

Clearinghouse Rule 14-009

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)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 3.045 relating to granting a limited special use authorization and denial of a special use authorization.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: § 961.335, Wis. Stats.

Statutory authority: § 961.335(8), Wis. 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.

Related statute or rule: § 961.335, Wis. Stats. and ch. CSB 3, Wis. Admin. Rule

Plain language analysis:

The proposed rule states the basis for denying or limiting a special use authorization which is based upon consideration of public health and safety. It includes consideration of the following: an act which causes a violation which would result in suspension or revocation under current rules; making false statements on an application; violating federal or state statutes related to have the ability to have controlled substances special use and an act which shows the person would be unable to safely use the SUA due to alcohol or other substance use.

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

Federal regulations requires any person who possesses, manufactures, distributes or dispenses any controlled substances to register with the U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control.

The proposed rule included the criteria used by the federal government in granting/denying a DEA registration because once the special use authorization permit is granted, the person would also need DEA registration.

Comparison with rules in adjacent states:

Illinois: In Illinois 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: provided false or fraudulent material information in any application; has been convicted of a felon 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.

Iowa: In Iowa, a registration to manufacture, distribute, dispense, prescribe, import or export, conduct research or instructional activities or conducts chemical analysis with controlled substances in Iowa 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.

Michigan: Michigan has 7 different licenses for controlled substances based upon the purpose of the applicant. 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.

Minnesota: In Minnesota, a person who engages in research, teaching or educational projects involving the use, study or testing of controlled substances is required to apply for a registration permit. 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; violation of the provisions of the rules of the board;

Summary of factual data and analytical methodologies:

The proposed rule states the basis for denying or limiting a special use authorization which is based upon consideration of public health and safety.

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

This rule was posted for economic impact comments for a period of 14 days and none were received.

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 Tom.Engels@wisconsin.gov, or by calling (608) 266-8608.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at Sharon.Henes@wisconsin.gov.

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

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8935, or by email to Sharon.Henes@wisconsin.gov. Comments must be received at or before the public hearing to be held on March 4, 2014 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 3.045 is created to read:

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

- (1) An act constituting a violation under CSB 3.08(1).
- (2) Making any materially false statement or giving any materially false information in connection with an application for a special use authorization.
- (3) Violating any federal or state statute or rule which substantially relates to the ability to manufacture, obtain, possess, use, administer, or dispense a controlled substance for a special use.
- (4) An act which shows the person to be unable to safely use the SUA permit due to alcohol or other substance use.

SECTION 2. 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 _____

Agency _____

Member of the Board
Controlled Substances Board