

VETERINARY MEDICINE BOARD[811]

Regulatory Analysis

Notice of Intended Action to be published: Iowa Administrative Code 811—Chapter 12
“Standards of Practice”

Iowa Code section(s) or chapter(s) authorizing rulemaking: 169.5
State or federal law(s) implemented by the rulemaking: Iowa Code chapter 169

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

November 13, 2023
10 a.m.

Second Floor Conference Room
Wallace State Office Building
Des Moines, Iowa

Public Comment

Any interested person may submit written comments concerning this Regulatory Analysis. Written comments in response to this Regulatory Analysis must be received by the Board of Veterinary Medicine no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Colin Tadlock
Iowa Department of Agriculture and Land Stewardship
Wallace State Office Building
502 East 9th Street
Des Moines, Iowa 50319
Email: colin.tadlock@iowaagriculture.gov

Purpose and Summary

This proposed rulemaking establishes minimum requirements for establishing a veterinarian/client/patient relationship. This relationship is needed to comply with federal prescription rules for dispensing medication to animals. The public greatly benefits from ensuring that antibiotics and other prescription medications are being used in a judicious manner when treating animals. This helps to prevent antibiotic resistance in both animals and in humans. In addition, the rulemaking sets record-keeping requirements and establishes minimum standards for veterinary facilities. This is important to ensure that proper care, and continuity of care, for patients is provided.

Analysis of Impact

1. Persons affected by the proposed rulemaking:

- Classes of persons that will bear the costs of the proposed rulemaking:

Licensed veterinarians in the state will bear the cost of maintaining accurate record-keeping systems along with safe, secure, and clean facilities.

- Classes of persons that will benefit from the proposed rulemaking:

All pet owners and producers of livestock within the state will benefit. Because veterinarians are an integral part of maintaining the health and welfare of companion animals and also maintaining food safety, the public can be assured that livestock are raised, treated, and harvested in a safe and humane way with adequate record keeping.

2. Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:

- Quantitative description of impact:

The only costs would be imposed on licensees, and those costs could vary depending upon the scope of their practices. Licensees are required to meet certain minimum standards to protect animals and the public, which can include required equipment, training, sanitation, record keeping, and supervision of staff.

- Qualitative description of impact:

See prior answer.

3. Costs to the State:

- Implementation and enforcement costs borne by the agency or any other agency:

The costs incurred to execute and enforce this chapter are borne by the Iowa Department of Agriculture and Land Stewardship and the Board. The major cost is staff time. Staff and estimated percentage of time allocated are as follows: Executive Secretary of the Iowa Board of Veterinary Medicine (State Veterinarian), 0.15 full-time equivalent (FTE) position; Program Planner 2, 0.60 FTE position; and two Compliance Investigators, 0.40 FTE position each (one Compliance Investigator, 0.80 FTE position). Other costs associated would include but are not limited to hiring expert witnesses, costs associated with hearings, legal staff, and office supplies.

- Anticipated effect on state revenues:

There is minimal effect on state revenues because some of the costs to the State are covered by the fees assessed by the Board for contested case proceedings, and the Board is generally funded by the license fees paid by the regulated community.

4. Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:

Removing this chapter would have a negative effect on the health and well-being of both companion animals and livestock within the state.

5. Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:

There does not appear to be any less costly method because it is critical to properly identify the requirements for a valid veterinarian/client/patient relationship in order to properly authorize and provide care for companion animals and livestock. In addition, minimal standards for issuance of prescriptions, record keeping, and facility requirements are needed to ensure proper care for animals.

6. Alternative methods considered by the agency:

- Description of any alternative methods that were seriously considered by the agency:

No alternative methods were considered.

- Reasons why alternative methods were rejected in favor of the proposed rulemaking:

No alternative methods were considered for the reasons previously stated.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

Because some requirements in Chapter 12 are required by federal law, some provisions of the rulemaking cannot be altered to reduce any alleged impacts on small business. The requirements imposed on veterinarians and veterinary clinics may vary depending on the type of practice, record-keeping system, inventory management system, and facilities that they utilize.

Text of Proposed Rulemaking

ITEM 1. Rescind 811—Chapter 12 and adopt the following **new** chapter in lieu thereof:

CHAPTER 12
STANDARDS OF PRACTICE

811—12.1(169) Veterinarian/client/patient relationships.

12.1(1) The board shall determine, on a case-by-case basis, if a valid veterinarian/client/patient relationship exists. This relationship is deemed to exist when all of the following criteria have been met:

a. The licensed veterinarian has assumed the responsibility for making medical judgments regarding the health of the patient and the need for medical treatment, and the client has agreed to follow the instructions of the licensed veterinarian;

b. The licensed veterinarian has sufficient knowledge of the patient to initiate at least a general or preliminary diagnosis of the medical condition of the patient. Sufficient knowledge means that the licensed veterinarian has recently seen or is personally acquainted with the keeping and care of the patient by virtue of any of the following:

(1) A physical examination of the patient within the past 12 months;

(2) A professional visit within the past 12 months to the premises where the patient or representative patients are housed, kept, located or grazed; or

(3) The licensed veterinarian has been temporarily designated by a licensed veterinarian, who has a prior veterinarian/client/patient relationship, to provide reasonable and appropriate medical care. The veterinarian making the designation must meet the requirements of either subparagraph 12.1(1)“*b*”(1) or 12.1(1)“*b*”(2), and the designated veterinarian must have access to the patient’s medical records.

The 12-month time period in paragraph 12.1(1)“*b*” does not apply until June 14, 2023.

c. The licensed veterinarian is readily available or provides for follow-up care in case of adverse reactions or failure of the regimen of therapy, or, if unavailable, has designated another available licensed veterinarian who has access to the patient’s records to provide reasonable and appropriate medical care.

12.1(2) A valid veterinarian/client/patient relationship cannot be established by contact solely based on a telephonic or electronic communication.

12.1(3) In the absence of a veterinarian/client/patient relationship:

a. Advice that is provided through electronic means can only be general and not specific to a particular animal or its diagnosis or treatment.

b. Advice and recommendations may be provided via veterinary telephonic or electronic communication in an emergency, but only until the animal can be examined in person by a licensed veterinarian.

12.1(4) Both the licensed veterinarian and the client have the right to establish or decline a valid veterinarian/client/patient relationship. Once the licensed veterinarian and the client have agreed and entered into a relationship, and the licensed veterinarian has begun patient care, the licensed veterinarian cannot neglect the patient and must continue to provide professional services related to the patient’s injury or illness within the previously agreed limits. As subsequent needs and costs for patient care are identified, the licensed veterinarian and the client must confer and reach agreement on the continued care and responsibility for fees. If the informed client declines future care or declines to assume responsibility for the fees, the relationship may be terminated by either party.

12.1(5) If no ongoing medical condition exists, a licensed veterinarian may terminate a valid veterinarian/client/patient relationship by notifying the client that the licensed veterinarian no longer wishes to serve that patient and client. However, if an ongoing medical or surgical condition exists, the patient should be referred to another licensed veterinarian for diagnosis, care and treatment and the former attending licensed veterinarian should continue to provide care as needed during the transition.

12.1(6) Concerns about licensed veterinarian or staff safety may result in immediate termination of the veterinarian/client/patient relationship.

12.1(7) In emergencies, a veterinarian has an ethical responsibility to provide essential services for an animal when necessary to save the animal’s life or relieve extreme suffering, subsequent to a client agreement (or until such agreement can be obtained when a client is not present or cannot be reached). Such emergency care may be limited to relieve extreme pain or suffering, or to stabilization of the patient for transport to another source of animal care or euthanasia when deemed necessary by the veterinarian. When a veterinarian cannot be available to provide services, the veterinarian should provide readily accessible information to assist a client in obtaining emergency services, consistent with the needs of the locality. In an emergency, if a veterinarian does not have the expertise or the necessary equipment and facilities to adequately diagnose or treat a patient, the veterinarian should advise the client that more qualified or specialized services are available elsewhere and offer to expedite referral to those services.

12.1(8) A licensed veterinarian who in good faith engages in the practice of veterinary medicine by rendering or attempting to render emergency or urgent care to a patient when a client cannot be identified, and a veterinarian/client/patient

relationship is not established, is not subject to discipline based solely on the veterinarian's inability to establish a veterinarian/client/patient relationship.

811—12.2(169) Controlled substances, drugs, prescription medications and specific restricted immunization products. When state or federal law restricts a drug, medication or immunization product intended for use by or on the order of a licensed veterinarian, the licensed veterinarian can only sell, distribute or order the drug or medication in the course of the licensed veterinarian's professional practice. A prescription veterinary drug, medication or immunization product shall not be deemed to be used "in the course of the licensed veterinarian's professional practice" unless a valid veterinarian/client/patient relationship exists.

12.2(1) Prescriptions. Orders for all such drugs, medications or immunization products shall be accompanied by the licensed veterinarian's original prescription that shows the following:

- a. Licensed veterinarian's name, address and telephone number;
- b. Client's name;
- c. Patient's name or identification;
- d. Date issued;
- e. Drug, medication or product name, strength and quantity;
- f. Directions for use;
- g. Number of times the prescription may be refilled;
- h. Expiration date of the drug, medication or product; and
- i. Applicable withdrawal period (paragraph 12.2(2) "d") for livestock and poultry.

12.2(2) Extra-label use of veterinary drugs, medications and immunization products. Any extra-label use of veterinary drugs, medications or immunization products can only be administered by or under the order of a licensed veterinarian and is subject to the following criteria:

- a. There is a valid veterinarian/client/patient relationship as defined in subrule 12.1(1).
- b. For drugs or medications used in patients not intended for food, one of the following applies:
 - (1) There are no marketed drugs, medications or immunization products specifically labeled for the condition(s) diagnosed;
 - (2) The approved product is clinically ineffective; or
 - (3) In the licensed veterinarian's clinical judgment, the labeled dosage is inappropriate for the condition or the extra-label use should result in a better outcome for the patient.
- c. The health of the treated patient is immediately threatened, or suffering or death would result from a failure to treat the affected patient.
- d. The appropriate withdrawal period is specified when the drugs, medications or immunization products are used in animals intended as food. Extra-label drug use in food-producing animals must follow Food and Drug Administration—Animal Medicinal Drug Use Clarification Act regulations (21 CFR Part 530). Licensed veterinarians are encouraged to consult the Food Animal Residue Avoidance Databank (FARAD) or public peer-reviewed documents when determining appropriate withdrawal period.

811—12.3(169) Prescription drug or medication labeling and packaging. A licensed veterinarian shall comply with all of the following requirements for the storage, handling, dispensing and administering of a drug or medication.

12.3(1) All prescription drugs, medications and controlled substances shall be purchased, maintained, handled, prescribed and dispensed in compliance with state and federal requirements including but not limited to the requirements of the Iowa board of pharmacy, the U.S. Occupational Safety and Health Administration, the U.S. Department of Agriculture, the U.S. Food and Drug Administration, the U.S. Environmental Protection Agency and the U.S. Drug Enforcement Administration.

a. A valid veterinarian/client/patient relationship shall be established before prescription drugs or medications may be dispensed or a prescription released. All drugs or medications administered, prescribed or dispensed shall be documented in the patient's medical record. The sale of veterinary prescription drugs or medications or the extra-label use of any drug, medication or product by a licensed veterinarian without a valid veterinarian/client/patient relationship is not permissible.

b. If a veterinarian prescribes a drug for the client's animal, the veterinarian shall, upon request, provide the prescription to the client, unless barred by state or federal law or to prevent inappropriate use. The veterinarian may charge a fee for issuing the prescription. This paragraph does not apply to livestock as defined in Iowa Code section 717.1(4).

12.3(2) All drugs or medications dispensed shall be labeled with the following information:

- a. Name, telephone number and address of the veterinary clinic, hospital or service facility.
- b. Name of the prescribing licensed veterinarian.
- c. Date on which the prescription is dispensed.
- d. Directions for use, including any cautionary statements and withdrawal times when appropriate.
- e. Species of the patient.
- f. Name, or identification, or location of the patient.
- g. Name of the owner.
- h. Name, strength and dosage form of the drug or medication. If the drug or medication is a compounded product, all active ingredients must be listed on the label, with corresponding strengths or concentrations of each ingredient.
- i. Number of units dispensed.
- j. Expiration date. If the drug or medication is a compounded product with no assigned expiration date, the licensed veterinarian shall determine a beyond-use date as supported by the literature or by the licensed veterinarian's professional judgment when no such supportive information exists.
- k. Appropriate withdrawal period for livestock or poultry, when the patient or its product is intended as food.

12.3(3) All drugs or medications dispensed in the original container shall retain the original label and be labeled with the same information identified in subrule 12.3(2).

12.3(4) All drugs or medications that are dispensed in a container other than the original container shall be placed in a tamper-resistant container unless otherwise requested by the owner or unless the drug or medication is in a form or size that cannot be easily dispensed in a tamper-resistant container.

12.3(5) Drugs or medications that have expired shall be removed from current inventory and cannot be dispensed or sold. Expired drugs or medications shall be disposed of in accordance with local, state and federal regulations.

12.3(6) Drugs or medications shall be dispensed only for specific animals and for specific veterinary medical therapies with the exception of groups of similar animals and other groups such as pet fish, kennels and catteries for which dispensing shall be done judiciously within a valid veterinarian/client/patient relationship.

811—12.4(169) Veterinary medical records.

12.4(1) *Controlled substances records.* The licensed veterinarian must maintain a controlled substance log that contains complete, accurate and readily retrievable records of all controlled substances possessed, administered or dispensed.

a. Each record of a controlled substance that is dispensed must meet all U.S. Drug Enforcement Administration and Iowa board of pharmacy regulations for the controlled substances log.

b. Each log record must include the following information:

- (1) Name or identification of the patient.
- (2) Client's name and address, if not readily available from the licensed veterinarian's records.
- (3) Name, strength and quantity of the controlled substance dispensed.
- (4) Date on which the controlled substance was dispensed.
- (5) Initials of the dispensing licensed veterinarian or authorized auxiliary.
- (6) Name of the prescribing licensed veterinarian.

c. All controlled substances must be kept in a locked storage area, and access to the storage area must be limited pursuant to state and federal laws and regulations.

d. Each package or container in which a controlled substance is stored or dispensed must be clearly labeled pursuant to the requirements set forth in state and federal laws and regulations.

e. Each package or container in which a controlled substance is stored or dispensed must comply with all state and federal packaging requirements and with rule 811—12.2(169).

12.4(2) *Patient records.* Patient records are the property of the veterinary practice. Each licensed veterinarian shall maintain for at least five years an easily retrievable record for each patient that receives veterinary services. The record must be available for inspection by the client during normal business hours. The information within patient records is privileged and confidential and cannot be released except by court order, a public health emergency, consent of the client or as otherwise authorized by law. The licensed veterinarian in charge shall provide a copy of the complete record to the client not later than two business days after the licensed veterinarian or practice receives from the client a request for the record. A licensed veterinarian or veterinary practice may have an additional three business days to provide a copy of nondigital diagnostic images. The licensed veterinarian may charge reasonable and customary fees for the copying of records.

a. Records required for patients defined as "livestock" in Iowa Code section 717.1(4) include the following:

- (1) Name, address and telephone number of the client.
- (2) Name or identity of the patient, pen, herd, flock or group, including the identification number, if any.
- (3) Date of service.
- (4) Documentation of client consent.
- (5) Diagnosis or condition at the beginning of treatment of the patient, including results of tests.
- (6) Procedures/indications.
- (7) Name of drug or medication and treatment administered indicating dosage, frequency and route of administration.
- (8) Withdrawal period.
- (9) Record of diagnostic images taken.
- (10) Name of attending licensed veterinarian.
- b. Records required for other patients include the following:
 - (1) Name, address and telephone number of the client.
 - (2) Name and identity of the patient, including the identification number, if any.
 - (3) Date of birth (or estimated age), sex, species and breed of patient.
 - (4) Dates of care, custody or treatment of the patient.
 - (5) A history of the patient's condition as it pertains to the patient's medical status.
 - (6) Documentation of client consent.
 - (7) Diagnosis or condition at the beginning of treatment of the patient, including results of tests and body weight.
 - (8) Surgery record, including preanesthesia medication, anesthesia and the procedure performed.
 - (9) Name of drug or medication and treatment administered indicating dosage, frequency and route of administration.
 - (10) Progress and disposition of the case.
 - (11) Record of diagnostic images taken.
 - (12) Name of attending licensed veterinarian.

12.4(3) Stored diagnostic images.

- a. Each stored diagnostic image must be identified with the following information:
 - (1) The name of the licensed veterinarian or facility that took the diagnostic image.
 - (2) The name or identifying number, or both, of the patient.
 - (3) The name of the client.
 - (4) The date on which the diagnostic image was taken.
 - (5) The anatomical orientation depicted by the diagnostic image.
- b. Stored diagnostic images must be retained for at least five years.
- c. A stored diagnostic image of the patient or a copy must be released, upon the written or verbal request, to another licensed veterinarian who has the authorization of the client. Original diagnostic images shall be returned in a reasonable time.

12.4(4) General anesthesia. General anesthesia is a condition caused by the administration of a drug or combination of drugs sufficient to produce a state of unconsciousness or dissociation and blocked response to a given pain or alarming stimulus. The following standards relating to general anesthesia apply:

- a. Within 12 hours prior to the administration of a general anesthetic, the patient must receive a physical examination, with the results noted in the patient's medical records.
- b. The patient under general anesthesia must be under observation for a length of time appropriate to the species for the patient's safe recovery.
- c. The licensed veterinarian must provide a method of respiratory monitoring that may include observing the patient's chest movements, observing the rebreathing bag or using a respirometer.
- d. The licensed veterinarian must provide a method of cardiac monitoring, which may include the use of a stethoscope or electrocardiograph monitor.

811—12.5(169) Veterinary facilities.

12.5(1) Facility standards. The following standards apply to all facilities used by a licensed veterinarian to provide veterinary services.

- a. *Facilities for treatment or hospitalization.* In a facility where patients are examined and retained for treatment or hospitalization, the following must be provided:

(1) An examination room, separate from the reception room or office, with sufficient size to accommodate the licensed veterinarian, assistant, patient and client.

(2) Nonporous tabletops, countertops and floor coverings that can be adequately cleaned and disinfected.

(3) The ability to house patients separately and maintain sanitary conditions.

(4) Appropriate separation of patients with known or suspected infectious and contagious diseases from patients not known to have such diseases in a manner that reasonably guards against transmission of disease.

(5) Provision for daily exercise of patients unless the primary enclosure is of sufficient size to provide exercise.

(6) Exercise areas that are cleaned a minimum of once in each 24-hour period and more frequently as may be necessary to reduce disease hazards and odors.

(7) A sanitary area for performing surgeries under sterile conditions. If sterile surgical procedures are performed on the premises, the licensed veterinarian must maintain the following at all times:

1. Appropriate sterile surgical packs including drapes, sponges and instrumentation for use in each procedure.

2. For each sterile surgical procedure, equipment sterilized and surgical packs properly prepared for sterilization sufficient to kill microorganisms.

3. Clean attire, masks and gloves for use in any sterile procedure.

(8) Oxygen and equipment necessary to administer oxygen to the types of patients treated in the facility.

(9) Capability to provide diagnostic radiological images in the facility or through an outside facility.

(10) Provision for laboratory and pharmaceutical services in the facility or through another commercial facility.

b. Facilities for services. Veterinary service facilities where patients are only examined or provided vaccinations must provide the following:

(1) An examination room, separate from the reception room or office, with sufficient size to accommodate the licensed veterinarian, assistant, patient and client.

(2) Nonporous tabletops, countertops and floor coverings that can be adequately cleaned and disinfected.

(3) A secure and sanitary area for the storage of instruments, drugs and medications.

(4) Cooling/heating equipment for the storage of drugs, medications and immunization products.

(5) Capability to provide diagnostic radiological images in the facility or through an outside facility.

(6) Provision for laboratory and pharmaceutical services in the facility or through another commercial facility.

c. Mobile clinics. Mobile clinics are self-contained units for small animal, nonlivestock or nonpoultry patients and shall be equipped with the following:

(1) Hot and cold water.

(2) Nonporous tabletops, countertops and floor coverings that can be adequately cleaned and disinfected.

(3) An adequate power source for diagnostic equipment.

(4) A collecting tank for disposal of waste materials.

(5) Adequate lighting.

(6) Adequate heating, cooling and ventilation.

(7) Sterile instrumentation that meets the requirements of the level of surgery to be performed.

(8) Separate compartments for the transportation or holding of patients.

(9) A secure and sanitary area for the storage of instruments, drugs and medications.

(10) Cooling/heating equipment for the storage of drugs, medications and immunization products.

d. House/farm call units. House/farm call units are not self-contained units and must be equipped with or have access to all of the following:

(1) Water.

(2) Cooling/heating equipment for the storage of drugs, medications and immunization products.

(3) A secure and sanitary area for the storage of instruments, drugs and medications.

e. Emergency veterinary hospitals. "Emergency veterinary hospital" means an animal hospital that provides emergency treatment to an ill or injured patient. Any facility advertising as an emergency facility shall have a licensed veterinarian and auxiliary personnel on the premises during the hours of operation. Any facility that advertises using phrases similar or identical to "24-hour emergency veterinary hospital," "Emergency," "Open 24 hours" or "Day or night care" must have treatment services continuously available.

12.5(2) Safety and sanitation standards. A veterinary facility must have a safe and sanitary environment that:

a. Protects the health of the patients and guards against the transmission of infection.

- b.* Provides for proper routine disposal of waste materials in compliance with all applicable local, state, and federal laws and regulations and for proper disposal of hypodermic devices, sharps and biomedical waste. Hypodermic devices, sharps and biomedical waste shall be disposed of in accordance with applicable local, state and federal regulations.
- c.* Provides for proper sterilization or sanitation of all equipment used in diagnosis, treatment or surgery.
- d.* Ensures the maintenance of proper temperature and ventilation of the indoor facility.
- e.* Provides adequate lighting appropriate for the task being performed.
- f.* Includes legal and sanitary methods for the disposal or storage of deceased patients.
- g.* Meets the standards for radiological procedures as set by the Iowa department of health and human services.

12.5(3) Resources. A library of current journals or textbooks, or Internet access that provides readily accessible reference materials, shall be available.

These rules are intended to implement Iowa Code chapter 169.