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**TITLE 858 CONTROLLED SUBSTANCES ADVISORY COMMITTEE**

**Proposed Rule**
LSA Document #03-281

DIGEST

Amends 858 IAC 2-1 to revise the electronic prescription monitoring program. Effective 30 days after filing with the secretary of state.

**858 IAC 2-1-1** **858 IAC 2-1-3**
**858 IAC 2-1-2** **858 IAC 2-1-4**

SECTION 1. 858 IAC 2-1-1 IS AMENDED TO READ AS FOLLOWS:

**858 IAC 2-1-1 Definitions**
**Authority: IC 35-48-7-12**
**Affected: IC 35-48-2; IC 35-48-7-3**

Sec. 1. (a) As used in this article, "department" refers to the Indiana state police department.

(b) As used in this article, "dispense" means the actual or constructive transfer from one (1) person to another whether or not there is an agency relationship.

(c) As used in this article, "dispenser" has the meaning set forth in IC 35-48-7-3.

(d) As used in this article, "Schedule II controlled substance" means **a controlled substance classified in Schedule II:**
(1) ~~a controlled substance classified in Schedule II~~ under IC 35-48-2-6; or
(2) ~~a controlled substance classified in Schedule II~~ by rule adopted under IC 35-48-2-14.

**(e) As used in this article, "Schedule III controlled substance" means a controlled substance classified in Schedule III:**
**(1) under IC 35-48-2-8; or**
**(2) by rule adopted under IC 35-48-2-14.**

**(f) As used in this article, "Schedule IV controlled substance" means a controlled substance classified in Schedule IV:**
**(1) under IC 35-48-2-10; or**
**(2) by rule adopted under IC 35-48-2-14.**

**(g) As used in this article, "Schedule V controlled substance" means a controlled substance classified in Schedule V:**
**(1) under IC 35-48-2-12; or**
**(2) by rule adopted under IC 35-48-2-14.**

~~(c)~~ **(h)** As used in this article, "universal claim form" means a nationally recognized standard form developed by the National Council for Prescription Drug Programs used for billing drug claims to insurance plans. *(Controlled Substances Advisory Committee; 858 IAC 2-1-1; filed Oct 6, 1994, 1:30 p.m.: 18 IR 266; filed Jan 27, 2000, 7:49 a.m.: 23 IR 1383; readopted filed Nov 30, 2001, 2:47 p.m.: 25 IR 1344)*

SECTION 2. 858 IAC 2-1-2 IS AMENDED TO READ AS FOLLOWS:

**858 IAC 2-1-2 Applicability**
**Authority: IC 35-48-7-12**
**Affected: IC 35-48-7-8**

Sec. 2. This article shall apply ~~only~~ to Schedule II, **III, IV, and V** controlled substances and shall not apply to ~~Schedule III, IV, or V controlled substances, nor to~~ any other drug. *(Controlled Substances Advisory Committee; 858 IAC 2-1-2; filed Oct 6, 1994, 1:30 p.m.: 18 IR 267; readopted filed Nov 30, 2001, 2:47 p.m.: 25 IR 1344)*

SECTION 3. 858 IAC 2-1-3 IS AMENDED TO READ AS FOLLOWS:

**858 IAC 2-1-3 Prescription monitoring program**
**Authority: IC 35-48-7-12**
**Affected: IC 35-48-7-8**

Sec. 3. (a) Each time a Schedule II, **III, IV, or V** controlled substance is dispensed, the dispenser shall transmit to the central repository **the following** information: ~~outlined in IC 35-48-7-8.~~

**(1) The recipient's name.**
**(2) The recipient's or the recipient representative's identification number.**
**(3) The recipient's date of birth.**
**(4) The national drug code number of the controlled substance dispensed.**
**(5) The date the controlled substance is dispensed.**
**(6) The quantity of the controlled substance dispensed.**
**(7) The number of days of supply dispensed.**
**(8) The dispenser's United States Drug Enforcement Agency registration number.**
**(9) The dispenser's controlled substance registration number.**
**(10) The prescriber's United States Drug Enforcement Agency registration number.**
**(11) The prescriber's controlled substance registration number.**
**(12) An indication as to whether the prescription was transmitted to the pharmacist orally or in writing.**

(b) Dispensers reporting more than twenty (20) Schedule II, **III, IV, or V** prescriptions in any given month must transmit to the central repository information outlined in ~~IC 35-48-7-8~~ **subsection (a)** utilizing one (1) of the following:
(1) An electronic device compatible with the receiving device of the central repository.
(2) A computer diskette.
(3) A magnetic tape.

(c) Dispensers reporting less than twenty (20) Schedule II, **III, IV, or V** prescriptions in any given month may submit data utilizing a universal claim form or transmit the information utilizing the ways outlined in subsection (b).

(d) The committee may grant a waiver to a dispenser which is unable to transmit the required data in accordance with subsection (b) for a period of one hundred eighty (180) days from the effective date of this rule which one hundred eighty (180) day period may be extended by the committee at its discretion. During the effective period of the waiver and any extension granted by the committee, the dispenser shall submit the required data in a format acceptable to the committee. *(Controlled Substances Advisory Committee; 858 IAC 2-1-3; filed Oct 6, 1994, 1:30 p.m.: 18 IR 267; readopted filed Nov 30, 2001, 2:47 p.m.: 25 IR 1344)*

SECTION 4. 858 IAC 2-1-4 IS AMENDED TO READ AS FOLLOWS:

**858 IAC 2-1-4 Application for payment of pharmacy costs**
**Authority: IC 35-48-7-12**
**Affected: IC 35-48-7-9**

Sec. 4. (a) Before the department will pay for the purchase of hardware to comply with the program, an applicant must file an application provided by the department and provide the following information:
(1) The dispenser's name, address, and Indiana license number.
(2) A detailed description of the dispenser's current computer hardware, including the name and manufacturer of all components.

(3) A detailed description of the hardware the dispenser intends to purchase and two (2) price quotes from computer hardware vendors.
(4) The reason why the dispenser believes the computer hardware will be necessary to comply with the program.
(5) The number of Schedule II, **III, IV, and V** prescriptions the pharmacy dispenses in any given month.

(b) Upon receipt of an application requesting that the department pay for computer hardware, the committee shall evaluate the dispenser's current technology in determining whether the dispenser would be required to purchase new computer hardware. The committee shall take into account the ability of the dispenser to utilize any one (1) of the methods outlined in section 3 of this rule.

(c) The central repository shall provide grants to software vendors to update software in order for dispensers to comply with the program as outlined in contract form.

(d) The department and the central repository shall pay for telephone access charges, line charges, and switch charges for transmission of data by dispensers to the central repository. *(Controlled Substances Advisory Committee; 858 IAC 2-1-4; filed Oct 6, 1994, 1:30 p.m.: 18 IR 267; filed Jan 27, 2000, 7:49 a.m.: 23 IR 1384; readopted filed Nov 30, 2001, 2:47 p.m.: 25 IR 1344)*

***Notice of Public Hearing***

*Under IC 4-22-2-24, notice is hereby given that on January 23, 2004 at 9:30 a.m., at the Health Professions Bureau, Indiana Government Center-South, 402 West Washington Street, Conference Center Room W064, Indianapolis, Indiana the Controlled Substances Advisory Committee will hold a public hearing on proposed amendments to revise the electronic prescription monitoring program. Copies of these rules are now on file at the Indiana Government Center-South, 402 West Washington Street, Room W066 and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.*

Lisa R. Hayes
Executive Director
Health Professions Bureau