



**CONTROLLED SUBSTANCES BOARD
TELECONFERENCE
Contact: Dan Williams (608) 266-2112
Room 121A, 1400 East Washington Avenue, Madison
JUNE 16, 2014**

The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a description of the actions and deliberations of the Board.

AGENDA

11:30 A.M.

OPEN SESSION - CALL TO ORDER – ROLL CALL

- A. **Approval of Agenda (1)**
- B. **Adoption of CR 14-009 Amending CSB 3 Relating to Special Use Authorizations (2-7)**

ADJOURNMENT

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING : ORDER OF THE
PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD : ADOPTING RULES
: CLEARINGHOUSE RULE 14-009

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. Code.

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 the ability to have a 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 require 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 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.

Iowa: In Iowa, 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.

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; and 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 Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone (608) 261-2377; email at Sharon.Henes@wisconsin.gov.

TEXT OF RULE

SECTION 1. CSB 3.045 is created to read:

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

- (1) An act constituting a violation under s. CSB 3.08(1).
- (2) Making any materially false statement or giving any materially false information in connection with an application for a SUA.
- (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
Board or Department

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis

Original Updated Corrected

2. Administrative Rule Chapter, Title and Number

CSB 3.045

3. Subject

Granting a limited special use authorization and denial of a special use authorization

4. Fund Sources Affected

GPR FED PRO PRS SEG SEG-S

5. Chapter 20, Stats. Appropriations Affected

20.165(1)(g)

6. Fiscal Effect of Implementing the Rule

No Fiscal Effect Increase Existing Revenues Increase Costs
 Indeterminate Decrease Existing Revenues Could Absorb Within Agency's Budget
 Decrease Cost

7. The Rule Will Impact the Following (Check All That Apply)

State's Economy Specific Businesses/Sectors
 Local Government Units Public Utility Rate Payers
 Small Businesses **(if checked, complete Attachment A)**

8. Would Implementation and Compliance Costs Be Greater Than \$20 million?

Yes No

9. Policy Problem Addressed by the Rule

The current rules do not provide a basis for which the controlled substances board may exercise its discretion and deny a person a special use authorization or grant a limited special use authorization.

10. Summary of the businesses, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule that were contacted for comments.

This rule was posted for economic comments for a period of 14 days and no comments were received.

11. Identify the local governmental units that participated in the development of this EIA.

None

12. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

None.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The benefit of implementing the rule is to give the applicant notice of the basis for which a denial or granting of a limited special use authorization may occur.

14. Long Range Implications of Implementing the Rule

The long range benefit is for applicants to have notice of the basis for which a denial or limited special use authorization may occur.

15. Compare With Approaches Being Used by Federal Government

The federal regulations require 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. A DEA registration may be denied for the following: providing false information on an application, conviction of a law relating to controlled substances, having a state license has been disciplined or has committed acts would render registration inconsistent with the public interest.

16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Illinois, Iowa, Michigan and Minnesota list reasons for a denial of a registration or license related to controlled

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

substances similar to Wisconsin's special use authorization permit.

17. Contact Name

Sharon Henes

18. Contact Phone Number

(608) 261-2377

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