STATE OF WISCONSIN CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING	: ORDER OF THE
PROCEEDINGS BEFORE THE	: CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD	: ADOPTING RULES
	: (CLEARINGHOUSE RULE 03-056)

<u>ORDER</u>

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 buprenophine from a schedule V controlled substance to a schedule III controlled substance under federal law.

Analysis prepared by the Department of Regulation and Licensing.

<u>ANALYSIS</u>

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.

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.

CSB 2.29 CR03-56 (buprenorphine) Draft of 11-19-03