

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY - ANIMAL EUTHANASIA AND SEDATION RULES

Filed with the secretary of state on October 28, 2021

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(6) of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the director of the department of licensing and regulatory affairs by section 7333 of the public health code, 1978 PA 368, MCL 333.7333 and Executive Reorganization Order Nos. 1991-9, 1996-2, 2003-1, and 2011-4, MCL 338.3501, 445.2001, 445.2011, and 445.2030)

R 338.3501, R 338.3502, R 338.3503, R 338.3504, R 338.3505, R 338.3506, R 338.3507, R 338.3509, R 338.3510, R 338.3511, R 338.3512, R 338.3513, R 338.3514, R 335.3515, R 338.3516, R 338.3517, R 338.3518, R 338.3520, R 338.3521, R 338.3522, and R 338.3523 of the Michigan Administrative Code are amended, and R 338.3508 and R 335.3519 are rescinded, as follows:

Part 1. GENERAL PROVISIONS

R 338.3501 Definitions.

Rule 1. (1) As used in these rules:

(a) "Animal control shelter" means a facility operated by a municipality for the impoundment and care of animals that are found in the streets or at large, animals that are otherwise held due to the violation of a municipal ordinance or state law, or animals that are surrendered to the animal control shelter that holds a current registration issued by the Michigan department of agriculture and rural development (MDARD).

(b) "Animal protection shelter" means a facility operated by a person, humane society, society for the prevention of cruelty to animals, or any other nonprofit organization for the care of homeless animals that holds a current registration issued by MDARD.

(c) "Animal tranquilizer" means the term as defined in MCL 333.7333(20)(a), a commercially prepared solution of xylazine hydrochloride, a commercially prepared solution of ketamine, or a commercially prepared compound containing tiletamine and zolazepam.

(d) "Code" means the public health code, 1978 PA 368, MCL 333.1101 to 333.25211.

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

(f) "Euthanasia" means a method of humane death that minimizes pain, distress, and anxiety experienced by the animal prior to loss of consciousness and causes rapid loss of consciousness followed by cardiac or respiratory arrest and death. The euthanasia training described in these rules and euthanasia provided under these rules must comply with the American Veterinary Medical Association's guidelines for the euthanasia of animals.

(g) “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 section 7333(9) to (19) of the code, MCL 333.7333.

(h) “Sedation” of an animal means a state of central nervous system depression caused by the administration of an animal tranquilizer in which the animal is awake but calm, and with sufficient stimuli may be aroused. Sedation of an animal must be accompanied by the additional use of an anesthetic agent inducing unconsciousness in the animal before euthanasia via intracardiac injection is allowed.

(2) Unless otherwise defined in the rules, the terms defined in the code have the same meaning when used in these rules.

PART 2. ANIMAL EUTHANASIA

R 338.3502 Animal euthanasia; animal control shelters, animal protection shelters, class B dealers; authorization to apply for permit.

Rule 2. (1) An animal control shelter, animal protection shelter, or a class b dealer, may apply for a permit to buy, possess, store, handle, and administer animal tranquilizers in addition to xylazine hydrochloride for pre-euthanasia sedation or a commercially prepared, pre-mixed solution of sodium pentobarbital to practice euthanasia on animals pursuant to the training required in R 338.3507.

(2) Beginning no later than January 1, 2022, an animal control shelter, animal protection shelter, and class B dealer shall meet the training requirements in R 338.3507 in order to administer an animal tranquilizer for pre-euthanasia sedation or a commercially prepared, premixed solution of sodium pentobarbital to perform euthanasia on animals.

R 338.3503 Animal euthanasia; application for permit.

Rule 3. (1) An animal control shelter, animal protection shelter, or class B dealer shall apply to the department for a permit under R 338.3502, on a form provided by the department, together with the requisite fee, which shall contain all of the following information:

(a) The name, address, and MDARD registration number of the animal control shelter, animal protection shelter, or the USDA 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 commercially prepared, pre-mixed solution of sodium pentobarbital and animal tranquilizers.

(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 of the veterinarian who trained each individual.

(e) Beginning no later than January 1, 2022, or earlier, if a class B dealer chooses to administer an animal tranquilizer for pre-euthanasia sedation before that date, a class B dealer shall submit both of the following:

(i) The name and address of the class B dealer or an employee of the class B dealer and documentation from the trainer that he or she has completed the training required in R 338.3507.

(ii) The name of the individual in charge of the day-to-day operation of the class B dealer and documentation from the trainer that the individual received and can document completion of the training described in R 338.3507.

(f) Beginning no later than January 1, 2022, or earlier, if an animal control shelter or an animal protection shelter chooses to administer animal tranquilizers in addition to xylazine hydrochloride for pre-euthanasia sedation before that date, an animal control shelter or an animal protection shelter shall submit both of the following.

(i) The name and address of an employee and documentation from the trainer that the employee has completed the training required in R 338.3507.

(ii) The name of the individual in charge of the day-to-day operation and documentation from the trainer that the individual received and can document completion of the training described in R 338.3507.

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

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

Rule 4. A permit issued by the department must 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 permit holder shall notify the department, in writing, within 30 days of a change in the individual in charge of the day-to-day operation.

R 338.3505 Registration with United States Department of Justice.

Rule 5. The facility shall obtain a registration, pursuant to 21 CFR 1301.11 (2009), from the United States Department of Justice (DOJ) Drug Enforcement Administration (DEA), or its successor agency, before stocking, purchasing, or using a controlled substance to practice euthanasia. Purchases must be made pursuant to procedures established by the DOJ DEA.

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 R 338.3502, R 338.3503, and section 7333(9) and (10) of the code, MCL 333.7333, and does not employ an individual trained as described in R 338.3507 and section 7333(9) and (10) of the code, MCL 333.7333, or does not have a manager in charge of the day-to-day operation that is trained pursuant to section 7333(9) and (10) of the code, MCL 333.7333, then the animal control shelter, animal protection shelter, or class B dealer shall immediately notify the department, and shall securely store and cease to administer any commercially-prepared, pre-mixed solution of sodium pentobarbital or animal tranquilizer until the department is notified that both of the following has occurred:

(a) The individual in charge of the day-to-day operation has been trained as described in R 338.3507 and he or she has submitted documentation of the training to the department.

(b) An individual has been hired or an employee of the animal control shelter, or animal protection shelter, or the class B dealer has been trained as described in R 338.3507 and section 7333(9) and (10) of the code, MCL 333.7333.

(2) The permit holder shall notify the department within 30 days of any change in the name and address of the individual trained as described in section 7333(9) and (10) of the code, MCL 333.7333.

(3) A permit holder shall comply with all of the following:

- (a) Maintain a list of individuals who have received the training required in these rules.
- (b) Maintain a list of the veterinarians who trained each individual.
- (c) Update the lists required in this subrule every 6 months.
- (d) Keep the lists required in this subrule on the site of the class B dealer, animal control shelter, or animal protection shelter.
- (e) Make the lists required in this subrule available for inspection by the department or other authorized individual upon request.

R 338.3507 Animal euthanasia; training of personnel.

Rule 7. An applicant for a permit pursuant to R 338.3501(1) shall comply with the following requirements:

- (a) The applicant shall complete a training consistent with section 7333(9)(c) and (10)(c) of the code, MCL 333.7333.
- (b) The applicant shall complete a training that has been approved by the state veterinarian.
- (c) The applicant shall complete a training given by a veterinarian who is currently licensed in this state and is in good standing.

R 338.3508 Rescinded.

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 for euthanasia and animal tranquilizers for pre-euthanasia sedation. These procedures must be kept on the permitted premises and must be available for inspection by the department.

(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 department.

R 338.3510 Animal euthanasia; retention of records regarding receipt and administration of sodium pentobarbital and animal tranquilizers.

Rule 10. (1) The permit holder shall maintain separate records of the receipt of commercially prepared, pre-mixed solution of sodium pentobarbital and animal tranquilizers and the administration of a commercially prepared, pre-mixed solution of sodium pentobarbital and animal tranquilizers at the animal control shelter, animal protection shelter, or by the class B dealer.

(2) These records must include all of the following information pertaining to the receipt of commercially prepared, pre-mixed solution of sodium pentobarbital and animal tranquilizers:

- (a) The date of acquisition.
- (b) The quantity acquired.
- (c) The name of the drug.

- (d) The trade name of the drug.
- (e) The lot number and strength of a commercially prepared, pre-mixed solution of sodium pentobarbital or animal tranquilizer.
- (3) The records of the administration of the commercially prepared, pre-mixed solution of sodium pentobarbital or animal tranquilizer for the purpose of practicing euthanasia, must include all of the following:
 - (a) The quantity used.
 - (b) The time and date it was administered.
 - (c) The name of the individual who administered the animal tranquilizer or pre-mixed solution of sodium pentobarbital.
 - (d) The full description of the animal to which the commercially prepared, pre-mixed solution of sodium pentobarbital or animal tranquilizer was administered, which includes all of the following and is recorded in the animal's medical or shelter record:
 - (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.
 - (vi) The number associated with the animal if a numbering system is used.
- (4) The permit holder shall record receipt of controlled substances on DOJ DEA order forms pursuant to 21 CFR part 1305 (2019). 21 CFR part 1305 is available at no cost on the internet at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1305>. Printed copies of 21 CFR part 1305 are available for inspection and distribution at 10 cents per page from the Michigan Board of Pharmacy, Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan 48909.
- (5) The permit holder shall maintain records of administration of controlled substances pursuant to 21 CFR part 1304 (2019). 21 CFR part 1304 is available at no cost on the internet at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1304>. Printed copies of 21 CFR part 1304 also are available for inspection and distribution to the public at 10 cents per page from the Michigan Board of Pharmacy, the Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan 48909.
- (6) Permit holders shall keep records for a period of 2 years and shall make them available for inspection by the department or other authorized individual upon request.

R 338.3511 Storage of drugs used for euthanasia on animals.

Rule 11. An animal control shelter, an animal protection shelter, and a class B dealer shall store all drugs used for euthanasia on animals in a securely locked, substantially constructed cabinet located in the facility, with access limited to the individuals described in R 338.3503(b), (e), and (f).

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.

PART 3. ANIMAL FIELD SEDATION

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

Rule 13. (1) An animal control shelter, may apply for a permit to buy, possess, store, handle, and administer animal tranquilizers to sedate or immobilize an animal running at large that is dangerous or difficult to capture pursuant to the training required in R 338.3518.

(2) Beginning no later than January 1, 2022, an individual in charge of the day-to-day operations of an animal control shelter shall meet the training requirements in R 338.3518 in order to administer any animal tranquilizers on animals running at large that are dangerous or difficult to capture.

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

R 338.3514 Animal sedation; application for permit.

Rule 14. An animal control shelter shall apply, on a form provided by the department, for a permit to buy, possess, store, handle, and administer animal tranquilizers to sedate or immobilize an animal, to the department, together with the requisite fee. The application must contain all of the following information:

- (a) The name, address, and MDARD registration number of the animal control 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 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 code.
- (d) The name of the veterinarian who trained each employee.
- (e) Beginning no later than January 1, 2022, or earlier, if the animal control shelter uses an animal tranquilizer other than xylazine hydrochloride to sedate or immobilize animals before that date, the name and address of the employee and documentation from the trainer that he or she has completed the training required in R 338.3518.
- (f) Beginning no later than January 1, 2022, the name of the individual in charge of the day-to-day operation of the animal control shelter and documentation from the trainer that he or she has received and can document completion of the training described in R 338.3518.
- (g) If the trained individual is under contract with the shelter to perform tranquilizing services, all of the following must 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.

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

Rule 15. A permit issued by the department must 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 permit holder shall notify the department in writing, within 30 days of a change in the person in charge of the day-to-day operation.

R 338.3516 Registration with United States department of justice.

Rule 16. The facility shall obtain a registration pursuant to 21 CFR 1301.11 (2009), from the DOJ DEA, or its successor agency, when required by the DOJ DEA, before stocking, purchasing, and using a controlled substance. Purchases must be made pursuant to procedures established by the DOJ DEA.

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

Rule 17. (1) If an animal control shelter has been issued a permit pursuant to R 338.3513, R 338.3514, and section 7333(16) to (19) of the code, MCL 333.7333, and does not employ an individual trained as described in R 338.3518 and section 7333(16) to (19) of the code, MCL 333.7333, then the animal control shelter shall immediately notify the department, and shall securely store and cease to administer the animal tranquilizer until the department is notified that both of the following has occurred:

(a) An individual trained as described in section 7333(16)(c) of the code, MCL 333.7333, has been hired by the facility.

(b) The individual in charge of the day-to-day operation of the facility has been trained as described in section 7333(f) of the code MCL 333.7333.

(2) The permit holder shall notify the department within 30 days of any change in the name and address of the individual trained as described in section 7333(16)(c), (d), or (f) of the code, MCL 333.7333.

(3) A permit holder shall comply with all of the following:

(a) Maintain a list of individuals who have received the training required in these rules.

(b) Maintain a list of the veterinarians who trained each individual.

(c) Maintain documentation that the training has been approved by the state veterinarian.

(d) Update the lists required in this subrule every 6 months.

(e) Keep the lists required in this subrule on the site of the animal control shelter.

(f) Make the lists required in this section available for inspection by the department or other authorized individual upon request.

R 338.3518 Animal sedation; training of personnel.

Rule 18. An applicant for a permit pursuant to R 338.3513(1) shall comply with the following requirements:

(a) The applicant shall complete a training consistent with section 7333(16)(c) of the code, MCL 333.7333.

(b) The applicant shall complete a training that has been approved by the state veterinarian.

(c) The applicant shall complete a training given by a veterinarian who is currently licensed in this state and is in good standing.

R 338.3519 Rescinded.

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

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

(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 department.

R 338.3521 Animal sedation; retention of records for receipt and administration of tranquilizing drugs.

Rule 21. (1) The permit holder shall maintain separate records of the receipt of animal tranquilizers and administration of animal tranquilizers at the animal control shelter.

(2) The receipt of animal tranquilizer records must 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 of the drug.
- (e) The lot number and strength of the animal tranquilizer.

(3) The administration of the animal tranquilizer records must include all of the following:

- (a) The quantity used.
- (b) The time and date it was administered.
- (c) The name of the individual who administered the drug.
- (d) The full description of the animal to which the animal tranquilizer was administered, which includes all of the following and is recorded in the animal's shelter or medical record:
 - (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.
 - (vi) The number associated with the animal if a number system is used.

(4) The permit holder shall record receipt of controlled substances on DOJ DEA order forms pursuant to 21 CFR part 1305 (2019). 21 CFR part 1305 is available at no cost on the internet at

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1305>.

Printed copies of 21 CFR part 1305 are available for inspection and distribution at 10 cents per page from the Michigan Board of Pharmacy, Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan 48909.

(5) The permit holder shall maintain records of administration for controlled substances pursuant to 21 CFR part 1304 (2019). The 21 CFR part 1304 is available at no cost on the internet at

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1304>.

Printed copies of 21 CFR part 1304 are available for inspection and distribution at 10 cents

per page from the Michigan Board of Pharmacy, the Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan, 48909.

(6) Permit holders shall keep records for a period of 2 years and make them available for inspection by the department or other authorized individual upon request.

R 338.3522 Storage of animal tranquilizers.

Rule 22. All stocks of the animal tranquilizers must 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), (f) and (g).

R 338.3523 Inspections.

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