

Rulemaking Hearing Rules of the
Department of Commerce and Insurance
Controlled Substance Monitoring Act Advisory Committee

Chapter 1140-11
Controlled Substance Monitoring Database

New Rules

Table of Contents

1140-11-.01	Definitions
1140-11-.02	Access to Database
1140-11-.03	Alternative Identification of Patients
1140-11-.04	Submission of Information

1140-11-.01 Definitions.

- (1) The following definitions shall be applicable to this chapter:
 - (a) “Board” means the Board of Pharmacy created by Tenn. Code Ann., Title 63, Chapter 10;
 - (b) “Commissioner” means the Commissioner of Commerce and Insurance;
 - (c) “Committee” means the controlled substance monitoring database advisory committee created by Tenn. Code Ann. § 53-10-303;
 - (d) “Controlled substance dispensed identifier” means the National Drug Code Number of the controlled substance;
 - (e) “Database” means the controlled substance database created by Tenn. Code Ann., Title 53, Chapter 10, Part 3;
 - (f) “Department” means the Department of Commerce and Insurance;
 - (g) “Dispense” means to physically deliver a controlled substance covered by this chapter to any person, institution or entity with the intent that it be consumed away from the premises in which it is dispensed. “Dispense” does not include the act of writing a prescription by a practitioner to be filled at a pharmacy licensed by the Board;
 - (h) “Dispenser” means any health care practitioner who has authority to dispense controlled substances, pharmacists, and pharmacies that dispense to any address within this state;

- (i) “Dispenser identifier” means the Drug Enforcement Administration Registration Number of the dispenser as defined in Tenn. Code Ann. §53-10-302(7);
- (j) “Patient” means a person, animal or owner of an animal who is receiving medical treatment from a prescriber;
- (k) “Patient identifier” means the patient’s full name; address; including zip code; date of birth; and social security number or an alternative identification number as defined by this rule;
- (l) “Person” means any individual, partnership, association, corporation and the state of Tennessee, its departments, agencies and employees, and the political subdivisions of Tennessee and their departments, agencies and employees;
- (m) “Prescriber” means any health care practitioner who has the authority to issue prescriptions for controlled substances;
- (n) “Prescriber identifier” means the Drug Enforcement Administration Registration Number of the prescriber as defined by this rule.

Authority: Tenn. Code Ann. §§53-10-302, 53-10-303(f).

1140-11-.02 Access to Database.

- (1) The following persons shall have access to the controlled substance database with regard to a patient:
 - (a) the prescriber who is currently issuing the patient a controlled substance or controlled substances or who anticipates issuing the patient a controlled substance or controlled substances;
 - (b) the dispenser who is currently dispensing a controlled substance or controlled substances to the patient or who anticipates issuing the patient a controlled substance or controlled substances;
 - (c) a person who has the patient’s written permission to have access to the patient’s records in the database;
 - (d) the manager of any investigations or prosecution unit of a health-related board, committee or other governing body that licenses practitioners who has access to the database with the committee’s permission pursuant to Tenn. Code Ann. §53-10-308, may release the database information that that such

manager receives to the state of Tennessee health-related boards, health-related committees, the department, the department of health and representatives of health-related professional recovery programs; or

- (e) a district attorney who obtains an order from circuit or criminal court ordering the release of the information contained in the database, in compliance with Tenn. Code Ann. §53-10-306.
- (2) The persons listed in paragraph (1) of this rule shall have access to the information contained in the database by submitting a request for information in writing or by electronic means to the Committee on a form developed by the Committee and in compliance with the procedures developed by the Committee. The Committee shall not disseminate any information from the database without the submission of this written request, unless the dissemination of the information is directed by Court Order.

Authority: Tenn. Code Ann. §§53-10-303(f), 53-10-304(b), 53-10-305(e), 53-10-306, 53-10-308.

1140-11-.03 Alternative Identification of Patients.

- (1) If a patient does not have a social security number or refuses to provide his or her social security number to be used as a patient identifier, then the board shall use the patient's driver's license number or telephone number as the patient identifier in the database.
- (2) If a patient does not have a social security number, a driver's license number or a telephone number, then the board shall use the number "000-00-0000" as the patient identifier in the database.
- (3) If a patient or a patient's agent refuses to provide his or her social security number, driver's license number or telephone number to his or her prescriber or dispenser, then the board shall use the number "999-99-9999" as the patient identifier in the database.
- (4) If a patient's social security number is not available, then the board shall use the social security number, driver's license number or telephone number of the person obtaining the controlled substance on behalf of the patient as the patient identifier in the database or the numbers "000-00-0000" (does not have the data) or "999-99-9999" (refusal to provide data), as applicable.
- (5) If a patient is a child who does not have a social security number, then the board shall use the parent's or guardian's social security number, driver's license number, telephone number, or number "000-00-0000" (does not have data) or

number “999-99-9999” (refusal to provide data) as the patient identifier in the database.

- (6) If a patient is an animal, then the board shall use the owner’s social security, driver’s license number, telephone number, or number “000-00-0000” (does not have data) or number “999-99-9999” (refusal to provide data) as the patient identifier in the database.

Authority: Tenn. Code Ann. §§53-10-303(f) and 53-10-305.

1140-11-.04 Submission of Information.

- (1) A dispenser who is licensed in the State of Tennessee, who is dispensing controlled substances within or from outside of the State of Tennessee and who is treating patients in the State of Tennessee with controlled substances shall submit the required information to the Committee pursuant to Tenn. Code Ann. §53-10-305(a).
- (2) The dispenser shall submit the data that is required by Tenn. Code Ann. §53-10-305 in one of the following forms:
 - (a) an electronic device compatible with the Committee’s receiving device or the receiving device of the Committee’s agent;
 - (b) double-sided, high density micro floppy disk;
 - (c) one-half (1/2) inch, nine (9) track sixteen hundred (1,600) or six thousand two hundred and fifty (6,250) BPI magnetic tape; or
 - (d) other electronic or data format approved by the Committee.
- (3) The dispenser shall transmit the data that is required pursuant to Tenn. Code Ann. §53-10-305(a) in the May, 1995 version of the Telecommunications Format for Controlled Substances established by the American Society for Automation in Pharmacy (ASAP).
- (4) If the dispenser does not have an automated recordkeeping system capable of producing an electronic report of the required data in the format established by the ASAP, then the dispenser may request a waiver from the electronic reporting requirement from the Committee.
- (5) If the Committee grants the dispenser a waiver from the electronic reporting requirement, then the dispenser shall comply with an alternative method of reporting the data as determined by the Committee, such as submitting the required data in writing on a form approved by the Committee.

Authority: Tenn. Code Ann. §§53-10-303(f) and 53-10-305.

The rulemaking hearing rules set out herein were properly filed in the Department of State on the 22nd day of December, 2005 and will become effective on the 7th day of March, 2006.