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Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. T.C.A. § 4-5-205

Agency/Board/Commission:	Department of Health
Division:	
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Revision Type (check all that apply):

x Amendment
x New
__ Repeal

Rule(s) Revised (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
1140-11	Controlled Substance Monitoring Database
Rule Number	**Rule Title**
1140-11-.01	Definitions
1140-11-.02	Access to Database
1140-11-.04	Submission of Information
1140-11-.05	Practice Sites- Electronic Access
1140-11-.06	Prescriber and Dispenser Responsibilities

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to http://state.tn.us/sos/rules/1360/1360.htm)

Chapter 1140-11
Controlled Substance Monitoring Database

Amendments

Paragraph (1) of Rule 1140-11-.01 Definitions is amended by deleting the rule in its entirety and substituting instead the following, so that as amended, the new rule shall read:

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

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

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

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

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

(e) "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;

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

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

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

(i) "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;

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

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

(l) "Hardship" means a situation where a dispenser, including a veterinarian, 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;

(m) "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;

(n) "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;

(o) "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;

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

(q) "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;

(r) "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;

(s) "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;

(t) "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).

Rule 1140-11-.02 Access to Database is amended by deleting the rule in its entirety and substituting instead the following language, so that as amended, the new rule shall read as follows:

(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.

(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.

(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 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(f), 53-10-304(b), 53-10-305(e), 53-10-306, and 53-10-308.

Rule 1140-11-.04 Submission of Information is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the new rule shall read as follows:

(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;

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

(k) Source of payment.

(2) 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.

(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 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.

Authority: T.C.A. §§ 53-10-303(f), 53-10-304 and 53-10-305.

Chapter 1140-11
New Rules

1140-11-.05 Practice Sites – Electronic Access.

1140-11-.06 Prescriber and Dispenser Responsibilities (Effective April 1, 2013).

1140-11-.05 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.

1140-11-.06 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;

(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.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
NA					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Commissioner of Health on March 26, 2013, and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 01/10/13

Rulemaking Hearing(s) Conducted on: (add more dates). 03/07/13

BARBARA E. WEST
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY
MY COMMISSION EXPIRES: May 5, 2015

Date: 3-26-2013

Signature:

Name of Officer: John J. Dreyzehner, MD, MPH, FAOCEM

Title of Officer: Commissioner Department of Health

Subscribed and sworn to before me on: March 26, 2013

Notary Public Signature: Barbara E. West

My commission expires on: 05/05/2015

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Robert E. Cooper, Jr.
Attorney General and Reporter

3-28-13
Date

Department of State Use Only

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SECRETARY OF STATE

Filed with the Department of State on: 4/2/13

Effective on: 7/1/13

Tre Hargett
Secretary of State

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

Public Hearing Comments
Controlled Substance Monitoring Database Rules
March 7, 2013

Megan Frazier Grosvenor spoke on behalf of the Tennessee Veterinarians Medical Association. Ms. Frazier commented on Rules 1140-11-.01(k), 1140-11-.01(o); 1140-11-.04(6); 1140-11-.05; and1140-11-.06. Ms. Frazier requested that changes be made to the rules to reflect the 2012 amendment to Tenn. Code Ann. § 53-10-304(d), which specifically exempts veterinarians from reporting to the Controlled Substance Monitoring Database, provided that, "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."

In keeping with this amendment, Ms. Frazier asked that revisions be made the definition of hardship, as defined in 1140-11-.01(k); the definition of patient, as defined in 1140-11-.01(o), that veterinarians be exempted from the requirements of proposed rule 1140-11-.04(6) ,1140-11-.05(1); and 1140-11.06(1).

In response to the Tennessee Veterinarians Medical Association's concerns, the following changes have been made to the Controlled Substance Monitoring Database Emergency Rules:

The definition of hardship in Rule 1140-11-.01(k), has been changed, to read as follows:

> "Hardship" means a situation where a dispenser, including a veterinarian, 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 any other situations as determined by the Committee in its sole discretion.

The definition of 1140-11-.01(o) has been amended to read as follows: "Patient" means a person or an animal who is receiving medical treatment from a prescriber."

The definition "client" is added to as definition (b) to section 1140-11-.01 and all other subsequent definitions are renumbered. The definition of "client" is defined as, "Client" means the owner or custodian of any animal under the care of a licensed veterinarian."

Rule 1140-11-.04(1)(c) has also been amended to read as follows:

(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;
  ...

Ms. Baeteena Black spoke on behalf of the Tennessee Pharmacists Association.
Ms. Black made public comment about the provisions of 1140-11-.02 Access to Database. Ms. Black stated that the Tennessee Pharmacists Association was concerned that access to the database may not be given, absent a written request and that the language utilized in the current rule was language previously used prior to the enactment of the Patient Safety Act of 2012 and asked that the rule be updated. The rule currently reads as follows:

(3) The persons listed in paragraph (2) 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.

In response to Ms. Black's concerns, 1140-11-.02(3) has been deleted from the rules.

A comment received from Julia Morris, General Counsel of Vanderbilt University, was read into the record at the Rulemaking Hearing. Ms. Morris commented that under Rule 1140-11-.01 (m) : Healthcare Practitioner extender" it states " [t]he prescriber or dispenser shall be responsible for all actions by the agents." Ms. Morris commented that it was her belief that such a rule would open up prescribers and dispensers to vicarious liability. Ms. Morris also sought clarification regarding the ratio of extenders to prescribers and the ability of extenders to function for multiple prescribes. Further, Ms. Morris asked whether or not the patient was required to receive a copy of database print out and whether or not such print-out would be part of the medical record.

To address Ms. Morris' concerns regarding vicarious liability, Rule 1140-11-.01(m) has been amended to read identically to the current statute regarding this issue:

(m) "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."

Regulatory Flexibility Addendum
Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

Regulatory Flexibility Analysis

Pursuant to the regulatory Flexibility Act of 2007, 2007 Pub. Acts, c. 464, § 4, eff. June 21, 2007, the Department of Health submits the following regulatory flexibility analysis:

(1) The extent to which the rule may overlap, duplicate, or conflict with other federal, state, and local governmental rules:

The amended rule does not overlap, duplicate, or conflict with other federal, state, and local governmental rules.

(2) Clarity, conciseness, and lack of ambiguity in the rule:

The amended rule exhibits clarity, conciseness, and lack of ambiguity in the rule.

(3) The establishment of flexible compliance and reporting requirements for small businesses:

All reporting requirements are the same for small and large businesses and are designed to insure that complete and accurate data are reported to the database.

(4) The establishment of friendly schedules or deadlines for compliance and reporting requirements for small businesses:

There are no such requirements contained in the amended rule. However, the Department is taking steps to educate stakeholders on the staged implementation of the Prescription Safety Act, the sunset period for the Act, and the availability of a waiver for entities covered by the Act who lack internet access.

(5) The consolidation or simplification of compliance or reporting requirements for small businesses:

The reporting requirements allow for complete and accurate data to be reported to the database and the reporting requirement is the same for both small and large businesses.

(6) The establishment of performance standards for small businesses as opposed to design or operational standards required in the proposed rule:

The amended rule does not establish design or operational standards.

(7) The unnecessary creation of entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs:

The amended rule creates no entry barriers or other effects that would stifle legitimate entrepreneurial activity, curb innovation, or increase costs for legitimate businesses. This law does, by design, aim to increase costs and stifle entrepreneurial activity and innovation by "pill mill" operators and other prescribers involved in inappropriate prescribing.

Economic Impact Statement

(1) The type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, or directly benefit from the proposed rule:

Dispensers, pharmacies and other healthcare facilities that are required to report information pertaining to controlled substances dispensed pursuant to the Controlled Substance Monitoring Act of 2002. Currently there are approximately 2,191 small businesses, pharmacists and dispensers subject to the proposed rule and these persons and businesses would bear the cost of the program change addressed in the proposed rule.

(2) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:

The amended rule may require expenditures by the dispensers, pharmacies and other healthcare facilities reporting to the database. However, many affected businesses are currently capable of complying with the proposed rule. Those impacted small businesses which are not currently capable of reporting in the new format would be required to obtain the new version of the reporting software.

(3) A statement of the probable effect on impacted small businesses and consumers:

The amended rule will have some effect on impacted small businesses and consumers. There may be change in treatment methods for pain, as well as an increase in referrals to specialists. Additionally, there may be a decrease in drug diversion, and a decreased willingness to prescribe controlled substances for pain.

(4) A description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and objectives of the proposed rule that may exist, and to what extent the alternative means might be less burdensome to small business:

There is no less burdensome, less intrusive or less costly alternative methods of achieving the purpose and objectives of the proposed rule.

(5) A comparison of the proposed rule with any federal or state counterparts:

Federal: The Commissioner is not aware of any Federal Counterparts:
State: The Commissioner is aware of similar rules in other states, including Kentucky and Virginia.

(6) Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule:

It is not possible to exempt the impacted small businesses from all or any part of the requirements contained in the proposed rule because the impacted small businesses are required to report under the Controlled Substance Monitoring Act of 2002. However, there is a hardship waiver for covered entities when internet access is unavailable to them.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 "any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments." (See Public Chapter Number 1070 (http://state.tn.us/sos/acts/106/pub/pc1070.pdf) of the 2010 Session of the General Assembly)

These rule amendments and new rule are not expected to have an impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

In order to implement the Prescription Safety Act of 2012, amendments need to be made to the current rules governing the Controlled Substance Monitoring Database, TENN. COMP. R. & REG.1140-11. Several definitions in the Rules located at TENN. COMP. R. & REG.1140-11-.01 must be amended in order to comport with current law. Some existing definitions are outdated, and the Prescription Safety Act of 2012 makes additional specifications and qualifications which must be applied to other existing definitions. Additionally TENN. COMP. R. & REG.1140-11-.02, which pertains to persons who may access the Controlled Substance Monitoring Database, is amended to comport with statutory language in the Prescription Safety Act of 2012. These amendments will allow greater access to the database.

Pursuant to TENN. COMP. R. & REG.1140-11-.04 (3) dispensers of Controlled substances are required to report to the controlled substance Monitoring Database Advisory Committee as required under the Controlled Substance Monitoring Act of 2002 ("Act") The existing rule requires that the dispensers utilize the May, 1995 version of the Telecommunications Format for Controlled Substances ("1995 version") established by the American Society for Automation in Pharmacy (ASAP). However, it has been determined that the 1995 version does not have a mechanism for handling "compounds" which contain controlled substances. The ability to properly identify controlled substances contained in a compound is central to the purpose of the database itself which has recently been expanded in public Chapter 310, and became effective on July 1, 2011, and reads as follows:

> The purpose of the database is to assist in research, statistical analysis, criminal investigations, enforcement of state or federal laws involving controlled substances, and the education of health care practitioners concerning patients who, by virtue of their conduct in acquiring controlled substances, may require counseling or intervention for substance abuse, by collecting and maintaining data as described in this part regarding all controlled substances in schedule II, III and IV dispensed in this state, and schedule V controlled substances identified by the controlled substance database advisory committee as demonstrating a potential for abuse.

The 2009 version of the Telecommunications Format for Controlled Substances established by ASAP contain mechanisms for identifying the controlled substances in compounds. This rule amendment changes the reporting requirement for all dispensers of controlled substances and would make it mandatory that dispensers report to the database by utilizing the 2009 version of the ASAP format. Additionally, these rules implement the portion of the Prescription Safety Act of 2012 which requires prescribers to check a patient's profile on the database before prescribing that patient an opioid or benzodiazepine. In accordance with the Prescription Safety Act of 2012, this provision of the rules will not take effect until April 1, 2013.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

Pursuant to T.C.A. 53-10-303 (f), the Commissioner of Health holds the authority to promulgate all rules and regulations necessary under the Act.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

These rules will have an impact on the lives of every citizen of the State of Tennessee, all of whom have been affected in some way by prescription drug abuse and diversion. The impact of these rules will be more pronounced for physicians and other prescribers, pharmacists, pharmacies, medical practices, hospitals, and other healthcare facilities and delivery systems. These rules also greatly impact local law enforcement agencies, judicial drug task forces, and the Tennessee Bureau of Investigation. To a lesser extent, these rules impact TennCare, the Department of Health, and the Department of Mental Health and Substance Abuse Services. All government entities impacted by these rules strongly urge their adoption. Although private sector stakeholders will experience an increase in compliance responsibilities, the problems caused by prescription drug abuse and

diversion have galvanized private sector support for these rules.

(D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

Opinion No. 11-24, March 8, 2011; requested by Sen. McNally.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

State and local government expenditures may minimally increase as a result of this rule.

(F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Jane Young, General Counsel, Tennessee Department of Health

Stefan Cange, Assistant General Counsel, Tennessee Department of Health

(G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Stefan Cange

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Office of General Counsel
220 Athens Way
Plaza One, Suite 210
Nashville, TN 37243
615-741-1611
Stefan.Cange@tn.gov

(I) Any additional information relevant to the rule proposed for continuation that the committee requests.

Mr. Cange will supply any additional information the committee may request.

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) "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;~~

(Rule 1140-11-.01, continued)

~~(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.~~

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

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

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

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

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

(e) "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;

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

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

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

(i) "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;

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

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

(l) "Hardship" means a situation where a dispenser, including a veterinarian, 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;

(m) "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

(Rule 1140-11-.01, continued)

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;

(n) "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;

(o) "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;

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

(q) "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;

(r) "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;

(s) "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;

(t) "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.*

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.~~

(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.

(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

(Rule 1140-11-.01, continued)

Directors, Director of Quality Oversight, and Associate Director of Pharmacy.

(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

(Rule 1140-11-.01, continued)

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 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(f), 53-10-304(b), 53-10-305(e), 53-10-306, and 53-10-308.* ***Administrative History:*** *Original rule filed December 22, 2005; effective March 7, 2006.*

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.

(Rule 1140-11-.03, continued)

(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.*

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.~~

(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;

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

(k) Source of payment.

(2) 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.

(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.

(Rule 1140-11-.03, continued)

(6) The dispenser 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.

Authority: *T.C.A. §§53-10-303(f) and 53-10-305.* ***Administrative History:*** *Original rule filed December 22, 2005; effective March 7, 2006.*

1140-11-.05 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.

1140-11-.06 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

(Rule 1140-11-.03, continued)

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;

(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.