RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-11
CONTROLLED SUBSTANCE MONITORING DATABASE

TABLE OF CONTENTS

1140-11-.01 DEFINITIONS.

(1) "ARCOS" (the "Automation of Reports and Consolidated Orders System") is an automated, comprehensive drug reporting system, created pursuant to 21 U.S.C. § 827 and administered by the United States Drug Enforcement Administration, which monitors the flow of controlled substances from the point of manufacture, through commercial distribution channels, to the point of distribution or sale at the dispensing or retail level;

(2) "Board" means the Board of Pharmacy created by T.C.A., Title 63, Chapter 10, part 3;

(3) "Committee" means the Controlled Substance Database Committee created by T.C.A., Title 53, Chapter 10, part 3;

(4) "Controlled substance(s)" means a drug, substance, or immediate precursor in Schedules I through VI as defined or listed in the Tennessee Drug Control Act, compiled in T.C.A., Title 39, Chapter 17, part 4;

(5) "Database" means the controlled substance database created by T.C.A., Title 53, Chapter 10, part 3;

(6) "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. It does not include the act of writing a prescription by a practitioner to be filled at a pharmacy. For purposes of this part, physical delivery includes mailing controlled substances into this state;

(7) "Dispenser" means any health care practitioner who is licensed and has current authority to dispense controlled substances;

(8) "Healthcare practitioner" means:

(a) A physician, dentist, optometrist, veterinarian, or other person licensed, registered, or otherwise permitted to prescribe, distribute, dispense or administer a controlled substance in the course of professional practice; or

(b) A pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, or administer a controlled substance in the course of professional practice;

(9) "Healthcare practitioner delegate" means any person designated by a healthcare practitioner, who acts as an agent of the healthcare practitioner. A healthcare practitioner shall have the ability to authorize a healthcare practitioner delegate to check the controlled substance database as set forth in the Prescription Safety Act of 2016, Tenn. Code Ann. §§ 53-10-301,

(Rule 1140-11-.01, continued)

et seq. The healthcare practitioner shall be responsible for all actions taken by his or her agent, pursuant to this part;

(10) "Law enforcement personnel" means agents of the Tennessee Bureau of Investigation, agents of a judicial district drug task force, federal law enforcement officers commissioned by a federal government entity, certified law enforcement officers certified pursuant to T.C.A. § 38-8-107, and certified law enforcement officers in other states;

(11) "Patient" means a person or an animal who is receiving medical treatment from a prescriber;

(12) "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;

(13) "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; and

(14) "Prescriber" means an individual licensed as a medical doctor, podiatrist, dentist, optometrist, veterinarian, osteopathic physician, a physician assistant who has authority to issue prescriptions for controlled substances, or an advanced practice nurse with a certificate of fitness to prescribe.

Authority: *T.C.A. §§ 53-10-303(f), 53-10-305(e), and 53-10-311(b).* ***Administrative History:*** *Original rule filed December 22, 2005; effective March 7, 2006. Emergency rule filed January 4, 2013; effective through July 3, 2013. Repeal and new rule filed April 2, 2013; effective July 1, 2013. Amendment filed December 16, 2013; effective March 16, 2014. Amendments filed November 22, 2016; effective February 20, 2017. Amendments filed October 28, 2021; effective January 26, 2022.*

1140-11-.02 DRUGS OF ABUSE.

The Committee has found that Schedule V controlled substances demonstrate a potential for abuse and should be reported to the CSMD as authorized by T.C.A. § 53-10-304. However, Schedule V controlled substances which may be dispensed without a prescription, as set forth in 21 C.F.R. §§ 1306, et seq, do not have to be reported to the database.

Authority: *T.C.A. §§ 53-10-303(f), 53-10-304(c), 53-10-305(e), 53-10-310(e), and 53-10-311(b).* ***Administrative History:*** *Original rule filed December 22, 2005; effective March 7, 2006. Emergency rule filed January 4, 2013; effective through July 3, 2013. Repeal and new rule filed April 2, 2013; effective July 1, 2013. Amendment filed August 29, 2014; effective November 27, 2014. Amendments filed October 28, 2021; effective January 26, 2022.*

1140-11-.03 FEES.

(1) A fee of twenty-two dollars and fifty cents ($22.50) shall be paid to the Board for each request from law enforcement processed by Committee staff, unless an alternative arrangement has been agreed to.

(2) A fee of twenty-two dollars and fifty cents ($22.50) shall be paid to the Board for each request from any judge of a participating drug court pursuant to T.C.A. § 53-10-306 processed by Committee staff, unless an alternative arrangement has been agreed to.

Authority: *T.C.A. §§ 53-10-303 and 53-10-306.* ***Administrative History:*** *New rule filed November 22, 2016; effective February 20, 2017.*

1140-11-.04 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: *T.C.A. §§ 53-10-303(f) and 53-10-305.* ***Administrative History:*** *Original rule filed December 22, 2005; effective March 7, 2006. Rule was previously numbered 1140-11-.03 but was renumbered 1140-11-.04 with the addition of a new rule 1140-01-.03 filed November 22, 2016; effective February 20, 2017.*

1140-11-.05 MINIMUM REPORTING REQUIREMENTS FOR WHOLESALERS AND MANUFACTURERS.

(1) Wholesalers and manufacturers, as defined in T.C.A. § 63-10-204, shall submit a report of all wholesales and distributions of controlled substances at least once every month and no later than 45 days after the earliest transaction being reported.

(a) Any report submitted pursuant to this rule shall be in the ARCOS format, as specified in the most current version of the "Instructions for Reporting Wholesale Transactions" document, which will be made freely available on the Board of Pharmacy's website or the Controlled Substance Monitoring Database's website.

(b) Any report submitted pursuant to this rule shall be sent to the database or email address specified in the "Instructions for Reporting Wholesale Transactions" document.

(c) Any entity exempt from reporting to the Drug Enforcement Administration pursuant to 21 C.F.R. § 1304.33 shall not be required to submit reports of wholesales and distributions of controlled substances pursuant to this rule.

Authority: *T.C.A. § 53-10-312.* ***Administrative History:*** *New rule filed November 22, 2016; effective February 20, 2017. Rule was previously numbered 1140-11-.08 but was renumbered 1140-11-.05 with the deletion of rules 1140-11-.05 through 1140-11-.07 filed October 28, 2021; effective January 26, 2022.*