RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-11
CONTROLLED SUBSTANCE MONITORING DATABASE

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1140-11-.01 DEFINITIONS.

(1) The following definitions shall be applicable to this chapter:

(a) "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.

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

(c) "Client" means the owner or custodian of any animal under the care of a licensed veterinarian.

(d) "Commissioner" means the Commissioner of Health;

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

(f) "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;

(g) "Controlled substance dispensed identifier" means the National Drug Code Number of the controlled substance;

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

(i) "Department" means the Department of Health;

(j) "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;

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

(Rule 1140-11-.01, continued)

(l) “Dispenser identifier” means the Drug Enforcement Administration Registration Number of the dispenser as defined in T.C.A. § 53-10-302(8);

(m) "Hardship" means a situation where a dispenser does not have an automated recordkeeping system capable of producing an electronic report of the required data in the format established by the American Society for Automation in Pharmacy Telecommunications Format for Controlled Substances. "Hardship" may also include other situations as determined by the Committee in its sole discretion;

(n) "Healthcare practitioner" means:

1. 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

2. 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;

(o) "Healthcare practitioner extender" means any registered or licensed healthcare professional, and up to two (2) unlicensed persons designated by the prescriber or dispenser, who act as agents of the prescriber or dispenser. The prescriber or dispenser shall be responsible for all actions taken by the agents, pursuant to this part;

(p) "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;

(q) “Patient” means a person or an animal who is receiving medical treatment from a prescriber;

(r) “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;

(s) “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;

(t) “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;

(u) “Prescriber identifier” means the Drug Enforcement Administration Registration Number of the prescriber as defined by this rule.

Authority: *T.C.A. §§ 53-10-302 and 53-10-303(f).* ***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.*

1140-11-.02 ACCESS TO DATABASE.

(1) All prescribers with DEA numbers who prescribe controlled substances, and all dispensers in practice who provide direct care to patients in Tennessee for more than fifteen (15) calendar days per year, shall be registered in the database. New licensees shall have up to thirty (30) calendar days after notification of licensure to register in the database. Licensed veterinarians who never prescribe a controlled substance in an amount intended to treat a non-human patient for more than forty-eight (48) hours shall not be required to register in the database.

(a) All healthcare practitioner extenders, physician assistants, or advanced practice nurses with a certificate of fitness to prescribe who are registered in the database shall also submit to the database, within thirty (30) calendar days of registration, their supervising physician's driver's license number.

(b) When under the supervision of a new physician, the health care practitioner extender, physician assistant, or advanced practice nurse with a certificate of fitness to prescribe shall have thirty (30) calendar days from the date this change occurs to submit the new supervising physician's driver's license number.

(2) Information sent to, contained in, and reported from the database in any format shall be made available only as provided for in T.C.A. § 53-10-306 and to the following persons in accordance with this chapter:

(a) A prescriber conducting medication history reviews who is actively involved in the care of a patient or a bona fide prospective patient; a prescriber or supervising physician of the prescriber conducting a review of all medications dispensed by prescription attributed to that prescriber; or a prescriber having authority to prescribe or dispense controlled substances, to the extent the information relates specifically to a current or bona fide prospective patient of the prescriber, to whom the prescriber has prescribed or dispensed, is prescribing or dispensing, or considering prescribing or dispensing any controlled substance. Each authorized individual under this paragraph shall have a separate identifiable authentication for access;

(b) A dispenser or pharmacist not authorized to dispense controlled substances conducting drug utilization or medication history reviews who is actively involved in the care of a patient; or a dispenser having authority to dispense controlled substances to the extent the information relates specifically to a current or bona fide prospective patient to whom that dispenser has dispensed, is dispensing, or considering dispensing any controlled substance. Each authorized individual under this paragraph shall have a separate identifiable authentication for access;

(c) A county medical examiner appointed pursuant to T.C.A. § 38-7-104 when acting in an official capacity as established in T.C.A. § 38-7-109;

(d) Personnel of the following entities actively engaged in analysis of controlled substances prescription information as part of their assigned duties and responsibilities directly related to TennCare:

1. The Office of the Inspector General;

2. The Medicaid Fraud Control Unit; and

3. The Bureau of TennCare's Chief Medical Officer, Associate Chief Medical Directors, Director of Quality Oversight, and Associate Director of Pharmacy.

(Rule 1140-11-.02, continued)

(e) A quality improvement committee, as defined in T.C.A. § 68-11-272, of a hospital licensed under T.C.A. title 68 or title 33, as part of the committee's confidential and privileged activities under T.C.A. § 68-11-272(b)(4) with respect to the evaluation, supervision or discipline of a healthcare provider employed by the hospital or any of its affiliates or subsidiaries, who is known or suspected by the hospital's administrator to be prescribing controlled substances for the prescriber's personal use;

(f) A healthcare practitioner extender, who is acting under the direction and supervision of a prescriber or dispenser, and only to the extent the information relates specifically to a current or bona fide prospective patient to whom the prescriber or dispenser has prescribed or dispensed, or considering prescribing or dispensing any controlled substance. Each authorized individual under this paragraph shall have a separate identifiable authentication for access, and the prescriber or dispenser shall cancel the healthcare practitioner extender's access to the database upon the end of the agency relationship;

(g) A manager of any investigation 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 T.C.A. § 53-10-308. Such manager may release the database information to the state of Tennessee health related boards, health related committees, the department, and representatives of health-related professional recovery programs;

(h) The following personnel of the Department of Mental Health and Substance Abuse Services, who are actively engaged in analysis of controlled substance prescription information, as part of their assigned duties and responsibilities. These personnel shall have access to prescription information for specific patients. Additionally, aggregate controlled substances prescribing information may be provided to these personnel and may be shared with other personnel of the Department of Mental Health and Substances Abuse Services as needed to fulfill the assigned duties and responsibilities:

1. The Chief Pharmacist;

2. The State Opioid Treatment Authority (SOTA) or SOTA designees; and

3. The Medical Director; or

(i) A person who has the patient's written permission to have access to the patient's records in the database.

(3) Law enforcement personnel engaged in an official investigation and enforcement of state or federal laws involving controlled substances or violations of T.C.A., Title 53, Chapter 10, part 3 may access information contained in the database pursuant to this chapter.

(4) Law enforcement agencies and personnel seeking or receiving information from the database pursuant to this section shall comply with the following requirements:

(a) Any law enforcement agency or judicial district drug task force that requires one (1) or more of its officers or agents to have the authorization to request information from the database shall first pre-approve each such officer. Pre-approval shall be by the applicant's supervisor, who shall be either the chief of police, county sheriff, or the judicial district drug task force district attorney general in the judicial district in which the agency or task force has jurisdiction. By December 1 of each year, each district attorney general shall send to the board of pharmacy a list of applicants authorized to request information from the database from that general's judicial district for the next calendar year.

(b) If the Tennessee Bureau of Investigation (TBI) requires one (1) or more of its agents to have the authorization to request information from the database, each such agent shall first be pre-approved by the agent's immediate supervisor and division head. Approved applicants shall be sent to the board of pharmacy by the TBI director. By December 1 of each year, the TBI director shall send to the board of pharmacy a list of applicants authorized to request information from the database from the bureau for the next calendar year.

(c) An application submitted by law enforcement personnel shall include at least the following:

1. Applicant's name; title; agency; agency address; agency contact number; agency supervisor; and badge number, identification number or commission number, and the business email address of each applicant officer or agent, the appropriate district attorney general and, if a TBI agent, the TBI director and their email addresses; and

2. Signatures of the applicant, the applicant's approving supervisor and the district attorney general of the judicial district in which the applicant has jurisdiction or the approving TBI division head and the TBI director.

(d) When requesting information from the database, law enforcement personnel must provide a case number corresponding with an official investigation involving controlled substances.

(e) Law enforcement personnel, including judicial district drug task force agents and TBI agents, who are authorized to request information from the database, shall resubmit their identifying application information that was submitted pursuant to subparagraph (4)(c) to the appropriate district attorney general or to the TBI director, by November 20 of each year. Such resubmitted applications shall be sent by the appropriate district attorney general or the TBI director to the board of pharmacy by December 1 each year. If during the calendar year, a name is added to the list, removed from the list, or information about a person on the list changes, the appropriate district attorney general or TBI director shall immediately notify the board of pharmacy of any changes to the list submitted or in the information submitted for each officer or agent on the list application.

(5) Information obtained from the database may be shared with other law enforcement personnel or prosecutorial officials, only upon the direction of the officer or agent who originally requested the information, and may only be shared with law enforcement personnel from other law enforcement agencies who are directly participating in an official joint investigation.

(6) Any information obtained from the database that is sent to a law enforcement official or judicial district drug task force agent shall also be sent to the district attorney general of the judicial district in which such officer or agent has jurisdiction. Likewise, any database information sent to a TBI agent shall also be sent to the TBI director.

(7) Information obtained from the database by law enforcement personnel shall be retained by the law enforcement personnel's respective department or agency. The information obtained from the database shall not be made a public record, notwithstanding the use of the information in court for prosecution purposes. Information obtained from the database shall be maintained as evidence in accordance with each law enforcement agency's respective procedures relating to the maintenance of evidence.

(8) If a law enforcement officer, judicial district drug task force agent, or TBI agent has probable cause to believe, based upon information received from a database request, that a prescriber

(Rule 1140-11-.02, continued)

or pharmacist may be acting or may have acted in violation of the law, the officer or agent shall consult with the board of pharmacy inspector's office if a pharmacist is believed to have acted or is acting unlawfully or to the health related boards' investigations unit if a prescriber is believed to have acted or is acting unlawfully.

(9) At least every six (6) months, the board of pharmacy shall send a list to each district attorney general containing all requests made for database information during the previous six (6) months. The list shall include the name of the requesting officer or agent, the officer or agent's agency, the date of the request, and the nature of the request, including the case number, for each officer or agent making a request in such district attorney's judicial district. Likewise, a list shall be sent to the TBI director for all TBI agents making requests during the previous six (6) months.

(a) Each district attorney general and the TBI director shall use the list to verify database requests made during the preceding six (6) month period, and conduct an audit in accordance with T.C.A. § 53-10-306(j)(2). Verification of all database requests on the list received by each district attorney general and the TBI director must be sent back to the board of pharmacy within sixty (60) days of receipt. Where database information requests do not correspond to an investigation in the applicable jurisdiction or if the information requested was not relevant or pertinent to such an investigation, the district attorney general or TBI director shall so note on the verified list and shall investigate and make a report to the board of pharmacy within sixty (60) days.

(b) The results of the audit shall be discoverable by a prescriber, dispenser, or healthcare practitioner extender charged with violating any state or federal law involving controlled substances or under a notice of charges proffered by an appropriate licensing board for a violation of any law involving controlled substances, but only the results pertaining to that prescriber, dispenser, or healthcare practitioner extender are discoverable. If, however, there is an active criminal investigation involving a prescriber, dispenser, or healthcare practitioner extender, or the prescriber, dispenser, or healthcare practitioner extender is under investigation by any investigations or prosecution unit of the appropriate licensing board, the results of the audit shall not be discoverable by the prescriber, dispenser, or healthcare practitioner extender during either such period.

Authority: *T.C.A. §§ 53-10-303, 53-10-303(f), 53-10-304, 53-10-304(b), 53-10-305, 53-10-305(e), 53-10-306, and 53-10-308.* ***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.*

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 SUBMISSION OF INFORMATION.

(1) Each dispenser or dispenser's agent shall, regarding each controlled substance dispensed, submit to the database all of the following information:

(a) Prescriber identifier;

(b) Dispensing date of controlled substance;

(c) Patient identifier and/or client identifier;

(d) Controlled substance dispensed identifier;

(e) Quantity of controlled substance dispensed;

(f) Strength of controlled substance dispensed;

(g) Estimated number of days' supply;

(h) Dispenser identifier;

(i) Date the prescription was issued by the prescriber;

(Rule 1140-11-.05, continued)

(j) Whether the prescription was new or a refill; and

(k) Source of payment.

(2) Prior to January 1, 2016, the information in the database, as required by paragraph one (1) above, shall be submitted at least once every seven (7) days for all controlled substances dispensed during the preceding seven (7) day period. Information submitted after January 1, 2016, with the exception of information reported by veterinarians, shall be submitted for each business day but no later than the close of business on the following day.

(3) The data required by this rule shall be submitted to the database by any dispenser, or dispenser's agent, who dispenses a controlled substance contained in Schedules II, III, and IV, and Schedule V controlled substances identified by the Committee as demonstrating a potential for abuse.

(4) The reporting requirement shall not apply for the following:

(a) A drug administered directly to a patient;

(b) Any drug sample dispensed;

(c) Any drug dispensed by a licensed veterinarian; provided, that the quantity dispensed is limited to an amount adequate to treat the non-human patient for a maximum of forty-eight (48) hours;

(d) Any facility that is registered by the United States drug enforcement administration as a narcotic treatment program and is subject to the recordkeeping provisions of 21 CFR 1304.24; or

(e) Any drug dispensed by a licensed healthcare facility; provided, that the quantity dispensed is limited to an amount that is adequate to treat the patient for a maximum of forty-eight (48) hours.

(5) The dispenser, or dispenser's agent, shall submit the data that is required by T.C.A. § 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; or

(b) Other electronic or data format approved by the Committee.

(6) The dispenser, excluding a veterinarian, shall transmit the data that is required, pursuant to T.C.A. § 53-10-305, in the 2009 version of the Telecommunications Format for Controlled Substances established by the American Society for Automation in Pharmacy (ASAP).

(7) 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, or for whom electronic reporting would cause an undue hardship as determined by the Committee, then that dispenser may request a waiver from the electronic reporting requirement from the Committee. The waiver may be valid for two (2) years from ratification by the Committee.

(8) 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.

(Rule 1140-11-.05, continued)

Authority: *T.C.A. §§ 53-10-303(f), 53-10-304, and 53-10-305.* ***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 6, 2013; effective March 16, 2014. Rule was previously numbered 1140-11-.04, but was renumbered 1140-11-.05 with the addition of a new rule 1140-01-.03 filed November 22, 2016; effective February 20, 2017. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-11-.06 PRACTICE SITES – ELECTRONIC ACCESS.

(1) Each person or entity operating a practice site where a controlled substance is prescribed or dispensed to a human patient shall provide for electronic access to the database at all times when a prescriber or dispenser provides healthcare services to a human patient potentially receiving a controlled substance.

(2) This rule shall not apply to dispensers who are not required to report, pursuant to T.C.A. § 53-10-304(d) or § 53-10-305(g).

(3) A violation of paragraph one (1) above is punishable by a civil penalty not to exceed one hundred dollars ($100) per day assessed against the person or entity operating the practice site; provided, however, that the penalty shall only be imposed when there is a continued pattern or practice of not providing electronic access to the database

Authority: *T.C.A. §§ 53-10-303(f) and 53-10-310.* ***Administrative History:*** *Emergency rule filed January 4, 2013; effective through July 3, 2013. Repeal and new rule filed April 2, 2013; effective July 1, 2013. Rule was previously numbered 1140-11-.05, but was renumbered 1140-11-.06 with the addition of a new rule 1140-01-.03 filed November 22, 2016; effective February 20, 2017.*

1140-11-.07 PRESCRIBER AND DISPENSER RESPONSIBILITIES (EFFECTIVE APRIL 1, 2013).

(1) All prescribers or their designated healthcare practitioner's extenders, unless otherwise exempted by T.C.A. Title 53, Chapter 10, part 3, shall check the database prior to prescribing one of the controlled substances identified below in paragraph (3) to a human patient at the beginning of a new episode of treatment and shall check the database for the human patient at least annually when that prescribed controlled substance remains part of treatment.

(2) Before dispensing, a dispenser shall have the professional responsibility to check the database or have a healthcare practitioner extender check the database, if the dispenser is aware or reasonably certain, that a person is attempting to obtain a Schedule II-V controlled substance, identified by the Committee as demonstrating a potential for abuse for fraudulent, illegal, or medically inappropriate purposes, in violation of T.C.A. § 53-11-402.

(3) The controlled substances which trigger a check of the database pursuant to paragraph (1) above include, but are not limited to, all opioids and benzodiazepines.

(4) Prescribers are not required to check the database before prescribing or dispensing one of the controlled substances identified in paragraph (3) above or added to that list by the Committee if one (1) or more of the following conditions is met:

(a) The controlled substance is prescribed or dispensed for a patient who is currently receiving hospice care;

(b) The Committee has determined that prescribers in a particular medical specialty shall not be required to check the database as a result of the low potential for abuse by patients receiving treatment in that medical specialty;

(Rule 1140-11-.07, continued)

(c) The controlled substance is prescribed or dispensed to a patient as a non-refillable prescription as part of treatment for a surgical procedure that occurred in a licensed healthcare facility;

(d) The quantity of the controlled substance which is prescribed or dispensed does not exceed an amount which is adequate for a single, seven-day treatment period and does not allow a refill.

Authority: *T.C.A. §§ 53-10-303(f) and 53-10-310.* ***Administrative History:*** *Emergency rule filed January 4, 2013; effective through July 3, 2013. Repeal and new rule filed April 2, 2013; effective July 1, 2013. Rule was previously numbered 1140-11-.06, but was renumbered 1140-11-.07 with the addition of a new rule 1140-01-.03 filed November 22, 2016; effective February 20, 2017.*

1140-11-.08 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.*