

Document: Proposed Rule, **Register Page Number:** 26 IR 1725

Source: February 1, 2003, Indiana Register, Volume 26, Number 5

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TITLE 856 INDIANA BOARD OF PHARMACY

Proposed Rule LSA Document #02-258

DIGEST

Adds 856 IAC 2-7 concerning limited permits for humane societies, animal control agencies, or governmental entities operating an animal shelter; and storage, security, policy, and procedure for access, handling, and administration of Ketamine, Ketamine products, Tiletimine, and Zolazepam, and other controlled substances obtained under the limited permit. Effective 30 days after filing with the secretary of state.

856 IAC 2-7

SECTION 1. 856 IAC 2-7 IS ADDED TO READ AS FOLLOWS:

Rule 7. Limited Permits

856 IAC 2-7-1 Application

Authority: IC 35-48-3-2

Affected: IC 35-48-3-2

Sec. 1. (a) A humane society, animal control agency, or governmental entity that intends to operate an animal shelter or other animal impounding facility for the purpose of buying, possessing, and using drugs authorized by IC 35-48-3-2 shall apply for a limited permit in the form and manner required by the board.

(b) The applicant shall provide the following:

- (1) Name and address of the facility.**
- (2) Type of facility.**
- (3) Documentation describing the ownership of the facility.**
- (4) Fees set by the board in this rule.**
- (5) Information about the substances that the facility intends to administer.**
- (6) Written policies relating to storage, security, and procedures for access, handling, and administration of drugs.**
- (7) Proof that the employees of the applicant who will handle a controlled substance are sufficiently trained to use and administer the controlled substance.**
- (8) Proof that a licensed Indiana veterinarian holding a valid Indiana controlled substances registration and federal D.E.A. registration has been retained to provide technical advice to the facility.**

(c) No humane society, animal control agency, or governmental entity that intends to operate an animal shelter or other animal impounding facility for the purpose of buying, possessing, and using drugs authorized by IC 35-48-3-2 shall engage in any activity for which a permit is required until the permit is granted by the board. (Indiana Board of Pharmacy; 856 IAC 2-7-1)

856 IAC 2-7-2 Permit fees

Authority: IC 35-48-3-2

Affected: IC 35-48-3-2

Sec. 2. The board shall charge and collect the following fees:

- (1) Application for a limited permit, fifty dollars (\$50).**

(2) Annual renewal of limited permit, twenty-five dollars (\$25).
(Indiana Board of Pharmacy; 856 IAC 2-7-2)

856 IAC 2-7-3 Renewal of permit

Authority: IC 35-48-3-2
Affected: IC 35-48-3-2

Sec. 3. The renewal of the limited permits issued under this section shall be on the same schedule as other humane societies, animal control agencies, or governmental entities that hold controlled substance registrations issued by the board.
(Indiana Board of Pharmacy; 856 IAC 2-7-3)

856 IAC 2-7-4 Storage, handling, and use of controlled substances

Authority: IC 35-48-3-2
Affected: IC 35-48-3-2

Sec. 4. (a) Limited permit holders and their agents, representatives, and employees must comply with the requirements of this rule for the storage and handling of controlled substances.

(b) All facilities at which controlled substances are stored, handled, or used shall:

- (1) be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;**
- (2) have storage areas large enough to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;**
- (3) have a quarantine area for storage of controlled substances that are:**
 - (A) outdated, damaged, deteriorated, misbranded, or adulterated; or**
 - (B) in immediate or sealed secondary containers that have been opened;**
- (4) be maintained in a clean and orderly condition; and**
- (5) be free from infestation by insects, rodents, birds, or vermin of any kind.**

(c) All facilities used for storage of controlled substances by registrants under this section shall comply with the security requirements as provided by 856 IAC 2-3-31.

(d) All controlled substances shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such controlled substances, or with requirements in the current edition of an official compendium of drug information.

(e) If no storage requirements are established for a controlled substance, the controlled substance may be held at a controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(f) Controlled substances that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other controlled substances until they are destroyed by a designated agent of the board or returned to their supplier.

(g) Any controlled substance whose immediate or sealed outer or sealed secondary containers have been opened or used shall be:

- (1) identified as such; and**
- (2) quarantined and physically separated from other controlled substances until they are either destroyed by a designated agent of the board or returned to the supplier.**

(h) Limited permit holders shall establish and maintain inventories and records of all controlled substances stored or used at the facility.

(i) Inventories and records shall be made available for inspection and photocopying by any authorized official of any governmental agency charged with enforcement of this rule for a period of two (2) years following disposition of the controlled substances.

(j) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of any governmental agency charged with enforcement of this rule. *(Indiana Board of Pharmacy; 856 IAC 2-7-4)*

856 IAC 2-7-5 Training of staff

Authority: IC 35-48-3-2

Affected: IC 35-48-3-2

Sec. 5. (a) Only employees of the limited permit holder are eligible for training to store, handle, and use controlled substances. Volunteers are prohibited from storing, handling, or using controlled substances.

(b) The following training is required:

- (1) Completion of a comprehensive training program approved by the controlled substance advisory committee.**
- (2) Any additional training as required by the supervising veterinarian or site administrator.**

(c) A veterinarian licensed to practice in Indiana, holding a valid Indiana controlled substances registration and federal D.E.A. registration, must verify in writing that the employee has been trained adequately to store, handle, or use controlled substances. The written verification must be maintained at the facility in a reasonably retrievable manner.

(d) The limited permit holder or site administrator shall maintain documentary proof of training in a reasonably retrievable manner at the facility for review by an authorized official of any governmental agency charged with enforcement of this rule. *(Indiana Board of Pharmacy; 856 IAC 2-7-5)*

856 IAC 2-7-6 Protocol for administration of controlled substances

Authority: IC 35-48-3-2

Affected: IC 35-48-3-2

Sec. 6. In the event the consulting veterinarian is not physically present during the administration of controlled substances by employees of the limited permit holder, the veterinarian shall be available for consultation by telephonic or other electronic device. *(Indiana Board of Pharmacy; 856 IAC 2-7-6)*

856 IAC 2-7-7 Limitations on permit

Authority: IC 35-48-3-2

Affected: IC 35-48-3-2

Sec. 7. (a) Except as provided in subsection (b), only controlled substances for which the humane society, animal control agency, or governmental entity has received a permit may be stored, handled, and used at the facility.

(b) A licensed veterinarian who stores, handles, or uses controlled substances at the humane society, animal control agency, or governmental entity other than those authorized under the facility's limited permit, must apply for and obtain a controlled substance registration for the facility in the veterinarian's name.

(c) The veterinarian who holds the registration noted in subsection (b) is responsible for the proper storage, handling, and use of the controlled substances authorized for use under the veterinarian's controlled substance registration. *(Indiana Board of Pharmacy; 856 IAC 2-7-7)*

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on March 10, 2003 at 9:30 a.m., at the Indiana Government Center-South, 402 West Washington Street, Conference Center Room A, Indianapolis, Indiana the Indiana Board of Pharmacy will hold a public hearing on proposed new rules to provide a limited permit for animal shelters to handle Ketamine and other products. Copies of these rules are now on file at the Indiana Government Center-South, 402 West Washington Street, Room W041 and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Lisa R. Hayes
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Health Professions Bureau