

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING : ORDER OF THE
PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 19-157)

ORDER

An order of the Controlled Substances Board **to renumber and amend** CSB 3.04 (7); **to amend** CSB 3.02 (4), 3.03 (2), 3.04 (1) (a) and (note), (b), (c), and (d), (3) (intro) and (b), (4) (a) (intro.) and (5) (a) (intro.); **and to create** CSB 3.03 (2m), 3.042, and 3.08 (1) (f) and (g) relating to special use authorizations.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.335, Stats.

Statutory authority: s. 961.335 (8), Stats.

Explanation of agency authority:

The controlled substances board may promulgate rules relating to the granting of special use permits including, but not limited to, requirements for the keeping and disclosure of records, filing of applications and suspension or revocation of permits. [s. 961.335 (8), Stats.]

Related statute or rule: s. 961.335, Stats.

Plain language analysis:

Section 1 updates the rule to reflect current drafting standards by removing the phrase “but are not limited to.”

Sections 2 and 3 separates the current CSB 3.03 (2) into two separate subsections to create clarity. Special use authorizations are issued to individuals only. If a permit is issued to an individual who is designated by a college or university, or research unit, the students, laboratory technicians, research specialists or chemical analysts under the individual’s supervision do not need to obtain a special use authorization.

Section 4 updates language and creates clarity. This section removes “checklists” from the application and updates the note to reflect the current address. The reference to s. 961.335 is removed because the statute does not state the fee is \$25; rather it says up to \$25. The current

rule creates difficulty in applying for a special use authorization because it requires proof an application is submitted to the federal Drug Enforcement Administration and the Drug Enforcement Administration will not accept an application without proof the individual has a special use authorization. To resolve this situation, the proposed rule requires an affidavit that the individual intends to file an application with the Drug Enforcement Administration. Lastly this section removes proof of compliance with the requirements for security and instead requires a plan for security.

Section 5 clarifies that individuals providing euthanasia at humane shelters shall provide the documentation in the application including their completion of a board-approved euthanasia by injection course. In addition, for dog trainers and animal control applicants, it removes the phrase “unless other documentation is required by the board” to clarify that the letter is the requirement.

Section 6 moves the board’s discretion to request an appearance to the general application requirements to create clarity.

Section 7 creates the storage requirements. Controlled substances shall be stored in a safe or steel cabinet. The safe or cabinet must be bolted or cemented to the floor if it is less than 750 pounds so that it can’t be readily removed. It must meet requirements for forced entry and housed in a room which is locked during non-use hours. Other secure storage areas may be approved by the Controlled Substances Board if the storage will protect the controlled substances from theft and unauthorized use. The controlled substances must be locked up unless in use by the authorized user.

Sections 8, 9, 10 and 11 amends language to reflect the acronym “SUA” and defined term “SUA permit” for consistency throughout the rule.

Section 12 clarifies that it is a violation to not obtain a drug enforcement administration registration or if there is a violation of a state or federal law relating to controlled substances.

Summary of, and comparison with, existing or proposed federal regulation:

The federal government requires security controls for non-practitioners storing controlled substances. The drugs are to be stored in a safe or steel cabinet with the following specifications: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques. If the safe or steel cabinet weighs less than 750 pounds, it must be bolted or cemented to the floor or wall in a way that it can’t be readily removed. The room must limit access during working hours and provide security after working hours.

Comparison with rules in adjacent states:

Illinois: In Illinois, every person who, or proposes to, manufacture, distribute, or dispense any controlled substances; engages in chemical analysis, research, or instructional activities which utilize controlled substances; purchases, stores, or administers euthanasia drugs, provides canine

odor detection services; must obtain a registration issued by the Department of Financial and Professional Regulation. Registered persons may possess, manufacture, distribute, or dispense controlled substances, or administer euthanasia drugs to the extent authorized by their registration. Registration is site-specific, so persons operating at more than one site must have a separate registration for each. A registration to manufacture, distribute, or dispense a controlled substance or purchase, store, or administer euthanasia drugs may be denied, refused renewal, suspended or revoked if a person does any of the following: provided false or fraudulent material information in any application; has been convicted of a felony related to any controlled substance; has had their federal DEA registration suspended or revoked; has been convicted of bribery, perjury or other infamous crime; violated any provision of the controlled substances act; or failed to provide effective controls against the diversion of controlled substances in other than legitimate medical, scientific or industrial channels. [Ill. Admin. Code 77 § 3100]

Iowa:

In Iowa, researchers, analytical laboratories, animal shelters, dog training facilities, and teaching institutions are required to apply for a controlled substances registration permit with the Pharmacy Board. Registration applies to one site only, so persons operating at more than one site must have separate registrations for each. Registered persons may possess, manufacture, distribute, dispense, or conduct research using controlled substances to the extent authorized by their registration only and in conformity with the other provisions of Iowa's controlled substances registration law. A registration to manufacture, distribute, dispense, prescribe, import or export, conduct research or instructional activities or conduct chemical analysis with controlled substances may be denied if the board determines that the issuance of the registration would be inconsistent with the public interest. In determining the public interest, the board shall consider the following factors: maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels; compliance with applicable state and local law; any convictions related to any controlled substance; past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion; furnishing false or fraudulent material in any application for registration; suspension or revocation of the federal DEA registration; and any other factors relevant to and consistent with the public health and safety. [Iowa Admin. Code r. 657-10]

Michigan:

In Michigan, an individual in charge of a licensed dog pound or animal shelter, must obtain both a Drug Enforcement Agency (DEA) controlled substance registration and a Michigan controlled substance license for the limited purpose of buying, possessing, or administering a commercially prepared, premixed solution of sodium pentobarbital to practice euthanasia on animals. Michigan officers or state employees are exempted from licensure if that person is engaged in the enforcement of a state or local law relating to controlled substances and who is duly authorized to possess controlled substances in the course of that person's duties. Licensed researchers and manufacturers of a controlled substance may conduct research with those substances, perform chemical analysis, manufacture the substance, distribute the substance to other persons who are licensed or authorized, and conduct instructional activities with the

substances. Certain activities involving schedule 1 controlled substances may require a separate license. The license shall be granted unless the issuance of the license would be inconsistent with the public interest. In determining the public interest, the following shall be considered: maintenance of effective controls against diversion to other than legitimate and professionally recognized therapeutic, scientific, or industrial channels; compliance with applicable state and local law; conviction relating to a controlled substance; past experience in the manufacture or distribution of controlled substances and the existence in the applicant's establishment of effective controls against diversion; furnishing false or fraudulent material in an application for a controlled substance license; suspension or revocation of the federal DEA registration; and any other factor relevant to and consistent with the public health and safety. [Mich. Admin. Code r. 338]

Minnesota:

In Minnesota, any qualified person may use controlled substances in the course of a bona fide research project but cannot administer or dispense such drugs to human beings unless such drugs are prescribed, dispensed and administered by a person lawfully authorized to do so. Researchers involved in the use of controlled substances must apply annually for registration with the state Board of Pharmacy. Registration requires that the registrant have policies and procedures for effective controls against theft and diversion of all stocked inventory, unauthorized access, substance waste, and returns. The board may deny, suspend, revoke, or refuse to renew any registration based upon the following: fraud or deception in connection with securing the registration; habitual indulgence in the use of narcotics, stimulants, or depressant drugs or habitual indulgence in intoxicating liquors in a manner which could cause conduct endangering public health; unprofessional conduct or conduct endangering public health; gross immorality; conviction of theft of drugs or the unauthorized use, possession or sale thereof; and violation of the provisions of the rules of the board. [Minn. R 6800.4400]

Summary of factual data and analytical methodologies:

The Controlled Substances Board reviewed the chapter for statutory compliance and obsolete practices. The Controlled Substances Board also took into consideration obstacles encountered by individuals who apply and hold special use authorizations.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 3.02 (4) is amended to read:

CSB 3.02 (4) “Special use” means to manufacture, obtain, possess, use, administer, or dispense a controlled substance for purposes that include, ~~but are not limited to,~~ scientific research, instructional activities, chemical analysis, drug-detecting animal training, and euthanasia in humane shelters.

SECTION 2. CSB 3.03 (2) is amended to read:

CSB 3.03 (2) An SUA permit may be issued to an individual only. ~~Entities are not eligible to receive an SUA permit, except that an individual may be designated and authorized to receive the permit for a college or university department, research unit, or similar administrative organization unit. Students, laboratory technicians, research specialists, or chemical analysts under the designee’s supervision may possess and use the substances named in the designee’s permit for the authorized purposes without obtaining an individual permit.~~

SECTION 3. CSB 3.03 (2m) is created to read:

CSB 3.03 (2m) A SUA permit may be issued to an individual who is designated and authorized to receive a SUA permit for a college or university department, research unit, or similar administrative organizational unit. Students, laboratory technicians, research specialists, or chemical analysts under the individual’s supervision, may, without obtaining a SUA permit, possess and use a controlled substance, for the purposes authorized in the permit received for the department or unit.

SECTION 4. CSB 3.04 (1) (a), (a) (note), (b) (c), and (d) are amended to read:

CSB 3.04 (1) (a) Submit a completed application ~~and any required checklists using forms provided by the board.~~ A complete application shall include a detailed description of the anticipated uses for each identified controlled substance in Schedules I to V of ch. 961, Stats., including each identified controlled substance by name and schedule and the protocols for such uses.

Note: Application forms ~~and checklists~~ are available ~~upon request to the board office at 1400 E. Washington Ave. on the department’s website at dsps.wi.gov, or by request from the Department of Safety and Professional Services, P.O. Box 8935, Madison, Wisconsin 53708, or online at <http://dsps.wi.gov>, under “Professions”, then “Controlled Substance Special Use Authorization.” by calling (608) 266-2112.~~

(b) Pay the applicable permit fee of \$25 ~~as set forth in s. 961.335, Stats.~~ No fee for an SUA permit may be charged to an employee of a state agency or institution if the permit is necessary to perform employment functions.

(c) Provide ~~proof~~ an affidavit which states that the applicant ~~has submitted~~ intends to file an application for registration with the federal drug enforcement administration.

(d) Provide ~~proof of the applicant's compliance with the board's requirements~~ a plan for maintaining the physical security of the controlled substances identified in the application.

SECTION 5. CSB 3.04 (3) (intro.), (a) and (b), (4) (a) (intro.), and (5) (a) (intro.) are amended to read:

CSB 3.04 (3) In addition to sub. (1), individuals providing euthanasia at humane shelters shall also provide all of the following:

(a) Estimates as to the number of animals to be euthanized during the 1 year the SUA permit is in effect and dosage per animal.

(b) Documentation of the individual's completion of a board-approved euthanasia by injection course ~~by each staff member performing euthanasia.~~

~~(4) (a) Unless other documentation is required by the board,~~ A letter from the sheriff or chief of police, in the jurisdiction where the controlled substances are stored, that includes all of the following for dog training purposes:

~~(5) (a) Unless other documentation is required by the board,~~ A letter from the sheriff or chief of police, in the jurisdiction where the controlled substances are stored, that includes all of the following for euthanasia purposes:

SECTION 6. CSB 3.04 (7) is renumbered to CSB 3.04 (1) (g) and amended to read:

CSB 3.04 (1) (g) The ~~Appear before the board may request an appearance before the board if requested by the board~~ additional information is required.

SECTION 7. CSB 3.042 is created to read:

CSB 3.042 Storage. (1) Individuals holding a SUA permit shall store controlled substances in a safe or steel cabinet or box that meets all of the following requirements:

(a) Bolted or cemented to the floor or wall in such a way that it cannot be readily removed if the safe or steel cabinet or box weighs less than 750 pounds.

(b) Is able to withstand attempts at forced entry by individuals using common tools for a period of 10 minutes or lock manipulation for 20 hours. Fire resistance is not required.

(c) Is housed in a room which is locked during non-use hours.

(2) Notwithstanding sub. (1), a central safe used for other security purposes may be used if the controlled substances are locked in metal boxes sufficient to prevent casual access by others authorized to use the safe. Other secure storage areas may be approved by the board if the manner in which the controlled substances are stored will protect the controlled substances from theft and unauthorized use.

(3) Controlled substances shall be kept locked except when they are in active use by the authorized individual or under the supervision of an authorized individual under s. CSB 3.03 (2m).

SECTION 8. CSB 3.045 (intro.) is amended to read:

CSB 3.045. Limited special use authorization. The board may grant a limited SUA permit or deny a SUA permit based upon consideration of public health and safety including any of the following reasons:

SECTION 9. CSB 3.06 (1) (intro.), (a), and (b), (2) and (3) are amended to read:

CSB 3.06 Amendment. (1) A SUA permit shall be effective only for the individual, substances, and project specified on its face and for additional projects which derive directly from the state project. An individual holding a valid SUA permit may apply for an amendment to the permit by filing a written request with the board indicating the justification for the amendment and by paying a \$5 fee. The board may approve a request to amend a permit for any of the following reasons:

(a) A change to the original SUA permit holder.

(b) The addition of new individuals to the SUA permit who are participating in the functions for which the authorization was approved.

(2) An application for an amendment shall be submitted to the department and approved by the board prior to a SUA permit holder operating under the terms of the amendment.

(3) Individuals applying for an amendment shall provide any other information or documentation requested by the board including information and documentation related to previous ~~special use authorization~~ SUA permits.

SECTION 10. CSB 3.07 (1) (intro.), (a), and (b), (2) and (3) are amended to read:

CSB 3.07 Record-keeping; records retention; disclosure. (1) A SUA permit holder shall maintain updated and accurate records of all of the following:

(a) The purchase of controlled substances pursuant to the SUA permit, including receipts.

(b) The disbursement, use, and disposition of all controlled substances authorized by the SUA permit.

(2) A SUA permit holder shall retain the records described in sub. (1) for 4 years after the expiration of the ~~special use authorization~~ SUA permit.

(3) A SUA permit holder shall provide copies of the original records upon request of the board or the department of safety and professional services, except for those that are protected from disclosure by s. 961.335(7), Stats.

SECTION 11. CSB 3.08 (1) (a) and (2) are amended to read:

CSB 3.08 (1) (a) Any deviation from the SUA permit's specifications related to controlled substances, schedules of drugs, or amounts authorized.

(2) Any violation of a special use authorization permit may, in the board's discretion, result in the suspension or revocation of the ~~special use authorization~~ SUA permit.

SECTION 12. CSB 3.08 (1) (f) and (g) are created to read:

CSB 3.08 (1) (f) Failure to obtain a drug enforcement administration registration.

(g) A violation of state or federal law relating to controlled substances.

SECTION 13. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Dated July 10, 2020

Agency



Chair

Controlled Substances Board