

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 12-010)

PROPOSED ORDER

An order of the controlled substances board to create ch. CSB 3, relating to the requirements and procedures for granting special use authorizations.

Analysis prepared by the department of safety and professional services.

ANALYSIS

Statutes interpreted:

Section 961.335, Stats.

Statutory authority:

Sections 227.11 (2), 961.335 (8), Stats.

Explanation of agency authority:

Section 227.11 (2), Stats., permits an agency to promulgate rules interpreting the provisions of any statute enforced or administered by the agency if the agency deems such rules necessary to effectuate the purposes of the statute. Section 961.335 (8), Stats., expressly authorizes the Wisconsin controlled substances board to promulgate rules relating to the board's issuance of special use authorization permits (SUAs), including rules regarding the criteria and procedures for obtaining SUAs, records retention and disclosure requirements for permit holders, submissions of protocols, and suspension or revocation of SUAs.

Related statute or rule:

Sections 961.41, 961.42, and 941.43, Stats., establish Wisconsin's proscriptions against the unlawful manufacture, distribution, dispensing, delivery, or possession of any controlled substance. Section 961.335, Stats., provides for certain exceptions to those proscriptions. A search of Wisconsin's statutes and administrative code revealed only one reference to s. 961.335, Stats., the SUA statute, in s. 961.54 (3), Stats. Such reference is not related to the issuance of SUAs.

Plain language analysis:

The proposed administrative code chapter will set forth rules for the issuance of SUAs by the controlled substances board. These rules will include definitions of terms used in the chapter; general requirements for SUAs; procedures and criteria for obtaining an initial permit and an amendment to an initial permit; limitations on drugs and drug quantities for use in training narcotics dogs; requirements for recordkeeping, records retention, and disclosure of records related to SUAs; and acts constituting violations of an SUA permit.

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

The federal laws describing the requirements for manufacturers, distributors, and dispensers of controlled substances, Schedules I-V, are found at 21 U.S.C. ss. 821-830 (2010). All persons manufacturing, distributing, dispensing, or possessing for any purpose other than prescribed medical treatment, must obtain federal registration to do so. *Id.* The application requirements and procedures are set forth in the Code of the Federal Register at 21 C.F.R., Part 1301. There are 10 different categories of business activities, each of which requires separate registration: manufacturing; distributing; reverse distributing; dispensing or instructing; research – Sched. I; research – Sched.’s II-V; narcotic treatment program; importing; exporting; and chemical analysis. 21 C.F.R. s. 1301.13 (2011). Those regulations comprise the federal equivalent of the “special use authorizations” referred to in the new administrative rules proposed herein.

Comparison with rules in adjacent states:**Illinois:**

Statutes: Under the Illinois Controlled Substances Act, all persons who manufacture, distribute, or dispense any controlled substance, or engage in chemical analysis or instructional activities using controlled substances, or who purchases, stores, or administers euthanasia drugs must obtain a registration issued by the Illinois Department of Financial and Professional Regulation. The Act requires the department to promulgate rules administering the registration function. 720 Ill. Comp. Stat. 570/301 (2012). Registered persons may possess, manufacture, distribute, or dispense controlled substances, or administer euthanasia drugs to the extent authorized by their registration and in conformity with the other provisions of the Act. Registration is site-specific, so persons operating at more than one site must have separate registration for each. 720 Ill. Comp. Stat. 570/302 (a), (b), and (d) (2012). The department may deny, refuse to renew, suspend, or revoke a registration upon finding that the applicant or registrant has provided false information on an application, had his or her federal controlled substances registration suspended or revoked, been convicted of certain crimes, failed to take effective preventative measures against diversion, or violated any provision of the Illinois Controlled Substances Act or the Methamphetamine Precursor Control Act, or any of the rules promulgated under those Acts. 720 Ill. Comp. Stat. 570/304 (a) and (b) (2012).

<http://www.ilga.gov/legislation/ilcs/ilcs4.asp?DocName=072005700HArt%2E+III&ActID=1941&ChapterID=53&SeqStart=2600000&SeqEnd=5000000>.

Administrative rules: The Illinois Administrative Code sets forth rules promulgated by the Department of Financial and Professional Regulation for implementing the provisions of the Controlled Substances Act. Ill. Admin. Code tit. 77, ss. 3100.10 – 3100.530 (2004). Among other things, these rules require separate registrations for any of six different types of controlled substances activities deemed independent of each other. The independent-activities rule also describes several exceptions thereto. For instance, the first two of the different types of activities are 1) manufacturing controlled substances, and 2) distributing controlled substances. However, persons registered to manufacture a basic class of controlled substances, or one substance in particular, may distribute the same without a separate distribution registration. Ill. Admin. Code tit. 77, s. 3100.50 (a) and (b) (2004). Other rules provide instructions for registration applicants, and authorize the department to deny, limit, suspend, or revoke any registration upon finding the registrant in violation of any of the statutes or rules regarding controlled substances. Ill. Admin. Code tit. 77, s. 3100.160 (a) (2004).

<http://www.ilga.gov/commission/jcar/admincode/077/07703100sections.html>.

Comparison of approaches: The Illinois laws regarding registration for use of controlled substances do not address “special uses” in a separate, or stand-alone, section as Wisconsin law does. Similar to Wisconsin though, the Illinois Controlled Substances Act includes a registration requirement, and charges a state agency with the administration of that requirement. The Illinois statutes and rules also contain provisions for certain non-medicinal-related uses that are substantially similar to the provisions of Wisconsin’s special use authorization law, s. 961.335, Stats. One exception to the similarity is that, unlike the proposed Wisconsin rules, Illinois law does not specifically reference narcotic dog trainers in either its Controlled Substances Act or administrative code.

While Illinois’s approach to controlled substances user registration differs in part from the approach taken by the Wisconsin controlled substances board’s proposed rules, the fundamental policy of regulating uses of controlled substances not related to medical treatment is the same. Unlike Wisconsin’s controlled substances law, the Illinois law is silent regarding the use of controlled substances for training narcotic dogs. That silence may cause confusion for persons using controlled substances for that purpose. Wisconsin’s special use authorization statute provides for uses not specified in the statute by permitting the controlled substances board to approve “other special uses, without restriction because of enumeration” under s. 961.335 (1), Stats. Accordingly, in addition to the special uses the Wisconsin statute does specify, the controlled substances board’s proposed rules address other “special,” but well-known purposes, such as euthanasia at humane shelters or under municipal animal control laws, and the training of narcotic dogs. The controlled substances board believes increased clarity will result in less confusion for both permit applicants and administrators.

Iowa:

Statutes: The Iowa statutes require that all persons who manufacture, distribute, or dispense any controlled substance, or who propose to engage in the manufacture, distribution, or dispensing of any controlled substance, obtain and maintain a biennial registration from the Iowa Board of Pharmacy. 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. Iowa Code s. 124.302 1., 2., and 4. (2009). The pharmacy board may suspend, revoke, or restrict a registration to manufacture, distribute, or dispense a controlled substance upon certain findings, including that the registrant has committed such acts as would render the registrant's registration inconsistent with the public interest. Iowa Code s. 124.304 1. d. (2009). <http://www.state.ia.us/ibpe/pdf/IC124.pdf>

Administrative rules: Iowa's administrative code contains rules implementing the statutes regarding the use of controlled substances. The rules establish further specifications of who or what entities must register, and seven different types of activities, each of which requires separate registration. In addition, the rules include application instructions and procedures; specific requirements for the approved uses of controlled substances; descriptions of, and requirements for separate registrations of separate sites; requirements and procedures for modifying or terminating a current registration based on several different types of changes; and registration enforcement provisions. Beyond requiring "[m]anufacturers, distributors, reverse distributors, importers and exporters," of controlled substances to register, the list of persons and entities that must register includes all individual medical practitioners, pharmacies, hospitals, animal shelters, care facilities, researchers, dog trainers, analytical laboratories, and teaching institutions. Iowa Admin. Code r. 657-10.1 to .12. <http://www.legis.state.ia.us/asp/ACODocs/ruleList.aspx?agency=657&chapter=10>

Comparison of approaches: Like Illinois, and unlike Wisconsin, Iowa takes an approach to registration for controlled substances use that does not treat non-medicinal-related uses separately. Nevertheless, Iowa's controlled substances laws do require registration of persons using controlled substances for non-medicinal-related purposes, and charges a state agency with administering that requirement. Iowa sets forth comprehensive registration provisions in its administrative rules that are substantially similar to Wisconsin's special use authorization statute. In addition, the scope of Iowa's rules is more consistent with the Wisconsin board's proposed rules than not. Thus, Iowa's approach to administering its "special use" laws is essentially the same as the approach the Wisconsin controlled substances board contemplates in the instant rule-making proposal.

Michigan

Statutes: Michigan's controlled substances law is set forth in that state's public health code, 1978 Mich. Pub. Acts 368 page no. 7. The statutes require any person who manufactures, distributes, prescribes, or dispenses a controlled substance in Michigan to obtain a license for such purposes issued by the Michigan Board of Pharmacy or its Administrator. Mich. Comp. Laws s. 333.7303 (2009). The administrator is authorized to promulgate rules for controlled substances licensure and the enforcement thereof. Mich. Comp. Laws s. 333.7301 (2009). License holders may possess, manufacture, distribute, prescribe, dispense, or conduct research with the specified controlled substances to the extent authorized only, and as is consistent with all other provisions of the public health code. Licenses apply to specific sites, so persons operating at more than one site must have separate registrations for each. Persons licensed as pharmacists must also obtain a separate controlled substances license. Mich. Comp. Laws s. 333.7303 (1), (2), and (5) (2009). Under section 333.7311(1), the pharmacy board's disciplinary subcommittee may deny, limit, suspend, or revoke a license, or fine or reprimand a licensee, or

order the licensee to perform community service or make restitution upon certain specified findings, if the applicant or licensee has violated the statutory provisions enumerated under subsections (a) through (h). Mich. Comp. Laws s. 333.7311 (1) (a) – (h) (2009). The statutes require licensees to keep records of, and to annually inventory all stocked Schedule II-V controlled substances. Licensees must report their annual inventory to the Administrator. Mich. Comp. Laws s. 333.7321 (2) (2009).

[http://www.legislature.mi.gov/\(S\(ahsfmdrwjmid5rop1e5useu\)\)/mileg.aspx?page=getObject&objectName=mcl-368-1978-7-73](http://www.legislature.mi.gov/(S(ahsfmdrwjmid5rop1e5useu))/mileg.aspx?page=getObject&objectName=mcl-368-1978-7-73)

Administrative rules: Michigan's administrative code specifies the particular type of activities a controlled substances license authorizes. There are six types of activities, and persons engaging in more than one type must obtain separate licenses for each. The list of activity types briefly describes the permissible practices under each license. Mich. Admin. Code r. 338.3132 (1) (2011). Other rules include provisions regarding the use of controlled substances for animal euthanasia, theft and diversion of controlled substances, storage, record-keeping obligations, and exceptions to the licensure requirement. Mich. Admin. Code r. 338.3137 to .3143, and .3151 to .3153 (2011).

http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin_Num=33803101&Dpt=&RngHigh=33923405

Comparison of approaches: Similar to the controlled substances laws of Illinois, Iowa, and Wisconsin, Michigan's laws require that any person who uses controlled substances for purposes not related to medical treatment must obtain a license for such purposes from a state agency, in Michigan's case, the Michigan Board of Pharmacy. Unlike Illinois, Iowa, and Wisconsin, Michigan law compels licensed pharmacists to hold a separate license for the use of controlled substances within the scope of their practice. Moreover, Michigan's controlled substances statutes are far more comprehensive with respect to the licensing requirement than the Wisconsin special use authorization statute. The Michigan statutes contain many of the provisions that the Wisconsin controlled substances board proposes to codify as administrative rules. Michigan's approach to regulating controlled substances use thus differs significantly from Wisconsin's, and may ultimately be more onerous to its pharmacists than Wisconsin's approach.

Error! Hyperlink reference not valid.Minnesota:

Statutes: Chapter 151 of the Minnesota statutes authorizes the Minnesota Board of Pharmacy to regulate the practice of pharmacy, the manufacture, wholesale, and retail sale of drugs within that state, and to license wholesale drug distributors. The pharmacy board is also charged with administering chapter 152 of the Minnesota statutes, which pertains to the scheduling and regulation of controlled substances. Minn. Stat. s. 152.02 (2011). Pursuant to Minnesota Statutes 2011, section 151.06, subdivisions 1. (a) (1), (2), (6), (7), and (10)(c), the board must promulgate uniform rules for carrying out and enforcing the governing statutes. The statutes require the board to register, on an annual basis, every person engaged in manufacturing drugs, medicines, chemicals, or poisons for medicinal purposes. Minn. Stat. s. 151.25 (2011). The Minnesota pharmacy and controlled substances statutes do not specifically address uses that are not directly or indirectly related to medical treatment of patients. Pursuant to Minnesota Statutes 2011, section 151.06, subdivision 1. (7), the pharmacy board may deny, suspend, revoke, or refuse to renew any required registration or license on grounds such as fraud or deception in

securing a registration or license, unprofessional conduct or conduct endangering public health, and gross immorality. <https://www.revisor.mn.gov/statutes/?id=151>

Administrative rules: Chapter 6800 of the Minnesota administrative code pertains to the state's board of pharmacy and its oversight of pharmacists and pharmacies. The code provides for four general types of licenses: pharmacists, pharmacies, drug manufacturers and wholesalers, and controlled substances researchers. Any person engaging in research, teaching, or educational projects involving the use of controlled substances must obtain registration for these uses, renewable annually, from the board. Minn. R. 6800.4400 (2011). 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. Further, registrants must maintain adequate records showing purchases and purchase receipts, use, transfer, and disposal of the controlled substances specified in the registration. To track the effectiveness of the required controls, registrants must inventory stocked controlled substances annually. *Id.* Disciplinary proceedings against any pharmacy board licensee or registrant are governed by Minn. R. 6800.9100 to .9700 (2011). <https://www.revisor.mn.gov/rules/?id=6800>

Comparison of approaches: By administrative rule, Minnesota registers persons using controlled substances for research or instructional purposes separately from pharmacists and pharmacies. Minnesota's approach to regulating non-medicinal-related uses is, in that sense, similar to Wisconsin's. However, unlike Wisconsin, neither Minnesota's pharmacy or controlled substances statutes, nor its administrative rules address the use of controlled substances in humane shelters or for training narcotic dogs. Moreover, the law regarding research or educational use of controlled substances appears only in Minnesota's administrative code, and not in its statutes. The administrative rule specific to such uses references only persons involved in research or teaching. Finally, the enforcement procedures applicable to alternative use registration are subsumed within the pharmacy board's general enforcement authority, rather than set forth within the context of research or teaching use registration.

Minnesota's rules on controlled substances licensure thus appear to provide very little guidance to persons involved in research or teaching activities. For instance, there are no rules establishing the precise requirements and procedures for application registrants or for record-keeping, and none defining violations warranting disciplinary action. The absence of such written requirements and procedures would seem to promote a lack of clarity, and generate numerous inquiries from applicants and current registrants. Inadequate clarity with respect to registration requirements and procedures could also permit more challenges to board decisions on registration issues than may otherwise occur. The rules proposed by the Wisconsin controlled substances board would serve to avoid such potentialities, and in doing so, conserve scarce state resources.

Summary of factual data and analytical methodologies:

These proposed rules are for the purpose of clarifying the requirements and procedures regarding SUA permits for both applicants and the controlled substances board, and to establish procedures for the enforcement of an SUAs terms when violations occur. Under s. 961.335 (8), Stats., the board "may promulgate rules relating to the granting of special use permits...and suspension or

revocation of permits.” Pursuant to s. 227.23, Stats., following the enactment of s. 961.335, Stats., the board created various forms outlining SUA requirements and procedures. However, the controlled substances board currently has no clear rules covering the enforcement aspect of its authority under s. 961.335, Stats. Thus, these proposed rules will not only more clearly delineate the statutory requirements and the administrative procedures for obtaining and amending an SUA, it will also define those actions or the lack thereof that will result in permit suspension or revocation. As these new rules are necessary for both of such purposes, the board had no need to review empirical factual data, nor did it require the use of analytical methodologies in the drafting of this proposal.

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

The rules proposed herein were posted on both the state’s and the department’s administrative rules websites for 14 days to solicit comments regarding the rule’s potential economic impact on businesses, business sectors, professional associations, local government units, or potentially interested parties. In addition, e-mails solicitations were sent to several potentially interested parties. No responses to any of the solicitations were received.

Moreover, this proposal constitutes the first implementation of s. 961.335, Stats., the special permit authorization statute, by the Controlled Substances Board. Because the statutory requirements have been in place for several years, any economic or fiscal impact experienced by private businesses or public entities that may have resulted from the enactment of s. 961.335, Stats., has already been absorbed by such entities as a part of routine operations.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis are attached.

Effect on small business:

The department concludes that the proposed rules will have no economic impact on small businesses. This proposal tracks legislation that has been in effect for several years. The department’s Regulatory Review Coordinator may be contacted by email at Greg.Gasper@Wisconsin.gov, or by calling 608-266-8608.

Agency contact person:

Kris Anderson, Department of Safety and Professional Services, Division of Board Services, 1400 E. Washington Ave., Room 116, P.O. Box 8935, Madison, Wisconsin 53708; telephone: 608-261-2385; e-mail: KristineI.Anderson@Wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Kris Anderson, Department of Safety and Professional Services, Division of Board Services, 1400 E. Washington Ave., Room 151, P.O. Box 8935, Madison,

Wisconsin 53708-8935, or by e-mail: Kristine1.Anderson@Wisconsin.gov. Comments must be received by the date and time of the public hearing on this proposal to be included in the record of rule-making proceedings.

(TEXT OF RULE)

SECTION 1. Chapter CSB 3 is created to read:

CHAPTER CSB 3

SPECIAL USE AUTHORIZATION

CSB 3.01 Authority. The provisions in this chapter are adopted under the authority in s. 961.335 (8), Stats.

CSB 3.02 Definitions. In this chapter:

(1) “Board” means the controlled substances board.

(2) “Controlled substance” has the meaning given in s. 961.01 (4), Stats.

(3) “Humane shelter” means a facility that is intended to provide for and promote the welfare, protection, shelter, and humane treatment of animals, and that is operated by a humane society, animal welfare society, animal rescue group or other non-profit group. “Humane shelter” includes a shelter that provides foster care to animals.

(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.

(5) “Special use authorization” or “SUA” means permission from the board to manufacture, obtain, possess, use, administer, or dispense a controlled substance for a special use.

(6) “SUA permit” means a special use authorization permit granted to an individual by the board.

CSB 3.03 Permits generally.

(1) No individual may manufacture, obtain, possess, use, administer, or dispense a controlled substance for a special use without a valid SUA permit for such purpose.

(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.

(3) An SUA permit authorizes the holder to manufacture, obtain, possess, use, administer, or dispense the controlled substances specified in the permit and in the amounts specified in the permit. A permit holder shall use the authorized controlled substances only in the manner delineated in the SUA permit application, and as approved by the board. Any deviation from the permit's specifications and subsequent amendments shall constitute a violation of the permit and may result in revocation or suspension of the permit as set forth in s. CSB 3.08 (2).

(4) An SUA permit is valid for one year from the date of issuance. An SUA permit shall not be extended or renewed. A new application shall be completed and a new permit shall be granted to continue authorization beyond an existing permit's expiration date.

CSB 3.04 SUA permit application. (1) Every applicant for an SUA permit shall:

(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 - 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., P.O. Box 8935, Madison, Wisconsin 53708, or online at <http://dsps.wi.gov>, under "Professions," then "Controlled Substance Special Use Authorization."

(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 that the applicant has submitted an application for registration with the federal drug enforcement administration.

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

(e) Provide the calculations that led to the amounts requested in the application.

(f) Any individual applying for an SUA permit shall provide any other information or documentation requested by the board.

(2) In addition to sub. (1), researchers shall also provide the following:

(a) A detailed one-page description of each research protocol that involves the use of controlled substances.

(b) For research involving animals, verification of Institutional Animal Care and Use Committee approval.

(c) For research involving human subjects, verification of Institutional Review Board approval.

(3) In addition to sub. (1), humane shelters shall also provide all of the following:

(a) Estimates as to the number of animals and dosage per animal.

(b) Documentation of completion of a board approved euthanasia by injection course by each staff member performing euthanasia.

(4) In addition to sub. (1), narcotic dog trainers shall also provide the following:

(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:

1. Authorizing possession of controlled substances.
2. Accepting responsibility for the narcotic dog trainer.
3. Agreeing to supervise the narcotic dog trainer's storage and use of controlled substances.

(b) Verification of membership in a board approved national or Wisconsin police dog association for each narcotic dog trainer.

(c) For private narcotic dog trainers, an appearance before the board shall be required.

(5) In addition to sub. (1), municipal law enforcement animal control shall also provide all of the following:

(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:

1. Authorizing possession of controlled substances.
2. Accepting responsibility for the animal control officer.
3. Agreeing to supervise the animal control officer's storage and use of controlled substances.

(b) Documentation of completion of a board approved euthanasia course by the officer performing euthanasia.

(6) In addition to sub. (1), analytical labs shall also provide all of the following:

(a) An inventory listing the total weight in grams of each controlled substance in the lab or intended for purchase for the lab.

(b) Whenever the lab purchases or otherwise adds to its inventory a new controlled substance or an additional amount of a controlled substance that was not previously authorized in a permit, an amended SUA application that includes the total weight in grams for each such new or additional substance.

(c) A detailed description of standard operating procedures relating to the use of controlled substances that includes the receipt, use, and disposition of controlled substances.

(7) The board may request an appearance before the board if additional information is required.

CSB 3.05 Limitations on narcotic dog trainer drugs and drug quantities.

(1) Narcotic dog trainers shall be limited to having possession of the following drugs and quantities at any given time during the permit period:

(a) Up to 2 kilograms of marijuana. Marijuana may require periodic replacement during the permit period. Total use per year, taking into account replacement, shall be requested.

(b) Up to 30 grams of cocaine.

(c) Up to 30 grams of cocaine base, commonly known as crack cocaine.

(d) Up to 30 grams of heroin.

(e) Up to 30 grams of methamphetamine.

(2) A trainer may request, and the board may approve, with appropriate justification by the trainer, other controlled substances or different quantities of controlled substances.

CSB 3.06 Amendment. (1) A permit shall be effective only for the individual, substances and project specified on its face and for additional projects which derive directly from the stated 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 permit-holder.

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

- (c) An increase in the amount of a previously authorized controlled substance.
- (d) The addition of specific controlled substances or schedules not previously authorized.
- (e) The addition of further activity in accordance with s. 961.335(5), Stats.

(2) An application for an amendment shall be submitted to the department and approved by the board prior to a 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 permits.

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

- (a) The purchase of controlled substances pursuant to the permit, including receipts.
- (b) The disbursement, use, and disposition of all controlled substances authorized by the permit.
- (c) The total weight in grams of each controlled substance on hand.
- (d) Documentation related to any discrepancies in a controlled substance inventory and usage, and all documentation related to investigation of such discrepancies.

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

(3) A 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.

CSB 3.08 Violations. (1) The following acts shall constitute a violation of an SUA permit:

- (a) Any deviation from the permit's specifications related to controlled substances, schedules of drugs, or amounts authorized.
- (b) Failure to comply with this chapter or s. 961.335, Stats.
- (c) Failure to maintain physical security requirements for controlled substances as required by state and federal law.
- (d) Failure to comply with board approved euthanasia standards.

Note: The Board considers the most current version of the euthanasia standards as stated in the American Veterinary Medical Association (AVMA) panel on euthanasia available at <http://www.avma.org>.

(e) Failure to notify the board of the revocation or limitation of a drug enforcement administration registration, within 3 business days of the revocation or limitation.

(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 permit.

SECTION 2. 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 _____

Agency _____

Chairperson
Controlled Substances Board

CSB 3 (Special use authorizations) Legislative Draft 3/12/12