tiled May 21, 1973 3:15 pm

STATE OF WISCONSIN) DEPARTMENT OF HEALTH & SOCIAL SERVICES) SS CONTROLLED SUBSTANCES BOARD)

TO WHOM IT MAY CONCERN:

\_ (SB 1,2

I, Robert W. Warren, Chairman of the Controlled Substances Board, and custodian of the official records of said board, do hereby certify that the annexed rules and regulations relating to control of methadone and the addition of methaqualone to Schedule II, were duly approved and adopted by this board on May 16, 1973.

I further certify that said copy has been compared by me with the original on file in this board and that the same is a true copy thereof, and of the whole of such original.

> IN TESTIMONY WHEREOF, I have hereunto set my hand at the Capitol in the city of Madison, this 21st day of May A.D. 1973.

Chairman, Controlled Substances Board

DEPARTMENT OF STATE RECEIVED AND FILED

MAY 21 1973

TOT C. ZIMMEP

## ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES

Pursuant to authority vested in the Controlled Substances Board by section 161.11, Wis. Stats., said board hereby adopts rules as follows:

CSB Chapter 1, Sections CSB 1.01 through CSB 1.06 of the WISCONSIN ADMINISTRATIVE CODE are adopted to read:

## CSB Chapter 1: Control of Methadone.

CSB 1.01 Definitions. (1) An individual is "dependent on narcotic drugs" when his addiction reaches a stage where a daily administration of heroin or other morphine-like drugs is required to avoid the signs and symptoms of withdrawal.

(2) "Detoxification treatment for narcotic dependence" using methadone is the administering or dispensing of methadone as a substitute narcotic drug in decreasing doses to reach a narcotic-free state in a period not to exceed 21 days.

(3) "Treatment for narcotic dependence" using methadone is the continued administering or dispensing of methadone, in conjunction with provision of appropriate social and medical services, at relatively stable dosage levels for a period in excess of 21 days. An eventual narcotic-free state is the treatment goal for patients, but it is recognized that for some patients methadone may be needed for long periods of time.

<u>CSB 1.02 Use of Methadone.</u> Use of methadone is restricted to the following: (1) As an analgesic for severe pain other than the pain of narcotic withdrawal.

(2) For detoxification of narcotic dependent individuals.

(3) For methadone treatment of narcotic dependent individuals.

CSB 1.03 Authorization. Any hospital, community pharmacy, or program desiring to use methadone for any of the above 3 purposes shall require prior authorization from: (1) Food and drug administration.

(2) The state of Wisconsin - department of health and social services - controlled substances board.

CSB 1.04 Procedure for dispensing methadone. (1) Any physician desiring to use methadone in accordance with Wis. Adm. Code, section CSB 1.02 (2) must admit the patient to an approved hospital under Wis. Adm. Code, section CSB 1.03.

(2) Any physician desiring to use methadone as an analgesic under Wis. Adm. Code, section CSB 1.02 (1), may do so by utilizing (under conditions given below) services of those hospital pharmacies in the state which have been approved for the dispensing of methadone. Such approval by the FDA and the state of Wisconsin is given after review of an application made by the hospital administrator. On petition, the controlled substances board may grant authorization to community pharmacies to dispense methadone in remote areas where hospital pharmacies are not available.

(a) For inpatients who are hospitalized in an institution having a methadone-approved pharmacy, the physician may write an appropriate medication order.

(b) For outpatients requiring a prescription for methadone, the physician writing the prescription must file in advance with the hospital a yearly affidavit indicating an intent to prescribe methadone for outpatient analgesia. A list of physicians filing such affidavits is sent by the hospital to the FDA annually. The patient who receives a methadone prescription for outpatient analgesia must have the prescription filled at the methadone-approved pharmacy where the physician who wrote the prescription has a current affidavit on file.

(3) Any physician desiring to use methadone in accordance with Wis. Adm. Code, section CSB 1.02 (3) shall receive prior authorization from:

(a) The food and drug administration.

(b) The controlled substances board of the department of health & social services of the state of Wisconsin.

CSB 1.05 Programmatic conditions for use of methadone. (1) In addition to giving assurance to compliance with 21 Code of Federal Regulations 130.44, conditions for use of methadone, each authorized person shall be required to also adhere to the following state regulations:

(a) Each individual requiring participation in a methadonetreatment program shall have resided in the state of Wisconsin for30 days unless previously enrolled in a narcotics treatment program.

(b) Prior to a person being transferred to a medication unit each primary program will provide those elements of a comprehensive treatment program within a patient's own community that are indicated for his total rehabilitation. The patient shall be stabilized at his optimal dosage level and shall have demonstrated progress toward rehabilitation before he may be referred to a medication unit. <u>CSB 1.06 State inspection of programs and additional reporting</u> requirements. (1) Each authorized program shall consent to on-site inspection and visitations by the department of health and social services, pharmacy examining board, the food and drug administration and by the bureau of narcotics and dangerous drugs.

(2) Each authorized program shall be responsible for maintaining such records as required by the department of health and social services.

CSB Chapter 2, CSB Section 2.01 of the WISCONSIN ADMINISTRATIVE CODE is adopted to read:

CSB Chapter 2: Additions to Schedules in Sections 161.14, 161.16, 161.18, 161.20 and 161.22, Wis. Stats.

CSB 2.01 Addition of Methaqualone to Schedule II. The substance known as methaqualone is hereby added to section 161.16, Wis. Stats., Schedule II in subsection (6) which subsection is hereby created.

The rules contained herein shall take effect on July 1, 1973, as provided in section 227.026 (1), Wis. Stats.

May 21, 1973 Date

Controlled Substances Board

by Robert W. Warren, Chairman