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Sequence Number: 08-25-14
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File Date: 8-29-14
Effective Date: 11-27-14

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: Controlled Substance Monitoring Database
Contact Person: Stefan Cange
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Revision Type (check all that apply):
X Amendment
___ 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-.02	Access to Database

(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

Rule 1140-11-.02 Access to Database is amended by adding new subparagraphs (1)(a) and (1)(b) which shall read as follows:

(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.

Authority: T.C.A. §§ 53-10-303, 53-10-304, 53-10-305, 53-10-306, and 53-10-308.

* 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)
N/A					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Commissioner of Health (board/commission/ other authority) on 07/14/2014 (mm/dd/yyyy), 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: *05/16/14 (mm/dd/yy)*

Rulemaking Hearing(s) Conducted on: (add more dates). *07/14/14 (mm/dd/yy)*

Date: 7/17/14

Signature:

Name of Officer: Stefan Cange

Title of Officer: Assistant General Counsel, Department of Health

Subscribed and sworn to before me on: 7-17-14

Notary Public Signature:

My commission expires on: MY COMMISSION EXPIRES APRIL 19, 2017

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.

Robert E. Cooper, Jr.
Attorney General and Reporter

8-22-14
Date

Department of State Use Only

Filed with the Department of State on: 8-29-14

Effective on: 11-27-14

Tre Hargett
Secretary of State

FILED
AUG 29 AM 8:03
OFFICE OF
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.

There were no public comments, either written or oral.

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.

(If applicable, insert Regulatory Flexibility Addendum here)

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

The proposed 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 or rules.

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

(3) The establishment of flexible compliance and/or reporting requirements for small businesses.

All reporting requirements are the same for small and large businesses. The proposed rule does not contain any explicit penalty for noncompliance; a licensee that simply forgets to update their information or enters an incorrect number in the database accidentally will not be subject to discipline. However repeated or intentional noncompliance could be considered unprofessional conduct within the meaning of applicable laws and regulations that apply to impacted health professions.

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

A flexible compliance schedule exists, licensees will have 30 days after the change in a supervisory relationship to report updated information to the database.

(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 proposed 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 proposed rule creates no entry barriers or other effects that would stifle legitimate entrepreneurial activity, curb innovation, or increase costs for legitimate businesses.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council: Commissioner of Health

Rulemaking hearing date: 6/19/14

1. **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, and/or directly benefit from the proposed rule:**

   The proposed rule will affect every medical practice and small healthcare facility licensed in the state that employs advanced practice nurses and physician assistants with prescriptive authority, along with all medical practices or healthcare facilities that rely on healthcare extenders to check the CSMD. However, there are no compliance costs or benefits associated with the proposed rule.

2. **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:**

   There are no administrative costs required for compliance with the proposed rule. A basic familiarity with computers is the only skill necessary for compliance.

3. **Statement of the probable effect on impacted small businesses and consumers:**

   The proposed rule is unlikely to have an impact on small businesses or consumers. Compliance with the rule will require only a few moments of time. Information will be updated when supervisory relationships change, but this should only take a couple minutes at most (each time). A medical practice or facility which experiences an extremely high turnover of physicians, supervised prescribers (advance practice nurses, physician assistants), or healthcare extenders may be impacted, but such circumstances are unusual and are not likely to exist at a majority of impacted businesses.

4. **Description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule that may exist, and to what extent, such alternative means might be less burdensome to small business:**

   Due to the system architecture of the CSMD, there are no less burdensome, intrusive, or costly alternative methods of achieving the purpose and objectives of the proposed rule.

5. **Comparison of the proposed rule with any federal or state counterparts:**

   Federal: N/A

   State: N/A

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.**

   An exemption for small businesses would totally frustrate the purpose of the proposed rule. The proposed rule is intended to link healthcare practitioners with prescriptive authority and healthcare extenders with supervising physicians. This makes investigations and enforcement of the Legislature's laws difficult. Granting an exemption for small businesses would leave us where we are currently, since a majority of healthcare practitioners with prescriptive authority and healthcare extenders work in small businesses (private medical practices).

Impact on Local Governments

Pursuant to T.C.A. § 4-5-228(a), "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 financial impact on local governments."

The proposed rule amendments should not have a financial 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;

Rule 1140-11-.02 is being amended to require that those practitioners listed on the database provide their supervising physician's driver's license number and, in the event their supervising physician changes, to provide their new supervising physician's driver's license number within thirty days of the change.

This rule amendment is necessary to link providers with the provider's supervising physician. Currently, there is no other way to create this link in the database.

(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;

None.

(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 affect all providers enrolled in the controlled substance monitoring database who supervise other prescribers or who employ healthcare extenders to utilize the database on their behalf.

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

None.

(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;

These rule amendments should not result in any increase or decrease in state and local government revenue and expenditures.

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

Stefan Cange, Assistant General Counsel, 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, Assistant General Counsel, Department of Health

(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

Department of Health, Office of General Counsel, 665 Mainstream Drive, Nashville, Tennessee 37243, (615) 741-1611, Stefan.Cange@tn.gov.

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

None.

(Rule 1140-11-.01, continued)

(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).* ***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.*

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 that is registered in the database shall also

(Rule 1140-11-.02, continued)

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.

(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

(Rule 1140-11-.02, continued)

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.

(Rule 1140-11-.02, continued)

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. Emergency rule filed January 4, 2013; effective through July 3, 2013. Repeal and new rule filed April 2, 2013; effective July 1, 2013.*

1140-11-.03 ALTERNATIVE IDENTIFICATION OF PATIENTS.

(1) If a patient does not have a social security number or refuses to provide his or her social security number to be used as a patient identifier, then the board shall use the patient's driver's license number or telephone number as the patient identifier in the database.

(2) If a patient does not have a social security number, a driver's license number or a telephone number, then the board shall use the number "000-00-0000" as the patient identifier in the database.

(3) If a patient or a patient's agent refuses to provide his or her social security number, driver's license number or telephone number to his or her prescriber or dispenser, then the board shall use the number "999-99-9999" as the patient identifier in the database.

(4) If a patient's social security number is not available, then the board shall use the social security number, driver's license number or telephone number of the person obtaining the controlled substance on behalf of the patient as the patient identifier in the database or the numbers "000-00-0000" (does not have the data) or "999-99-9999" (refusal to provide data), as applicable.

(5) If a patient is a child who does not have a social security number, then the board shall use the parent's or guardian's social security number, driver's license number, telephone number, or number "000-00-0000" (does not have data) or number "999-99-9999" (refusal to provide data) as the patient identifier in the database.