

### State-Specific Controlled Substance Requirements

Updated 6/25/23

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Annual Business Report:	§16-101-34 Annual report. On or before December 31 of each year, every professional corporation shall file an annual report, in a form provided by the board, giving the name and address of the corporation, the names and addresses of the corporation officers, directors, shareholders, and employees who will render professional services.
Biennial Inventory (DEA):	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:
	<ul> <li>Separate biennial inventories must be completed for schedule II and schedule III-V controlled substances.</li> </ul>
	<ul> <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> </ul>
	<ul> <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.
	Hawaii follows the same biennial inventory guidelines as the DEA.
CE:	<u>Veterinarian:</u> All Veterinarian (VE) licensees on an "active" status must have completed at least 20 hours of Continuing Education (CE) credits from an approved sponsor every two years prior to renewing their license pursuant to HRS §471-9.
	Registered Veterinary Technicians: N/A
	Hawaii does not mandate controlled substance CE at this time
	Licensees must maintain their own CE records.
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." 24 Del. Admin. Code § 8.0
	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
	<ul> <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>
	HI Compounding: follow federal guidelines.



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Dispensing:	Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery. A controlled substance is dispensed when:  (1) It is compounded, prepared, labeled and packaged pursuant to the lawful order of a practitioner by a licensed pharmacist acting in the usual course of his professional practice and who is either registered individually or employed in a registered pharmacy or by a registered institutional practitioner, for delivery to the ultimate user;  (2) It is compounded, prepared, labeled and packaged for delivery to the ultimate user by a practitioner acting in the usual course of his professional practice;  (3) It is prepared, labeled, and packaged pursuant to the lawful order of a practitioner by a registered health care professional acting as an agent of the practitioner for delivery to the ultimate user by the practitioner; or  (4) It is prepackaged by a pharmacist for use in an emergency facility for delivery to the ultimate user by a licensed or registered health care professional pursuant to the order of a physician.  "Dispenser" means a practitioner who dispenses.  (e) A pharmacist may dispense controlled substances to any individual upon receipt of a prescription, originating from within the state, written with ink or indelible pencil or typewritten, dated and signed on the date when issued by a physician, dentist, podiotrist, or veterinarion and bearing the full mame and address of the patient for whom or of the owner of the animal for which the controlled substance is prescribed, the drug, quantity, strength, refill amount and the prescriber's name, address, business phone number and Drug Enforcement Administration registration number. If the prescription is for an animal, it shall state the species of animal for which the controlled substance is prescribed and dispensed.  (g) Filling and refill
Diversion Reporting:	(a) The theft or loss of any substance specified in section 329-61, Hawaii Revised Statutes, to include exempted items listed in section 329-64 Hawaii Revised Statutes, discovered by the permittee shall be reported in writing to the department within three calendar days of the receipt of the actual knowledge of the discrepancy.  (b) The report shall include the name of the common carrier or person who transports the substance, and the date of the shipment of the substance.  Haw. Code R. § 23-201-13
Euthanasia:	Only licensed veterinarians may perform euthanasia.
Ownership:	Hawaii laws are inconclusive regarding whether or not non-veterinarians can own a veterinary practice.



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Power of Attorney:	While Hawaii does not technically require you to get your POA notarized, notarization is strongly recommended. Under Hawaii law, when you sign your POA in the presence of a notary public, you signature is presumed to be genuine—meaning your POA is more ironclad.
Prescribing:	"Prescribe" means to direct, designate, or order the use of a formula for the preparation of a medicine for a disease or illness and the manner of using them.  "Prescriber" means one who is authorized to issue a prescription.  "Prescription" means an order for medication, which is dispensed to or for an ultimate user.  "Prescription" shall not include an order for medication that is dispensed for immediate administration to the ultimate user, such as a chart order to dispense a drug to a bed patient for immediate administration in a hospital.
	Restrictions: A prescriber MUST be physically within the borders of the State of Hawaii when issuing a
	prescription for a controlled substance. Hawaii restricts a practitioner from prescribing while physically out of the State of Hawaii.
	Excerpt from Hawaii Revised Statute 329-38:  (i) Prescriptions for controlled substances shall be issued only as follows:  (1) All prescriptions for controlled substances shall originate from within the State and be dated as of, and signed on, the day when the prescriptions were issued and shall contain:
	Prescribing regulations per Haw. Code R. § 23-200-15:  Prescriber registration: (a) A prescription for a controlled substance may be issued only by an individual practitioner who is registered by the department of public safety to prescribe controlled substances in the State of Hawaii.
	Script dimensions: All controlled substance prescription forms issued shall be no larger than 4-1/2" $\times$ 6-1/2" in size and no smaller than 4" $\times$ 5".
	Alterations: (b) Any alteration to the patient name, date issued, drug, quantity, strength, or refill section of a controlled substance prescription invalidates the prescription, unless authorized by the administrator.
	Schedule IIs: (c) Prescriptions for schedule II controlled substances shall be submitted to the pharmacist in duplicate. The pharmacist shall, within seven days after filling the prescription, forward the duplicate including the pharmacy's NABP number, the NDC number for the dispensed drug, and the patient's identification number to the department, or shall submit all information to the department as prescribed by the department. Requirements for forwarding duplicate schedule II prescriptions, may be waived by the department if the pharmacy is capable of providing the required information electronically in a format approved by the department. The department shall retain the original thereof on file for a period of two years after filling the same.
	Refills: No prescription for a schedule II controlled substance shall be filled later than the third day following the day of issuance;
	Records: (5) Prescription records stored in a computerized database must include the authorized number of refills and the date and dispensing pharmacist for each refill; and (6) No prescription which has been altered in any manner shall be filled or refilled without authorization from the administrator.
	Written prescriptions: A practitioner may sign a prescription in the same manner as the practitioner would sign a check or legal document (e.g., J.H. Smith or John H. Smith) and shall use both words and figures (e.g., alphabetically and numerically as indications of quantity, such as five (5)), to



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	indicate the amount of controlled substance to be dispensed. Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typed, shall be manually signed by the practitioner, and shall include the name, address, telephone number, and registration number of the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of the practitioner, but the prescribing practitioner shall be responsible in case the prescription does not conform in all essential respects to this chapter and any rules adopted pursuant to this chapter. In receiving an oral prescription from a practitioner, a pharmacist shall promptly reduce the oral prescription to writing, which shall include the following information; the drug name, strength, dosage form, quantity prescribed in figures only, and directions for use; the date the oral prescription was received; the full name, DEA registration number, and oral code number of the practitioner; and the name and address of the person for whom the controlled substance was prescribed or the name of the owner of the animal for which the controlled substance was prescribed. https://cca.hawaii.gov/pvl/files/2013/08/HRS 329-DPS.pdf
	E-prescribing: Hawaii <b>does not</b> have an e-prescribing mandate.
AWARxE PDMP:	<b>Veterinarians are exempt from using the AWARXE PDMP.</b> Any registrant of the Narcotics Enforcement Division (NED) that holds a controlled substance license (except pharmacies and veterinarians) must register as a data requestor through the AWARXE website.
Recordkeeping:	Patient records: DAG Shari Wong confirmed Federal law trumps State law; therefore, veterinarians
	must abide by the Federal record keeping requirement of <b>two years.</b>
	Controlled substance records: must be kept for <b>two years</b>
	§329-36 Records of registrants. Persons registered to manufacture, distribute, prescribe or dispense
	controlled substances under this chapter shall keep records and maintain inventories in
	conformance with the record-keeping and inventory requirements of federal law and with any
	additional rules the department of public safety issues.
	https://cca.hawaii.gov/pvl/files/2013/08/HRS 329-DPS.pdf
Relief Professionals (Locum	" <u>Locum tenens practitioner</u> " means a practitioner:
Tenens):	(1) Who is licensed in this State and registered under section 329-32 to administer,
	prescribe, or dispense a controlled substance in the course of professional practice, 7
	who temporarily substitutes for another registered practitioner for a period not to
	exceed sixty days at that other practitioner's registered place of business; and
	(2) Whose Drug Enforcement Administration controlled substance registration number
	has not been transferred to the State of Hawaii.
	Locum tenens practitioners are not eligible to receive an oral code number as designated by
	section 328-16(k).
	https://cca.hawaii.gov/pvl/files/2013/08/HRS 329-DPS.pdf
State-Scheduled CS's:	N/A
State CS License:	Hawaii <b>does require</b> DEA registrant practitioners to obtain a second state controlled substance
	registration through the Hawaii Department of Public Safety - Narcotics Enforcement Division, before
	obtaining a DEA registration, as well as an active Veterinary Medical Professional License to practice
	in Hawaii.
	Hawaii CSR Application
	Fee: \$115 (practitioner)
	Renewal: annually
	Hawaii CSR Renewal Application
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	"Controlled substance" means a drug, substance, or immediate precursor in schedules I through v of Chapter 329 part II, Hawaii Revised Statutes." <u>Haw. Code R. § 23-200-2</u>
Supervision:	"Supervising physician" means a physician licensed to practice medicine in the State and registered under section 329-33, who supervises a physician assistant and retains full professional and legal responsibility for the performance of the supervised physician assistant and the care and treatment of the patient.
	§16-101-2 Definition of direct supervision.  "direct supervision" means the licensed veterinarian shall be in the same immediate building or complex as the unlicensed veterinarian or other employees who are receiving the supervision, except for emergency pet ambulance services in which direct supervision may be rendered via telecommunications or two-way radio by a licensed veterinarian.
Telemedicine:	No existing laws. Where telemedicine occurs is not defined.
Veterinary Professional License:	Veterinary licenses are renewed June 30 <sup>th</sup> on even-numbered year.  View Registration status: <a href="https://mypvl.dcca.hawaii.gov">https://mypvl.dcca.hawaii.gov</a>
	§16-101-25 Display of license. The license, together with evidence of current validation, shall be conspicuously displayed in the place of business and evidence of current validation shall be in possession of the person to whom it was issued at all times.
VCPR:	Hawaii has guidelines regarding establishing VCPR but they are not legally binding, although it is recommended to follow the guidelines. Hawaii follows the <u>AVMA's Principles of Veterinary Medical Ethics definition of a VCPR</u> .
	VCPR must be established in-person and only applies to one vet.

#### **Information and Resources**

#### FEDERAL:

Drug Enforcement Administration, Los Angeles Division 255 East Temple Street, 17th Floor Los Angeles, CA 90012

Phone: (213) 621-6700

#### **DEA Local Office**

Honolulu - (808) 541-1930 Maui - (808) 244-1136

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: <a href="https://www.deadiversion.usdoj.gov/schedules/">www.fda.gov/Drugs/DevelopmentApprovalProcess/UCM070829</a> Diversion Control Division: <a href="https://www.deadiversion.usdoj.gov/schedules/">https://www.deadiversion.usdoj.gov/schedules/</a>



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### **STATE**:

Hawaii Board of Veterinary Examiners website: <a href="https://cca.hawaii.gov/pvl/boards/veterinary/">https://cca.hawaii.gov/pvl/boards/veterinary/</a> Hawaii Board of Pharmacy website: <a href="https://cca.hawaii.gov/pvl/boards/pharmacy/">https://cca.hawaii.gov/pvl/boards/pharmacy/</a>