

WISCONSIN LEGISLATIVE COUNCIL STAFF

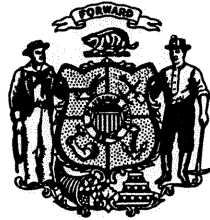


OCT 04 1999

RULES CLEARINGHOUSE

Ronald Sklansky
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(608) 266-1946

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CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE 99-125

AN ORDER to create CSB 2.25, relating to the scheduling of certain drugs under ch. 961, Stats., the uniform controlled substances act.

Submitted by **DEPARTMENT OF REGULATION AND LICENSING**

08-24-99 RECEIVED BY LEGISLATIVE COUNCIL.
09-22-99 REPORT SENT TO AGENCY.

RS:DD:jal;rv

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

Comment Attached YES NO

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

Comment Attached YES NO

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

Comment Attached YES NO

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS
[s. 227.15 (2) (e)]

Comment Attached YES NO

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

Comment Attached YES NO

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL
REGULATIONS [s. 227.15 (2) (g)]

Comment Attached YES NO

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

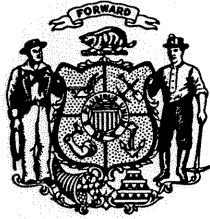
Comment Attached YES NO

WISCONSIN LEGISLATIVE COUNCIL STAFF

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CLEARINGHOUSE RULE 99-125

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Revisor of Statutes Bureau and the Legislative Council Staff, dated September 1998.]

2. Form, Style and Placement in Administrative Code

- a. The full statutory citation should precede the text of the treated statutory provision; e.g., "961.16 (3) (cm)" should precede "~~Carfentanal~~ Carfentanil;"
- b. The treatment of s. 961.16 (3) (cm), Stats., is not referred to in the title of s. CSB 2.25.
- c. In s. CSB 2.25 (3), the statute being repealed should be s. 961.16 (10) (a), Stats. (Emphasis added.)
- d. In s. CSB 2.25 (4m), "(61R-trans)" should be "(6aR-trans)," based on current s. 961.16 (10) (a), Stats..



State of Wisconsin \ DEPARTMENT OF REGULATION & LICENSING

Tommy G. Thompson
Governor

Marlene A. Cummings
Secretary

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August 24, 1999

TO: Ron Sklansky, Director
Rules Clearinghouse
Wisconsin Legislative Council
1 East Main Street, Suite 401

FROM: Pamela A. Haack, Paralegal
Office of Administrative Rules
Department of Regulation and Licensing
Room 171, 1400 East Washington Avenue
(608) 266-0495

RE: Proposed Rule-Making Order of the Controlled Substances Board

Attached please find a proposed rule-making order of the Controlled Substances Board submitted under s. 227.15, Wis. Stats. The proposed order contains citations to the statutory authority under which the board intends to adopt the proposed rules and a description of the effect of the proposal.

Please stamp or sign a copy of this letter to acknowledge receipt. Please call me at 266-0495 if I can be of any assistance to the Clearinghouse in reviewing this rule.

Thank you.

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 99-)

ORDER

An order of the Controlled Substances Board to *create* CSB 2.25, relating to the scheduling of certain drugs under chapter 961, Stats., the Uniform Controlled Substances Act.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes authorizing promulgation: ss. 961.11 (1) and (2), 961.15, 961.17 and 961.19, Stats.

Statutes interpreted: ss. 961.16, 961.18 and 961.20, Stats.

This proposed rule-making order of the Controlled Substances Board involves the scheduling of six drugs under chapter 961, Stats., the Uniform Controlled Substances Act (CSA). A review the federal controlled Substances Act (FCSA) indicates that the federal Drug Enforcement Administration (DEA) has scheduled five drugs under the FCSA that are not currently scheduled in this state. Also, the DEA has changed the scheduling of one drug resulting in its currently being federally classified differently than in this state.

✓ The proposed rule would add Remifentanyl to Schedule II of the CSA, add Fenproporex, Modafinil, Sibutramine and Zolpidem to Schedule IV, and transfer Dronabinol from Schedule II to Schedule III. It also corrects the spelling of the Schedule II drug, Carfentanyl.

Drugs that are classified as "controlled substances" under federal and state laws are subject to higher civil and criminal penalties for their illicit possession, distribution and use than other drugs that are not so classified. Health care providers are also subject to greater recordkeeping requirements respecting their obtaining, prescribing and dispensing of such drugs. This is due to the fact that certain drugs have a greater likelihood of abuse, addiction and adverse consequences to patient health if utilized inappropriately than do other drugs. The primary agency involved in investigating and evaluating drugs for their abuse and addictive potential is the FDA. In doing so, it utilizes several factors that are counterparts to those listed in s. 961.11 (1m), Stats., including scientific testing and public input in determining whether a drug should be subjected to higher recordkeeping and penalty provisions for controlled substances, and, if so, into which schedule the medication should be placed. The classifications of the drugs under this rule will bring this state's treatment of them into conformity with that accorded at the federal level.

TEXT OF RULE

SECTION 1. CSB 2.25 is created to read:

CSB 2.25 Addition of remifentanil to schedule II; transfer of dronabinol from schedule II to schedule III; addition of fenproporex, modafinil, sibutramine and zolpidem to schedule IV. (1) Section 961.16 (3) (cm), Stats., is amended to read:

961.16 (3) (cm) ~~Carfentanil~~ Carfentanil; *corrected name not mentioned in title*

(2) Section 961.16 (3) (xm), Stats., is created to read:

(xm) Remifentanil; *Schedule II*

Dronabinol ←

(3) Section 961.16 (1) (a), Stats., is repealed. *(10)*

(4) Section 961.18 (4m), Stats., is created to read:

(4m) HALLUCINOGENIC SUBSTANCES. ^a Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. food and drug administration approved drug product. (Other names for dronabinol are (6R-trans)-6a, 7, 8, 10a-tetrahydro-6, 6. 9-trimethyl-3-pentyl-6H-dibenzo(b, d)pyran-1-ol, and (-)-delta-9-(trans)-tetrahydrocannabinol.)

(5) Section 961.20 (2) (o), Stats., is created to read:

Sched. II

(o) Zolpidem. *care 2011 2011*

(6) Section 961.20 (2m) (at), (bu) and (f), Stats., is created to read:

Schedule II

(at) Fenproporex.

(bu) Modafinil.

(f) Sibutramine.

(END OF TEXT OF RULE)

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.

Dated _____ Agency _____
Chairperson
Controlled Substances Board

FISCAL EFFECT

1. The anticipated fiscal effect on the fiscal liability and revenues of any local unit of government of the proposed rule is: \$0.00.
2. The projected anticipated state fiscal effect during the current biennium of the proposed rule is: \$0.00.
3. The projected net annualized fiscal impact on state funds of the proposed rule is: \$0.00.

INITIAL REGULATORY FLEXIBILITY ANALYSIS

These proposed rules will be reviewed by the department through its Small Business Review Advisory Committee to determine whether there will be an economic impact on a substantial number of small businesses, as defined in s. 227.114 (1) (a), Stats.

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8/23/99

JAN 28 2000

**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 99-125)**

**TO: Senator Judy Robson, Senate Co-Chairperson
Joint Committee for the Review of Administrative Rules
Room 15 South, State Capitol
Madison, Wisconsin 53702**

PLEASE TAKE NOTICE that the CONTROLLED SUBSTANCES BOARD is submitting in final draft form rules relating to the scheduling of certain drugs under chapter 961, Stats., the Uniform Controlled Substances Act.

Please stamp or sign a copy of this letter to acknowledge receipt. If you have any questions concerning the final draft form or desire additional information, please contact Pamela Haack at 266-0495.



State of Wisconsin \ DEPARTMENT OF REGULATION & LICENSING

Tommy G. Thompson
Governor

Marlene A. Cummings
Secretary

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(608) 266-2112
FAX#: (608) 267-0644

Administrative Rules in Final Draft Form

Controlled Substances Board

Relating to: Scheduling Drugs

Rule: CSB 2.25

Clearinghouse Rule: No. 99-125

**STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD**

**IN THE MATTER OF RULE-MAKING : REPORT TO THE LEGISLATURE
PROCEEDINGS BEFORE THE : ON CLEARINGHOUSE RULE 99-125
CONTROLLED SUBSTANCES BOARD : (s. 227.19 (3), Stats.)**

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS:

No new or revised forms are required by these rules.

III. FISCAL ESTIMATES:

These rules will have no significant impact upon state or local units of government.

IV. STATEMENT EXPLAINING NEED:

This proposed rule-making order of the Controlled Substances Board involves the scheduling of six drugs under chapter 961, Stats., the Uniform Controlled Substances Act (CSA). A review the federal controlled Substances Act (FCSA) indicates that the federal Drug Enforcement Administration (DEA) has scheduled five drugs under the FCSA that are not currently scheduled in this state. Also, the DEA has changed the scheduling of one drug resulting in its currently being federally classified differently than in this state.

The proposed rule would add Remifentanyl to Schedule II of the CSA, add Fenproporex, Modafinil, Sibutramine and Zolpidem to Schedule IV, and transfer Dronabinol from Schedule II to Schedule III. It also corrects the spelling of the Schedule II drug, Carfentanil.

Drugs that are classified as "controlled substances" under federal and state laws are subject to higher civil and criminal penalties for their illicit possession, distribution and use than other drugs that are not so classified. Health care providers are also subject to greater recordkeeping requirements respecting their obtaining, prescribing and dispensing of such drugs. This is due to the fact that certain drugs have a greater likelihood of abuse, addiction and adverse consequences to patient health if utilized inappropriately than do other drugs. The primary agency involved in investigating and evaluating drugs for their abuse and addictive potential is the FDA. In doing so, it utilizes several factors that are counterparts to those listed in s. 961.11 (1m), Stats., including scientific testing and public input in determining whether a drug should be subjected to higher recordkeeping and penalty provisions for controlled substances, and, if so, into which schedule the

medication should be placed. The classifications of the drugs under this rule will bring this state's treatment of them into conformity with that accorded at the federal level.

V. NOTICE OF PUBLIC HEARING:

A public hearing was held on December 1, 1999. R. Martin Smith, Madison, representing the Department of Justice Crime Labs, appeared at the public hearing. There were no other appearances nor were any written comments received.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

All of the recommendations suggested in the Clearinghouse Report were accepted in whole.

VII. FINAL REGULATORY FLEXIBILITY ANALYSIS:

The rules will have no significant economic impact on small businesses, as defined in s. 227.114 (1) (a), Stats.

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 99-125)

ORDER

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Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

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TEXT OF RULE

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CSB 2.25 Addition of remifentanil to schedule II; transfer of dronabinol from schedule II to schedule III; addition of fenproporex, modafinil, sibutramine and zolpidem to schedule IV; spelling correction of carfentanil. (1) Section 961.16 (3) (cm), Stats. is amended to read:

Section 961.16 (3) (cm) ~~Carfentanil~~ Carfentanil;

(2) Section 961.16 (3) (xm), Stats., is created to read:

(xm) Remifentanil;

(3) Section 961.16 (10) (a), Stats., is repealed.

(4) Section 961.18 (4m), Stats., is created to read:

(4m) HALLUCINOGENIC SUBSTANCES. Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. food and drug administration approved drug product. (Other names for dronabinol are (6aR-trans)-6a, 7, 8, 10a-tetrahydro-6, 6. 9-trimethyl-3-pentyl-6H-dibenzo(b, d)pyran-1-ol, and (-)-delta-9-(trans)-tetrahydrocannabinol.)

(5) Section 961.20 (2) (o), Stats., is created to read:

(o) Zolpidem.

(6) Section 961.20 (2m) (at), (bu) and (f), Stats., is created to read:

(at) Fenproporex.

(bu) Modafinil.

(f) Sibutramine.

(END OF TEXT OF RULE)

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.

Dated _____

Agency _____

Chairperson
Controlled Substances Board

FISCAL EFFECT

1. The anticipated fiscal effect on the fiscal liability and revenues of any local unit of government of the proposed rule is: \$0.00.
2. The projected anticipated state fiscal effect during the current biennium of the proposed rule is: \$0.00.
3. The projected net annualized fiscal impact on state funds of the proposed rule is: \$0.00.

FINAL REGULATORY FLEXIBILITY ANALYSIS

These rules will have no significant economic impact on small businesses, as defined in s. 227.114 (1) (a), Stats.

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1/28/2000