

AUG 17 2001

**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 01-071**

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 Dihydroetorphine under ch. 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
CONTROLLED SUBSTANCES BOARD**

**IN THE MATTER OF RULE-MAKING : REPORT TO THE LEGISLATURE
PROCEEDINGS BEFORE THE : ON CLEARINGHOUSE RULE 01-071
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:

By final rule of the Drug Enforcement Administration (DEA), adopted effective November 17, 2000, Dihydroetorphine was classified as a schedule II controlled substance under the federal Controlled Substances Act (CSA). Dihydroetorphine has not been so scheduled under the Wisconsin Controlled Substances Act in Chapter 961, Stats. The objective of the rule is to bring the treatment of the drug into conformity with that at the federal level.

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. Health care providers are also subject to greater record keeping 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 DEA administers the CSA. In doing so, it is empowered to schedule a drug as a controlled substance. International control of Dihydroetorphine in Schedule I of the Single Convention on Narcotic Drugs, 1961 in 1998, forms the basis for the DEA action. Dihydroetorphine is a derivative of thebaine, a natural constituent of opium and thus a controlled substance under 21 U.S.C. 812 and 21 CFR Part 1308.12 (b) (1) (16).

V. NOTICE OF PUBLIC HEARING:

A public hearing was held on August 1, 2001. There were no appearances at the public hearing nor were any written comments received.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 2.d. In the next to last sentence of the second paragraph of the department's analysis, is the reference to "1961 in 1998" accurate:

Response: Yes.

The remaining 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.

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8/10/01

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PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 01-071)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.26, relating to the scheduling of Dihydroetorphine under ch. 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) and 961.15, Stats.

Statutes interpreted: s. 961.16, Stats.

By final rule of the Drug Enforcement Administration (DEA), adopted effective November 17, 2000, Dihydroetorphine was classified as a schedule II controlled substance under the federal Controlled Substances Act (CSA). Dihydroetorphine has not been so scheduled under the Wisconsin Controlled Substances Act in Chapter 961, Stats. The objective of the rule is to bring the treatment of the drug into conformity with that at the federal level.

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TEXT OF RULE

SECTION 1. CSB 2.26 is created to read:

CSB 2.26 Addition of dihydroetorphine to schedule II. (1) Section 961.16 (2) (a) 4r., Stats., is created to read:

Section 961.16 (2) (a) 4r. Dihydroetorphine.

(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 ESTIMATE

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 a substantial number of small businesses, as defined in s. 227.114 (1) (a), Stats.

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8/10/01



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Ronald Sklansky
Clearinghouse Director

Richard Sweet
Clearinghouse Assistant Director

Terry C. Anderson
Legislative Council Director

Laura D. Rose
Legislative Council Deputy Director

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 01-071

AN ORDER to create CSB 2.26, relating to the scheduling of dihydroetorphine under ch. 961, Stats., the uniform controlled substances act.

Submitted by **DEPARTMENT OF REGULATION AND LICENSING**

06-18-01 RECEIVED BY LEGISLATIVE COUNCIL.

07-17-01 REPORT SENT TO AGENCY.

RS:DD:jal;tlu

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



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CLEARINGHOUSE RULE 01-071

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. In the department's analysis, it is not clear why ss. 961.17 and 961.19, Stats., are listed as statutory authority for the rule.
- b. In the department's analysis, it is not clear why ss. 961.18 and 961.20, Stats., are listed as statutes interpreted by the rule.
- c. In the last sentence of the first paragraph of the department's analysis, it is suggested that "rules" and "these drugs" be in the singular.
- d. In the next to last sentence of the second paragraph of the department's analysis, is the reference to "1961 in 1998" accurate?



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Comment Attached YES NO

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

Comment Attached YES NO

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REGULATIONS [s. 227.15 (2) (g)]

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Comment Attached YES NO



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FISCAL ESTIMATE

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 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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6/18/01