



Carol Roessler
STATE SENATOR

October 1, 2003

To: Member of the Senate Committee on Health, Children, Families, Aging and Long Term Care.

From: Senator Carol Roessler, Chair

Re: Clearinghouse Rule 03-056 relating to rescheduling buprenorphine from a schedule V controlled substance to a schedule III controlled substance

CR 03-056 has been referred to the Senate Committee on Health, Children, Families, Aging and Long Term Care Committee. By final rule of the Drug Enforcement Administration (DEA) adopted effective October 7, 2002, buprenorphine was reclassified from a schedule V controlled substance to a schedule III controlled substance under the federal Controlled Substance Act (CSA). Buprenorphine is currently only classified as a schedule V controlled substance under the Wisconsin Controlled Substances Act Chapter 961, Wis. Stats. The objective of the rule is to bring state classification of buprenorphine into conformity with federal law.

If you would like the Committee to hold a hearing on CR 03-056, please contact Jennifer Halbur in my office at 266-5300 by Friday October 17th 2003.

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 03-056)

September 29, 2003

TO: Alan J. Lasee
President of the Senate
Room 219 South, State Capital
Madison, Wisconsin 53702

PLEASE TAKE NOTICE that the CONTROLLED SUBSTANCES BOARD is submitting in final draft form rules relating to rescheduling buprenorphine from a schedule V controlled substance to a schedule III controlled substance under federal law.

If you have any questions concerning the final draft form or desire additional information, please contact Joel Garb at 261-2385

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 03-056)

PROPOSED ORDER

An order of the Controlled Substances Board to repeal CSB 2.17 (1) (1m) (a) and to create CSB 2.29 (1) relating to rescheduling buprenorphine from a schedule V controlled substance to a schedule III controlled substance under federal law.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes authorizing promulgation: ss. 961.11 and 961.18, Wis. Stats.

Statutes interpreted: s. 961.18 (5), Stats.

By final rule of the Drug Enforcement Administration (DEA), adopted effective October 7, 2002, buprenorphine was reclassified from a schedule V controlled substance to a schedule III controlled substance under the federal Controlled Substances Act (CSA). Buprenorphine is currently only classified as a schedule V controlled substance under the Wisconsin Controlled Substances Act in Chapter 961, Wis. Stats. The objective of the rule is to bring state classification of buprenorphine into conformity with federal law.

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. In December 2001, the federal Department of Health and Human Services forwarded a recommendation to reschedule buprenorphine to schedule III of the Controlled Substances Act. (CSA). The recommendation was based on a reevaluation of buprenorphine's abuse potential and dependence profile in light of numerous scientific studies and years of human experience with the drug. The DEA completed an independent eight factor analysis in accordance with 21 U.S.C. 811 (c). The DEA made findings in accordance with 21 U.S.C. 812 (b) that buprenorphine has potential for abuse less than the drugs or other substances in schedules I and II, has currently accepted medical use in treatment in the United States, and abuse may lead to moderate or low physical dependence or high psychological dependence. These findings form basis for the DEA action in rescheduling buprenorphine.

TEXT OF RULE

SECTION 1. CSB 2.17 (1) is repealed.

Section 961.22 (1m) is repealed.

SECTION 2. CSB 2.29 is created to read:

CSB 2.29 Transfer of buprenorphine from schedule V to schedule III. (1) Section 961.18 (5m), Stats., is created to read:

(5m) **NARCOTIC DRUGS NOT LIMITED BY QUANTITY.** Any material, compound, mixture, or preparation containing any of the following narcotic drugs, including any of their salts, isomers and salts of isomers that are theoretically possible within the specific chemical designation:

(a) Buprenorphine

(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

The Department of Regulation and Licensing will incur \$500 in costs to print and distribute the rule change.

FINAL REGULATORY FLEXIBILITY ANALYSIS

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



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Ronald Sldansky
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 03-056

AN ORDER to repeal CSB 2.17 (1) and (1m) (a); and to create CSB 2.29 (1), relating to rescheduling buprenorphine from a schedule V controlled substance to a schedule III controlled substance under federal law.

Submitted by **DEPARTMENT OF REGULATION AND LICENSING**

06-16-2003 RECEIVED BY LEGISLATIVE COUNCIL.

07-15-2003 REPORT SENT TO AGENCY.

RNS:DD



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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Clearinghouse Director

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CLEARINGHOUSE RULE 03-056

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 October 2002.]

2. Form, Style and Placement in Administrative Code

Is the placement of buprenorphine in s. 961.18 (5), Stats., consistent with the introductory paragraph of sub. (5) of that section? The introductory paragraph refers to “limited quantities” and all the existing paragraphs that follow refer to limited quantities of the included drugs. Proposed par. (i) appears to be inconsistent with the current structure of sub. (5).

4. Adequacy of References to Related Statutes, Rules and Forms

The reference in the treatment clause of SECTION 1 should read: “CSB 2.17 (1)”; i.e., the reference to “(1m) (a)” should be deleted. Similarly, the reference to s. 961.22 (1m) (a) that follows should read simply “s. 961.22 (1m).” In the treatment clause of SECTION 2, “(1)” should be deleted.

**STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD**

**IN THE MATTER OF RULE-MAKING : REPORT TO THE LEGISLATURE
PROCEEDINGS BEFORE THE : ON CLEARINGHOUSE RULE 03-056
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:

None

III. FISCAL ESTIMATES:

These rules will have no significant economic impact.

IV. STATEMENT EXPLAINING NEED:

In this rule the Controlled Substances Board repeals CSB 2.17 (1) and creates CSB 2.29 relating to rescheduling buprenorphine from a schedule V controlled substance to a schedule III controlled substance under federal law. This results in a state classification in conformity with federal law.

V. NOTICE OF PUBLIC HEARING:

A public hearing was held on August 6, 2003. There were no appearances and no written comments were received.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

The recommendations suggested in the Clearinghouse Report were accepted in whole.

2. Form, Style and Placement in Administrative Code

The comment questioned whether the newly created paragraph placing buprenorphine in s. 961.18 (5) was consistent with the other elements contained therein, given that subsection (5) paragraphs (a) through (h) all concerned controlled substances in specifically delineated limited quantities as noted in subsection (5)'s introductory paragraph. Buprenorphine, however, was not limited by a specifically delineated quantity. The Clearinghouse Report comment was well taken. The rule has been modified to create a new section (5m) for narcotic drugs not limited by quantity.

4. Adequacy of References to Related Statutes, Rules and Forms

The requested change was made.

VII. 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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