

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

BOARD OF PHARMACY - ANIMAL EUTHANASIA AND SEDATION RULES

(By authority conferred on the director of the department of licensing and regulatory affairs by sections 16145(3) and 7333(8) of 1978 PA 368, MCL 333.16145(3) and 333.7333(8) and Executive Reorganization Order Numbers 1996-1, 1996-2, 2003-1, and 2011-4, MCL 330.3101,445.2001, 445.2011, and 445.2030)

Part 1. General Provisions

R 338.3501 Definitions.

Rule 1. As used in these rules:

(a) "Administrator" means the board of pharmacy or its designated or established authority, as defined in section 7103 of the code.

(b) "Code" means 1978 PA 368, MCL 333.1101 to 333.25211.

(c) "Department" means the department of licensing and regulatory affairs.

(d) "Individual" means an animal control officer; law enforcement officer; a person who is under contract with an animal control shelter or an animal protection shelter; or, a person who is currently employed by an animal control shelter, an animal protection shelter, or a class b dealer, as used in these rules and sections 7333(8) to 7333(21) of the code.

History: 2013 AACCS.

Part 2. Animal Euthanasia

R 338.3502 Animal euthanasia; authorization to apply for permit.

Rule 2. An animal control shelter or animal protection shelter registered by the Michigan department of agriculture and rural development pursuant to 1969 PA 287, MCL 287.331 to 287.340, or a class b dealer licensed with the United States department of agriculture pursuant to 7 U.S.C. § 2134, may apply for a permit to store, handle, and use a commercially prepared, pre-mixed solution of sodium pentobarbital to practice euthanasia on animals.

History: 2013 AACCS.

R 338.3503 Animal euthanasia; application for permit; renewal.

Rule 3. (1) An animal control shelter or animal protection shelter that holds a current registration issued by the Michigan department of agriculture and rural development or a class b dealer licensed with the United States department of agriculture shall apply, on a form

provided by the administrator, together with the requisite fee, for a permit to store, handle, and use sodium pentobarbital. The application submitted to the administrator shall contain all of the following information:

(a) The name, address, and Michigan department of agriculture and rural development registration number of the animal control shelter or animal protection shelter, or the U.S. department of agriculture license number of the class b dealer.

(b) The name, address, and biographical data of the individual who is in charge of the day-to-day operation of the animal control shelter, animal protection shelter, or class b dealer and who is responsible for the storage and recordkeeping of the sodium pentobarbital.

(c) The name, address, and biographical data of the individual responsible for designating employees who will practice euthanasia pursuant to the code.

(d) The name and address of each individual certified to have received a minimum of 8 hours of training in the use of sodium pentobarbital to practice euthanasia, and the name of the veterinarian who trained each individual.

(2) A permit issued under this rule is valid for 2 years and may be renewed upon application to the administrator and payment of the requisite fee.

History: 2013 AACCS.

R 338.3504 Permit for animal euthanasia; form; non-transferable; change in responsible person.

Rule 4. A permit issued by the administrator shall show the name and address of the facility and the name of the individual in charge of the day-to-day operation. The permit is not transferable. The administrator shall be notified, in writing, within 10 days of a change in the individual in charge of the day-to-day operation.

History: 2013 AACCS.

R 338.3505 Registration with United States department of justice.

Rule 5. The facility shall obtain a registration, in accordance with 21 C.F.R. part 1301.11, from the United States department of justice, drug enforcement administration, or its successor agency, before stocking, purchasing, or using sodium pentobarbital to practice euthanasia. Purchases shall be made in accordance with procedures established by the drug enforcement administration.

History: 2013 AACCS.

R 338.3506 Animal euthanasia; trained personnel; notification of changes; documentation of training.

Rule 6. (1) If the animal control shelter, animal protection shelter, or class b dealer has been issued a permit pursuant to section 7333(8) of the code, and does not employ an individual trained as described in section 7333(8), then the animal control shelter, animal protection shelter, or class b dealer shall immediately notify the administrator, and shall securely store and cease to administer any commercially-prepared, pre-mixed solution of

sodium pentobarbital until the administrator is notified that either of the following has occurred:

(a) An individual trained as described in section 7333(8) of the code has been hired by the facility.

(b) An employee of the facility has been trained as described in section 7333(8) of the code.

(2) The administrator shall be notified of any change in the name and address of the individual trained as described in section 7333(8) of the code within 10 days of this change.

(3) A list of individuals certified as having received training and the veterinarians who trained them shall be updated in writing every 6 months, kept on site, and be available for inspection.

History: 2013 AACCS.

R 338.3507 Animal euthanasia; training of personnel.

Rule 7. (1) An employee of an animal control shelter, animal protection shelter, or class b dealer who practices euthanasia on animals shall document completion of a minimum of 8 hours of training given by a licensed veterinarian in the use of sodium pentobarbital.

(2) Training of the individual shall be under the instruction of a veterinarian who is currently licensed in this state and is in good standing. The training shall include both lecture and self-study instruction and clinical experience. At a minimum, the individual shall demonstrate competency to give intercardial, intraperitoneal, and intravenous injections, in addition to making a positive determination of death.

History: 2013 AACCS.

R 338.3508 Animal euthanasia; notification of completion of training; issuance of permit.

Rule 8. Upon receiving notification of an individual's successful completion of the minimum of 8 hours of training from a licensed veterinarian, the department shall issue a permit to the animal control shelter, animal protection shelter, or class b dealer where the individual is employed. An individual's proficiency in the use of sodium pentobarbital may be shown by completion of a self-assessment program or other evaluation approved by the board of veterinary medicine. A self-assessment program or other evaluation that examines an individual's proficiency in the use of sodium pentobarbital that has been approved by the Michigan department of agriculture and rural development is deemed approved by the Michigan board of veterinary medicine. The permit is subject to the provisions of section 7333 of the code.

History: 2013 AACCS.

R 338.3509 Animal euthanasia; establish and maintain written procedures; monitoring continued proficiency and compliance.

Rule 9. (1) An animal control shelter, animal protection shelter, or class b dealer shall establish and maintain written procedures for the administration of a commercially prepared, pre-mixed solution of sodium pentobarbital. These procedures shall be kept on the licensed premises and shall be available for inspection.

(2) An individual's continued proficiency and compliance with written procedures by an animal control shelter, an animal protection shelter, or a class b dealer, in addition to compliance with all rules and regulations, may be monitored by the administrator or the board of veterinary medicine.

History: 2013 AACCS.

R 338.3510 Animal euthanasia; retention of records regarding dispensation of sodium pentobarbital.

Rule 10. (1) Records of the receipt and dispensation of sodium pentobarbital shall be maintained at the animal control shelter, animal protection shelter, or by the class b dealer. These records shall include all of the following information pertaining to the sodium pentobarbital:

(a) The date of acquisition.

(b) The quantity acquired.

(c) The drug name.

(d) The trade name of the drug.

(e) The lot number and strength of a commercially prepared, pre-mixed solution of sodium pentobarbital.

(f) A complete record of the dispensation of the pre-mixed solution for the purpose of practicing euthanasia, that shows the quantity used, the time and date it was dispensed, and the name of the individual who administered the pre-mixed solution.

(2) Records of receipt shall be kept on drug enforcement administration (DEA) order forms pursuant to 21 C.F.R part 1305. The Code of Federal Regulations, Title 21, Food and Drugs, part 1305 is available at no cost on the internet at <http://www.access.gp.gov/nara/cfr>. Printed copies of 21 C.F.R. part 1305 are available for inspection and distribution at cost from the Michigan Board of Pharmacy, Department of Licensing and Regulatory Affairs, 611 West Ottawa, Lansing, Michigan 48909.

(3) Records of dispensation shall be kept pursuant to 21 C.F.R. part 1304. The Code of Federal Regulations, Title 21, Food and Drugs, part 1304 is available at no cost on the internet at <http://access.gpo.gov/nara/cfr>. Printed copies of 21 C.F.R. part 1304 also are available for inspection and distribution to the public at cost from the Michigan Board of Pharmacy, the Department of Licensing and Regulatory Affairs, 611 West Ottawa, Lansing, Michigan 48909.

(4) Records shall be kept for a period of 2 years and shall be available for inspection by the department or other authorized individual.

History: 2013 AACCS.

R 338.3511 Storage of sodium pentobarbital.

Rule 11. An animal control shelter, an animal protection shelter, or a class b dealer shall store all stocks of sodium pentobarbital in a securely locked, substantially constructed cabinet located in the facility, with access limited to the individuals described in R 338.3503 (b) and (d).

History: 2013 AACCS.

R 338.3512 Inspections.

Rule 12. The department may conduct an inspection of an animal control shelter, an animal protection shelter, or a class b dealer before a permit is issued. The department or authorized individual may make periodic, additional, unannounced inspections.

History: 2013 AACCS.

PART 5. ANIMAL SEDATION

R 338.3513 Animal sedation; authorization to apply for permit; renewal.

Rule 13. (1) An animal control shelter or animal protection shelter registered by the Michigan department of agriculture and rural development pursuant to 1969 PA 287, MCL 287.331 to 287.340, may apply, on a form provided by the administrator, together with the requisite fee, for a permit to store, handle, and use a commercially-prepared and federally-approved animal tranquilizer to sedate, feral, wild, difficult to handle, or other animals for euthanasia, or to tranquilize an animal running at large that is dangerous or difficult to capture.

(2) A permit issued under this subrule (1) of this rule is valid for 2 years and may be renewed upon application to the administrator and payment of the requisite fee.

History: 2013 AACCS.

R 338.3514 Animal sedation; application for permit.

Rule 14. An animal control shelter or animal protection shelter holding a current registration issued by the Michigan department of agriculture and rural development shall apply, on a form provided by the administrator, for a permit to store, handle, and use animal tranquilizers. The application submitted to the administrator shall contain all of the following information:

(a) The name, address, and Michigan department of agriculture and rural development registration number of the animal control shelter or animal protection shelter.

(b) The name, address, and biographical data of the individual who is in charge of the day-to-day operation of the animal control shelter or animal protection shelter and who is responsible for the storage and recordkeeping of the animal tranquilizing drugs.

(c) The name, address, and biographical data of the individual responsible for designating employees who will practice tranquilizing pursuant to the act.

(d) The name and address of each individual certified to have received a minimum of 16 hours of approved training, including 3 hours of practical training, in the use of animal tranquilizers to sedate feral, wild, difficult to handle, or other animal for euthanasia, or to tranquilize an animal running at large that is dangerous or difficult to capture, and the name of the veterinarian who trained each individual, as required under section 7333(14)(c) of the code.

(e) If the trained individual is under contract with the shelter to perform tranquilizing services, all of the following shall be provided:

(i) An application indicating that tranquilizing services are being performed under contract.

(ii) The name and address of the employment agency with whom the services are being offered under a contract.

(iii) The name of the individual responsible for each individual under contract with the shelter.

History: 2013 AACCS.

R 338.3515 Permit for animal sedation; form; non-transferable; change in responsible person.

Rule 15. A permit issued by the administrator shall show the name and address of the facility and the name of the person in charge of the day-to-day operation. This permit is not transferable. The administrator shall be notified, in writing, within 10 days of a change in the person in charge of the day-to-day operation.

History: 2013 AACCS.

R 338.3516 Registration with United States department of justice.

Rule 16. The facility shall obtain a registration, in accordance with 21 C.F.R. part 1301.11, from the United States department of justice, drug enforcement administration, or its successor agency, when required by the drug enforcement agency, before stocking, purchasing, and using animal tranquilizers. Purchases shall be made in accordance with procedures established by the drug enforcement administration.

History: 2013 AACCS.

R 338.3517 Animal sedation; trained personnel; notification of changes; documentation of training.

Rule 17. (1) If an animal control shelter or animal protection shelter has been issued a permit pursuant to section 7333(14) and (15) of the code, and does not employ an individual trained as described in section 7333(14)(c) or (15)(c), then the animal control shelter or animal protection shelter shall immediately notify the administrator, and shall securely store and cease to administer the animal tranquilizer until the administrator is notified that either of the following has occurred:

(a) An individual trained as described in section 7333(14)(c) or (15)(c) of the code has been hired by the facility.

(b) An employee of the facility has been trained as described in section 7333(14)(c) or (15)(c) of the code.

(2) The administrator shall be notified of any change in the name and address of the individual trained as described in section 7333(14)(c) or (15)(c) of the act within 10 days of training.

(3) The list of individuals certified as having received training and the veterinarian or veterinarians who trained them, as well as documentation that the training has been approved by the Michigan board of veterinary medicine, shall be updated in writing every 6 months, kept on site, and available for inspection.

History: 2013 AACCS.

R 338.3518 Animal sedation; training of personnel.

Rule 18. (1) An individual who practices sedation on animals shall document completion of 16 hours of approved training, including 3 hours of practical training, in the use of animal tranquilizers given by a licensed veterinarian, as required under section 7333(14)(c) of the code.

(2) Training of the individual shall be under the instruction of a doctor of veterinary medicine currently licensed in this state and in good standing. The training shall include all of the following:

(a) Lecture and clinical experience.

(b) Instruction about types of commercially-prepared, federally-approved animal tranquilizers currently available, as well as their drug reversals.

(c) Proper doses of tranquilizing drugs for each species for which the drugs are approved and drug dosage calculating.

(d) Administration techniques for the animal tranquilizers and their reversals.

(e) Drug contraindications and precautions.

(f) Animal monitoring techniques for tranquilized animals.

(g) Methods for identifying and handling drug-related emergencies.

(3) An outline of the training shall be presented to the Michigan board of veterinary medicine for written approval prior to the start of training. Training in the use of animal tranquilizers that has been approved by the Michigan department of agriculture and rural development is deemed approved by the Michigan board of veterinary medicine. Documentation that the individual's training has been approved by the Michigan department of agriculture and rural development shall be submitted to the Michigan Department of Licensing and Regulatory Affairs with the application for a permit.

History: 2013 AACCS.

R 338.3519 Animal sedation; notification of completion of training; issuance of permit.

Rule 19. Upon receiving notification of an individual's successful completion of the minimum 16 hours of approved training from a licensed veterinarian, the department shall issue a permit to the animal control shelter or the animal protection shelter. An individual's

proficiency may be shown by completion of a self-assessment program or other evaluation by the board of veterinary medicine.

History: 2013 AACCS.

R 338.3520 Animal sedation; establish and maintain written procedures; monitoring continued proficiency and compliance.

Rule 20. (1) An animal control shelter or animal protection shelter shall establish and maintain written procedures for the administration of animal tranquilizers. These procedures shall be kept on the licensed premises and shall be available for inspection.

(2) An individual's continued proficiency and a shelter's compliance with written procedures, in addition to compliance with all rules and regulations, may be monitored by the administrator or the board of veterinary medicine.

History: 2013 AACCS.

R 338.3521 Animal sedation; retention of records for dispensation of tranquilizing drugs.

Rule 21. (1) Records of the receipt and dispensation of animal tranquilizers shall be maintained at the animal control shelter or animal protection shelter. The records shall include all of the following information pertaining to an animal tranquilizer:

- (a) The date of acquisition.
- (b) The quantity acquired.
- (c) The drug name.
- (d) The trade name.
- (e) The lot number and strength of the animal tranquilizer.

(f) A complete record of the dispensation of the animal tranquilizer that shows the quantity used, the time and date it was dispensed, the name of the administering individual, and a full description of the animal to which the animal tranquilizer was administered which includes all of the following:

- (i) The species of the animal.
- (ii) The breed of the animal.
- (iii) The sex of the animal.
- (iv) The age of the animal.
- (v) The approximate weight of the animal.

(2) Records of dispensation for controlled drugs shall be kept pursuant to 21 C.F.R. part 1304. The code of federal regulations title 21, food and drugs, part 1304 is available at no cost on the internet at <http://www.gpoaccess.gov/nara/cfr>. Printed copies of 21 C.F.R. part 1304 are available for inspection and distribution at cost from the Michigan Board of Pharmacy, the Department of Licensing and Regulatory Affairs, 611 West Ottawa, Lansing, MI 48909.

(3) Records shall be kept for a period of 2 years and shall be available for inspection by the department or other authorized official.

History: 2013 AACCS.

R 338.3522 Storage of animal tranquilizers.

Rule 22. All stocks of the controlled and noncontrolled animal tranquilizers shall be stored in a securely locked, substantially constructed cabinet located in the facility, with access limited to the individuals described in R 338.3514 (b) and (d).

History: 2013 AACS.

R 338.3523 Inspections.

Rule 23. The department may conduct an inspection of an animal control shelter or animal protection shelter before a permit is issued. The department or other authorized official may periodically make additional, unannounced inspections.

History: 2013 AACS.