegocounty.gov/content/dam/sdc/deh/hmd/pdf/HMG-8006%20(09-2020).pdf
Dispensing:	If the facility is dispensing it should obtain a pharmacy license from the CA State Board of Pharmacy. https://www.pharmacy.ca.gov/applicants/phy.shtml
Diversion Reporting:	Any controlled substance loss (significant or not), must be reported to the California Board of Pharmacy within 14 calendar days from the date of loss for losses due to licensed employee theft (pursuant to Business and Professions Code, §4104), or 30 calendar days (pursuant to <u>California Code of Regulations, Title 16, §1715.6</u>) for any other type of loss.
	A copy of the DEA-106 form can be sent to the Board of Pharmacy if one was completed and submitted to the DEA. However, notifications of controlled substance drug losses sent to the Board of Pharmacy may be in any format that includes the following information: Name and Address
	 Date(s) of Loss or Theft Type of Theft or Loss
	Name of the carrier (if "Lost in Transit")
	 Name, quantity, and strength of the drug(s) lost or stolen
	 Person submitting the loss notification with contact information Board of Pharmacy license numbers of all parties involved
	Optional, but helpful information to include:
	Previous number of thefts or losses
	 NDC number(s)
	 Any details that may be pertinent to the loss (if applicable)
	Notifications can be sent to the Board of Pharmacy in one of three ways:
	 <u>Send us a message</u>, By fax to (916) 574-8614, or
	 By tax to (916) 574-8614, or By mail to: 2720 Gateway Oaks Drive, Suite 100, Sacramento, CA 95833
	To report an impaired licensee, <u>file a complaint</u> with the California State Board of Pharmacy within 14 days of discovery. <u>CA BOP reference</u>



Π

CALIFORNIA

Euthanasia: Ownership:	You <u>are required</u> to report loss or theft of prescription forms <u>within three days of discovery</u> . After you have filed a police report and have the report number, log into your CURES account and report the loss or theft. For additional information, contact the Security Prescription Printer Program at <u>SecurityPrinter@doj.ca.gov</u> <u>https://oag.ca.gov/cures</u> the following individuals may perform euthanasia: Licensed veterinarians Registered Veterinary Technicians who have received proper training Employees of an animal control shelter or humane society who have received proper training In California, any person can own a veterinary practice; however, <u>premise permits can only be issued to a</u> California licensed veterinarian who is designated as the licensee manager.
Prescriptions:	Veterinarians are the only health care professionals who are legally allowed to prescribe, dispense or furnish dangerous drugs to animals, after meeting certain requirements such as establishing a VCPR. <u>Section 2032.1 of the California Code of Regulations</u>
	 Section 4170 of the B&P code states: no prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met: (1) The dangerous drugs are dispensed to the prescriber's own patient. (2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient. (3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons. (4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers. (5) The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4). (6) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice. According to <u>B&P Sections 4170 (6) and (7)</u> it is the client's right to get the prescription from the local pharmacy or an Internet pharmacy.
Permits:	California law requires veterinary practice owners to <u>register their premise with the California VMB</u> regardless of practice type. <u>https://www.vmb.ca.gov/laws_regs/vmb_act.pdf</u> <u>Premise permits can only be issued to a California licensed veterinarian who is designated as the licensee</u> <u>manager</u> . The licensee manager acts for and on behalf of the licensed premise, and is responsible for management of the registered premise.
	Fee: \$525/annually The <u>California Business and Professions (B&P) Code Section 4853</u> specifically states that a premise permit is required in any premise where "veterinary medicine, veterinary dentistry, veterinary surgery, and the various branches thereof is being practiced." According to the law, the definition of a "premise" includes "a building, kennel, mobile unit, or vehicle."



Π

CALIFORNIA

	The Minimum Standards of Veterinary Practice can be found in the <u>California Code of Regulations, Title 16,</u> Sections 2030-2032
Power of Attorney Notarization:	California law requires that the Durable Power of Attorney must be notarized or signed by at least two witnesses. In California, a principal cannot act as one of the witnesses. Cal. Prob. Code <u>§§</u> 4121(c) and 4122
Recordkeeping:	<u>Controlled substance & Patient records:</u> Records must be kept for at least 2 years from the date of each inventory or record [21 CFR §1304.04(a)] OR 3 years from the date of the animal's last visit [21 CCR §2032.3(b)], whichever is greater, and must be available for inspection and copying by authorized Drug Enforcement Administration or Board personnel. <u>https://www.vmb.ca.gov/enforcement/controlled_subs.shtml#:~:text=Records%20must%20be%20kept%20for,Enforcement%20Administration%20or%20Board%20personnel.</u>
State CS License:	California <u>does not</u> 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 California.
State Scheduled CS:	No CA specific controlled substances that have been scheduled.
Supervision:	 2034 Definitions (c) "Veterinary assistant" means any individual who is not an R.V.T. or a licensed veterinarian. (d) "Supervisor" means a California licensed veterinarian or if a job task so provides an R.V.T. (e) "Direct Supervision" means: (1) the supervisor is physically present at the location where animal health care job tasks are to be performed and is quickly and easily available; and (2) the animal has been examined by a veterinarian at such time as good veterinary medical practice requires consistent with the particular delegated animal health care job tasks. (f) "Indirect Supervision" means: (1) that the supervisor is not physically present at the location where animal health care job tasks are to be performed, but has given either written or oral instructions ("direct orders") for treatment of the animal patient; and (2) the animal has been examined by a veterinarian at such times as good veterinary medical practice requires, consistent with the particular delegated animal health care task and the animal patient; and (2) the animal has been examined by a veterinarian at such times as good veterinary medical practice requires, consistent with the particular delegated animal health care task and the animal is not anesthetized as defined in Section 2032.4. 2035 Duties of Supervising Veterinarians (a) The supervising veterinarian of a R.V.I., permit holder or veterinary assistant shall make all decisions relating to the diagnosis, treatment, management and future disposition of the animal patient. (c) The supervising veterinarian shall have examined the animal patient prior to the delegation of any animal health care task to an R.V.I., permit holder or veterinary assistant shall make all decisions relating to the diagnosis, treatment, management and future disposition of the animal patient. (c) The supervising veterinarian shall have examined the animal patient prior to the delegation of any animal health care t
Telemedicine:	A VCPR cannot be established solely by telephonic or electronic means. (16 CCR § 2032.1(e)) It is unprofessional conduct for a veterinarian to administer, prescribe, dispense or furnish a drug, medicine, appliance, or treatment of whatever nature for the prevention, cure, or relief of a wound, fracture or bodily injury or disease of an animal without having first established a veterinarian-client-patient relationship with the animal patient or patients and the client, except where the patient is a wild animal or the owner is unknown. Telemedicine shall be conducted within an existing VCPR [except in emergencies].
	" <u>telemedicine</u> " shall mean the mode of delivering animal health care services via communication technologies to facilitate consultation, treatment, and care management of the patient. (<u>16 CCR § 2032.1(f)</u>)



State-Specific Controlled Substance Requirements

Veterinary Assistant	VACSP holders or permit holders are approved by the Board to obtain and administer controlled substances in
Assistant Controlled	an animal hospital setting (i.e. veterinary premises required to be registered with the Board) and under supervision of the Premises Licensee Manager.
Substances Permit (VACSP):	In order for veterinary assistants to obtain or administer controlled substances, veterinary assistants must hold a Veterinary Assistant Controlled Substances Permit (VACSP) issued by the Board. Link to BreEZe (or link to www.vmb.ca.gov to file a paper application) to apply for a VACSP.
(VCPR):	 A veterinarian-client-patient relationship shall be established by the following: The client has authorized the veterinarian to assume responsibility for making medical judgments regarding the health of the animal, including the need for medical treatment; The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian is personally acquainted with the care of the animal(s) by virtue of an examination of the animal or by medically appropriate and timely visits to the premises where the animals are kept; and The veterinarian has assumed responsibility for making medical judgments regarding the health of the animal and has communicated with the client a course of treatment appropriate to the circumstance (16 CCR § 2032.1).
	 A VCPR may continue to exist, in the absence of client communication when: 1. A VCPR was established with an original veterinarian, and another designated veterinarian serves in the absence of the original veterinarian;
	 The designated veterinarian has assumed responsibility for making medical judgments regarding the health of the animal; The designated veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian is personally acquainted with the care of the animal(s) by virtue of an examination of the animal(s) or by medically appropriate and timely visits to the premises where the animals are kept, or has consulted with the veterinarian who established the VCPR; and The designated veterinarian has continued the medical, treatment, diagnostic and/or therapeutic plan as was set forth and documented in the medical record by the original veterinarian (<u>16 CCR §2032.15</u>).

Information and Resources

FEDERAL:

Drug Enforcement Administration, Los Angeles Division 255 E. Temple Street Los Angeles, CA 90012 Phone: (213) 621-6700

Drug Enforcement Administration, San Francisco Division 450 Golden Gate Ave. P.O. Box 36035 San Francisco, CA 94102 Phone: (415) 436-7900



State-Specific Controlled Substance Requirements

Drug Enforcement Administration, San Diego Division 4560 Viewridge Avenue San Diego, CA 92123-1672 Phone: (858) 616-4100

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:

California Veterinary Medical Board website <u>www.vmb.ca.gov</u> California Pharmacy Board website <u>www.pharmacy.ca.gov</u> CURES <u>ag.ca.gov/bne/cures.phpp</u> NDC drug number <u>www.fda.gov/Drugs/DevelopmentApprovalProcess/UCM070829</u> Diversion Control Division <u>https://www.deadiversion.usdoj.gov/schedules/</u>

California Law: <u>www.leginfo.ca.gov</u> or <u>www.oal.ca.gov</u>

Veterinary Practice Act, Business & Professions Code section 4800 - 4917 Veterinary Medical Board Regulations, Title 16 Code of Regulations sections 2000 - 2085.13 Pharmacy Laws, Business & Professions Code section 4000 through 4426. Pharmacy Board Regulations, Title 16 Code of Regulations sections 1700-1795 Controlled Substances Act, Health and Safety Code section 11000-11717