

1991 Senate Bill 532

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1991 WISCONSIN ACT 306

AN ACT *to renumber* 453.02 (1); *to amend* 453.05 (1) and 453.05 (3); and *to create* 450.125, 453.02 (1g), 453.02 (3), (3g) and (3r), 453.02 (4e), (4m) and (4s), 453.02 (5m), 453.02 (6m), 453.02 (8) to (11), 453.068 and 453.07 (3) of the statutes, **relating to:** prescribing, labeling, dispensing and administering veterinary drugs and providing a penalty.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 450.125 of the statutes is created to read:
450.125 Drugs for animal use. In addition to complying with the other requirements in this chapter for distributing and dispensing, a pharmacist who distributes or dispenses a drug for animal use shall comply with s. 453.068.

SECTION 2. 453.02 (1) of the statutes is renumbered 453.02 (1m).

SECTION 3. 453.02 (1g) of the statutes is created to read:

453.02 (1g) “Administer”, when used in reference to administering a drug to an animal, means directly applying the drug, whether by injection, ingestion or any other means, to the body of the animal.

SECTION 4. 453.02 (3), (3g) and (3r) of the statutes are created to read:

453.02 (3) “Client” means the person who owns or who has primary responsibility for the care of a patient.

(3g) “Dispense” means the act of delivering a drug to a person who may lawfully possess the drug, including the compounding, packaging or labeling necessary to prepare the drug for delivery.

(3r) “Drug” has the meaning given in s. 450.01 (10).

SECTION 5. 453.02 (4e), (4m) and (4s) of the statutes are created to read:

453.02 (4e) “Extra-label use” means use of a drug in a manner that is not in accordance with the directions for

use that are contained on the label affixed to the container in which the drug is dispensed.

(4m) “Food-producing animal” means an animal that is raised to produce food for human consumption.

(4s) “Patient” means an animal that is examined or treated by a veterinarian.

SECTION 6. 453.02 (5m) of the statutes is created to read:

453.02 (5m) “Pharmacist” means an individual who is licensed as a pharmacist under ch. 450.

SECTION 7. 453.02 (6m) of the statutes is created to read:

453.02 (6m) “Prescription” means a written or oral order from a veterinarian to a pharmacist or to another veterinarian that authorizes the pharmacist or other veterinarian to dispense a drug, or from a veterinarian to a client that authorizes the client to make extra-label use of a drug.

SECTION 8. 453.02 (8) to (11) of the statutes are created to read:

453.02 (8) “Veterinarian-client-patient relationship” means a relationship between a veterinarian, a client and the patient in which all of the following apply:

1. The veterinarian has assumed the responsibility for making medical judgments regarding the health of the patient and the patient’s need for medical treatment, and the client has agreed to accept those medical judgments and to follow the related instructions of the veterinarian.

2. The veterinarian has sufficient knowledge of the patient to initiate a general or preliminary diagnosis of

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the medical condition of the patient because the veterinarian has recently examined the patient or has made medically appropriate and timely visits to the premises on which the patient is kept.

3. The veterinarian is readily available for follow-up treatment of the patient if the patient has an adverse reaction to veterinary treatment.

(9) “Veterinary drug” means any of the following:

(a) A drug that is recognized as a drug for animal use in the official U.S. pharmacopeia or the official national formulary or any supplement to either of them.

(b) A drug that is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in an animal.

(c) A drug that is intended to affect the structure or function of the body of an animal, including medicated feed or a growth-promoting implant, but not including feed that does not contain a drug.

(d) A substance that is intended for use as a component of a drug described in par. (a), (b) or (c).

(e) A drug that is produced and intended for human use but that is prescribed by a veterinarian for animal use.

(10) “Veterinary over-the-counter drug” means a drug that is labeled for animal use, that may be dispensed without a prescription and that is not required to bear the label statement: “CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.”

(11) “Veterinary prescription drug” means a drug that may not be dispensed without the prescription of a veterinarian.

SECTION 9. 453.05 (1) of the statutes is amended to read:

453.05 (1) Except as provided under sub. (2), no person may offer to practice, advertise to practice or practice veterinary medicine, or use, in connection with his or her name, any title or description which may convey the impression that he or she is a veterinarian, without a license or temporary permit from the examining board. For purposes of this subsection, a person who makes extra-label use of a drug on an animal without a prescription or in any manner not authorized by that prescription is considered to be practicing veterinary medicine.

SECTION 10. 453.05 (3) of the statutes is amended to read:

453.05 (3) Any person violating this section shall may for the first offense be fined not ~~less than \$25 nor more than \$200~~ \$1,000, and for any 2nd offense within 3 years be fined not ~~less than \$500 nor more than \$1,000~~ \$3,000.

SECTION 11. 453.068 of the statutes is created to read:

453.068 Drugs for animal use. (1) **PRESCRIBING; DISPENSING.** (a) *Extra-label use on animal; prescription required.* No person may make extra-label use of a drug on an animal without a prescription or in any manner not authorized by that prescription.

(b) *Form of prescription.* A prescription shall include all of the following:

1. The name and address of the veterinarian and, if the prescription is a written order, the signature of the veterinarian.

2. The name and address of the client.

3. The species and identity of the patient for which the prescription is issued.

4. The name, strength and quantity of the drug prescribed.

5. The date on which the prescription is issued.

6. The directions for administering the drug.

7. If the patient is a food-producing animal, the withdrawal time for the veterinary drug.

8. If the prescription authorizes extra-label use, the manner in which the client may use the drug.

9. Any cautionary statements required by law.

(c) *Prescribing, dispensing and administering requirements for veterinarian.* A veterinarian may not do any of the following:

1. Prescribe for or dispense to a client a veterinary prescription drug or a drug for extra-label use without personally examining the patient unless a veterinary-client-patient relationship exists between the veterinarian, client and patient and the veterinarian determines that the client has sufficient knowledge to administer the drug properly.

2. Prescribe or dispense a veterinary prescription drug to a client unless the veterinarian indicates in the appropriate records described under sub. (3), within 72 hours after the prescription is issued or the drug is dispensed, that the prescription has been issued or that the drug has been dispensed.

3. Prescribe a drug to a client for extra-label use on a patient unless all of the following apply:

a. A veterinary-client-patient relationship exists between the veterinarian, client and patient and the veterinarian has made a careful medical diagnosis of the condition of the patient within the context of that veterinarian-client-patient relationship.

b. The veterinarian determines that there is no drug that is marketed specifically to treat the patient’s diagnosed condition, or determines that all of the drugs that are marketed for that purpose are clinically ineffective.

c. The veterinarian recommends procedures for the client to follow to ensure that the identity of the patient will be maintained.

d. If the patient is a food-producing animal, the veterinarian prescribes a sufficient time period for drug withdrawal before the food from the patient may be marketed.

(2) **LABELING.** A veterinarian or pharmacist may not dispense a drug that has been prepared, mixed, formulated or packaged by the veterinarian or pharmacist unless the veterinarian or pharmacist affixes to the container in which the drug is dispensed a label containing

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all of the information specified in sub. (1) (b), except the address of the client. A veterinarian or pharmacist may not dispense a veterinary prescription drug that has been repackaged by its manufacturer for dispensing unless the veterinarian or pharmacist affixes to the container in which the drug is dispensed a label containing all of the information specified in sub. (1) (b), except the address of the client. A veterinarian or pharmacist may dispense a veterinary over-the-counter drug without affixing any information to the container in which the drug is dispensed if a label that has been affixed to the container by its manufacturer provides adequate information for its use.

(3) PRESCRIPTION RECORDS. A veterinarian shall maintain complete records of each veterinary prescription drug that the veterinarian receives, prescribes, dispenses or administers, and of each prescription issued by the veterinarian that authorizes extra-label use. Records of each veterinary prescription drug shall include the name of each veterinary prescription drug that is received, the name and address of the person from whom the drug is received and the date and quantity received, the name and address of the person to whom the drug is dispensed and the date and quantity dispensed and, if the veterinarian prescribes or administers the drug, the information specified in sub. (1) (b). Records of each prescription authorizing extra-label use shall include the information specified in sub. (1) (b). A veterinarian shall maintain records of each veterinary prescription drug under this subsection for not less than 3 years after the

date on which the veterinarian prescribes, dispenses or administers the drug or extra-label use.

(4) ENFORCEMENT. (a) *Inspections.* Except as provided in par. (b), if the examining board has reason to believe that a person is violating or has violated this section, the examining board, the attorney general or the district attorney of the proper county may do any of the following:

1. Inspect the premises on which the person possesses, prescribes, dispenses, labels or administers veterinary drugs.

2. Inspect pertinent records, equipment, materials, containers or facilities that are relevant to determining whether the person is violating or has violated this section.

3. Collect relevant samples of veterinary drugs.

(b) *Records exempt from inspection.* The examining board, attorney general or district attorney may not inspect a person's financial, pricing, personnel or sales records under this subsection, other than the records described under sub. (3).

SECTION 12. 453.07 (3) of the statutes is created to read:

453.07 **(3)** In addition to or in lieu of a reprimand or denial, limitation, suspension or revocation of a license, certificate or permit under sub. (2), the examining board may assess against the applicant for or the holder of the license, certificate or permit a forfeiture of not more than \$5,000 for each violation of s. 453.068.