PRESCRIPTION MONITORING PROGRAM STATE PROFILES – TENNESSEE

Research current through July 2014.

This project was supported by Grant No. G1399ONDCP03A, awarded by the Office of National Drug Control Policy. Points of view or opinions in this document are those of the author and do not necessarily represent the official position or policies of the Office of National Drug Control Policy or the United States Government.

TENNESSEE

http://health.state.tn.us/boards/Controlledsubstance/index.shtml
Andrew Holt, Administrator
(615) 253-1300
Andrew.holt@tn.gov

- Status of Program – operational
- Housing Entity – Department of Health
- Advisory Commission – yes
- Funding – not specified in PMP statutes or regulations
- Drugs Monitored – Schedules II – V
- Who's Required to Report Dispensing Information – dispenser or dispenser's agent; dispenser means a pharmacy, pharmacist, or healthcare practitioner licensed to dispense controlled substances
- Exemptions from Reporting – drug administered directly to a patient; drug samples; drugs dispensed by a veterinarian as long as the quantity dispensed is limited to an amount adequate to treat the non-human patient for a maximum of 48 hours; licensed narcotic treatment programs; drugs dispensed by a licensed healthcare facility as long as the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of 48 hours
- Nonresident Pharmacies Required to Report – yes
- Veterinarians Required to Report – yes
- Data Collection Interval – weekly/7 days; eff. Jan. 1, 2016, daily
- Notice to Consumers – no
- Interstate Sharing – with other PMPs and authorized users in other states
- Persons Authorized to Receive Information – county medical examiner; law enforcement and judicial/prosecutorial officials; licensing/regulatory boards; personnel of the office of the inspector general, the Medicaid fraud control unit, and the bureau of TennCare related to participants in TennCare; chief pharmacist, the state opioid treatment authority, and the medical director of the department of mental health and substance abuse services; quality improvement committee of hospital; patient; third party with signed consent form; prescribers; dispensers
- Delegates Allowed – yes
- De-identified Data Provided – yes
- Unsolicited Reports – to licensing boards
- Training Required – no
- Mandatory Enrollment – yes; all prescribers and dispensers
- Mandatory Access – yes; multiple circumstances; see States that Require Prescribers and/or Dispensers to Access PMP in Certain Circumstances, compilation of statutes, on NAMSDL's website for further information

West's Tennessee Code Annotated (2014)
Title 53. Food, Drugs and Cosmetics
Chapter 10. Legend Drugs
Part 3. Tennessee Prescription Safety Act of 2012

§ 53-10-303. Controlled substance database committee; membership; meetings; duties and responsibilities

<Text of section effective until July 1, 2016. See, also, section effective July 1, 2016.>

(a) There is created the controlled substance database committee. The committee members shall be:

(1) The executive director of the board of pharmacy, who shall serve as database manager;

(2) The director of the department of health's division of health-related boards;

(3) The executive director of the board of medical examiners;

(4) One (1) of the governor-appointed and licensed members of each of the following health care professional licensure boards or committees to be chosen by the licensing board or committee:

(A) The board of medical examiners;

(B) The board of osteopathic examination;

(C) The board of dentistry;

(D) The board of registration in podiatry;

(E) The optometry board;

(F) The board of veterinary medical examiners;

(G) The board of nursing;

(H) The board of medical examiners' committee for physician assistants; and

(I) The board of pharmacy; and

(5) One (1) of the members of the board of pharmacy and one (1) of the members of the board of medical examiners who were appointed to those boards to represent the general public. The boards shall choose those representatives.

(b) The committee shall have a chair and vice chair, who shall be elected annually from its members.

(c) The committee shall meet at least annually and as often as deemed necessary either at the call of the chair or upon request of at least three (3) members of the committee. A quorum for purposes of official actions by the committee shall be seven (7) members.

(d) The members of the committee chosen to serve by the individual licensure boards and committees, while serving on this committee, shall be deemed to be performing official duties as members of their original board or committee and shall be entitled to the same per diem and travel reimbursements as they would receive for performing their duties for their original board or committee. The member's original board or committee shall pay those per diems and travel reimbursements.

(e) At all times, except when considering, reviewing, discussing, advising or taking action in reference to specifically named individuals or dispensers identified from information contained in, or reported to the database, the committee shall be subject to title 8, chapter 44, part 1, regarding public meetings.

(f) The commissioner shall have the authority to promulgate rules and regulations, pursuant to the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, necessary for implementation of this part. The commissioner shall promulgate rules regarding:

(1) Establishing, maintaining and operating the database;

(2) Access to the database and how access is obtained;

(3) Control and dissemination of data and information in the database; and

(4) The sharing and dissemination of data and information in the database with other states or other entities acting on behalf of a state.

(g) The committee shall advise the commissioner of health with respect to any contemplated rulemaking under this part. The committee may make formal recommendations to the commissioner of health.

(h)(1) The committee shall have the duty to examine database information to identify unusual patterns of prescribing and dispensing controlled substances that appear to be higher than normal, taking into account the particular specialty, circumstances, patient-type or location of the prescriber or dispenser.

(2)(A) If the committee determines that a pharmacist or pharmacy has an unusually high pattern of dispensing controlled substances that is not explained by other factors, it shall refer the pharmacist or pharmacy to the chief board of pharmacy investigator.

(B) When the pharmacy investigator completes the investigation of any pharmacy or pharmacist referred to it by the committee pursuant to this subsection (h), the investigator shall report the results of the investigation back to the committee as follows:

(i) The investigator shall report that the investigation was dismissed if the results of the investigation indicate that the pharmacist or pharmacy had an unusually high dispensing pattern for explainable, legitimate and lawful reasons; or

(ii) The investigator shall report that the investigation was referred to the pharmacy board if the results indicate that a prescriber has an unusually high pattern of prescribing or dispensing controlled substances that are not explained by other factors.

(C) If the action taken by the board indicates that the pharmacist or pharmacy had an unusually high dispensing pattern for explainable, legitimate and lawful reasons, the committee shall take that finding into consideration before it again refers the same pharmacist or pharmacy to the investigator based upon similar conduct.

(3)(A) If the committee determines that a prescriber has an unusually high pattern of prescribing or dispensing controlled substances that are not explained by other factors, it shall refer the prescriber to the health related boards' investigation unit.

(B) When the boards' investigator completes the investigation of any prescriber referred to it by the committee pursuant to this subsection (h), the investigator shall report the results of the investigation back to the committee as follows:

(i) The investigator shall report that the investigation was dismissed if the results of the investigation indicate that the prescriber had an unusually high dispensing pattern for explainable, legitimate and lawful reasons; or

(ii) The investigator shall report that the investigation was referred to the health related boards if the results indicate that a prescriber has an unusually high pattern of prescribing or dispensing controlled substances that are not explained by other factors.

(C) If the action taken by the board indicate that the prescriber had an unusually high dispensing or prescribing pattern for explainable, legitimate and lawful reasons, the committee shall take that finding into consideration before it again refers the same prescriber to the health related boards' investigation unit based upon similar conduct.

(4) If a pharmacy investigator or a member of the health related boards' investigation unit has reason to believe during any part of an investigation that a prescriber or dispenser is in violation of a criminal law, the investigator is authorized to report the conduct to the appropriate district attorney general.

West's Tennessee Code Annotated (2014)
Title 53. Food, Drugs and Cosmetics
Chapter 10. Legend Drugs
Part 3. Tennessee Prescription Safety Act of 2012

§ 53-10-304. Controlled substance database; administration; purpose; data reporting

<Text of section effective until July 1, 2016. See, also, section effective July 1, 2016.>

(a) There is created within the department a controlled substance database to be attached administratively and for purposes of staffing to the board of pharmacy. The executive director of the board shall be responsible for determining staffing.

(b) The board and the committee shall establish, administer, maintain and direct the functioning of the database in accordance with this part. The board, upon concurrence of the committee, may, under state procurement laws, contract with another state agency or private entity to establish, operate, or maintain the database. Additionally, the board, upon concurrence of the committee, shall determine whether to operate the database within the board or contract with another entity to operate the database, based on an analysis of costs and benefits.

(c) 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 Schedules 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.

(d) The data required by this part shall be submitted in compliance with this part 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 controlled substance database committee as demonstrating a potential for abuse. The reporting requirement shall not apply for the following:

(1) A drug administered directly to a patient;

(2) Any drug sample dispensed;

(3) 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;

(4) 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

(5) 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.

West's Tennessee Code Annotated (2014)
Title 53. Food, Drugs and Cosmetics
Chapter 10. Legend Drugs
Part 3. Tennessee Prescription Safety Act of 2012

§ 53-10-305. Controlled substance database registration; dispenser information; electronic transmission

<Text of section effective until July 1, 2016. See, also, section effective July 1, 2016.>

(a) All prescribers with DEA numbers who prescribe controlled substances and dispensers in practice providing direct care to patients in Tennessee for more than fifteen (15) calendar days per year shall be registered in the controlled substance 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.

(b)(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;

(D) Controlled substance dispensed identifier;

(E) Quantity of controlled substance dispensed;

(F) Strength of controlled substance dispensed;

(G) Estimated days supply;

(H) Dispenser identifier;

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

(J) Whether the prescription was new or a refill;

(K) Source of payment; and

(L) Other relevant information as required by rule.

(2) The information in the database, as required by subdivision (b)(1), shall be submitted by a procedure and in a format established by the committee, at least once every seven (7) days for all the controlled substances dispensed during the preceding seven-day period.

(c) The committee shall have the authority to shorten the length of time dispensers are required to submit to the database through the promulgation of rules pursuant to the Uniform Administrative Procedures Act, compiled in title 4, chapter 5. When the committee shortens the length of time dispensers are required to submit to the database, the department shall provide notice to all dispensers who are registered in the database at least sixty (60) days prior to the date in which the rule goes into effect. If the committee shortens the length of time which dispensers must submit information to the database, a dispenser may provide to the committee a written statement indicating why it creates a hardship for that dispenser to submit information within that time period, and the committee may grant an extension up to seven (7) days within which that dispenser must submit the information to the database. Such a hardship extension shall be valid for two (2) years and may be renewed by the committee upon request of the dispenser.

(d) Any dispenser, except veterinarian dispensers, that uses a computerized system to record information concerning the dispensing of controlled substances, shall submit the required information to the database utilizing nationally recognized pharmacy telecommunications format standards.

(e) The board shall maintain the database in an electronic file or by other means established by the committee in such a manner so as not to infringe on the legal use of controlled substances, and in such a manner as to facilitate use of the database by the committee for identification of:

(1) Prescribing and dispensing practices and patterns of prescribing and dispensing controlled substances; and

(2) Individuals, facilities or entities that receive prescriptions for controlled substances from prescribers, and who subsequently obtain dispensed controlled substances from a dispenser in quantities or with a frequency inconsistent with generally recognized standards of dosage for that controlled substance, or by means of forged or otherwise false or altered prescriptions.

(f) The committee or a designee appointed by the committee shall review information in the database. If the committee or its designee determines from review that a prescriber or dispenser may have committed a violation of the law, the committee shall notify the entity responsible for licensure, regulation, or discipline of that prescriber or dispenser and shall supply information required by the entity for an investigation of the violation of the law that may have occurred.

(g)(1)(A) The committee shall by rule establish the electronic format in which the information required under this section shall be submitted to the database and shall allow for waiver of electronic reporting for individual dispensers for whom it would cause undue hardship as determined by the committee. The waiver may be valid for two (2) years from ratification by the committee.

(B) The committee may authorize a designee to initially approve a waiver subject to ratification by the committee.

(2) The committee shall ensure the database system records and shall maintain for reference:

(A) Identification of each person who requests or receives information from the database;

(B) The information provided to each person; and

(C) The date and time the information is requested or provided.

(h) The committee shall make rules to:

(1) Effectively enforce the limitations on access to the database as described in this part; and

(2) Establish standards and procedures to ensure accurate identification of individuals requesting information or receiving information from the database without a request.

West's Tennessee Code Annotated (2014)
Title 53. Food, Drugs and Cosmetics
Chapter 10. Legend Drugs
Part 3. Tennessee Prescription Safety Act of 2012

§ 53-10-306. Confidentiality; disclosure; penalties

<Text of section effective until July 1, 2016. See, also, section effective July 1, 2016.>

(a) Information sent to, contained in, and reported from the database in any format is confidential and not subject to title 10, chapter 7, regarding public records, and not subject to subpoena from any court and shall be made available only as provided for in § 53-10-308 and to the following persons in accordance with the limitations stated and rules promulgated pursuant to this part, or as otherwise provided for in § 53-10-311:

(1) Personnel of the committee specifically assigned to conduct analysis or research;

(2) Authorized committee, board, or department of health personnel or any designee appointed by the committee engaged in analysis of controlled substances prescription information as a part of the assigned duties and responsibilities of their employment;

(3) A prescriber conducting medication history reviews who is actively involved in the care of the 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 referenced under this subdivision (a)(3) shall have a separate identifiable authentication for access;

(4) 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 the patient; or a dispenser having authority to dispense controlled substances to the extent the information relates specifically to a current or a bona fide prospective patient to whom that dispenser has dispensed, is dispensing, or considering dispensing any controlled substance. Each authorized individual referenced under this subdivision (a)(4) shall have a separate identifiable authentication for access;

(5) A county medical examiner appointed pursuant to § 38-7-104 when acting in an official capacity as established in § 38-7-109; provided, any access to information from the database shall be subject to the confidentiality provisions of this part except where information obtained from the database is appropriately included in any official report of the county medical examiners, toxicological reports or autopsy reports issued by the county medical examiner under § 38-7-110(c);

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

(A) The office of inspector general;

(B) The medicaid fraud control unit; and

(C) The bureau of TennCare's chief medical officer, associate chief medical directors, director of quality oversight, and associate director of pharmacy;

(7) A quality improvement committee as defined in § 68-11-272 of a hospital licensed under title 68 or title 33, as part of the committee's confidential and privileged activities under § 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;

(8) Law enforcement personnel; provided, that such personnel are engaged in the official investigation and enforcement of state or federal laws involving controlled substances or violations under this part; and that any law enforcement personnel receiving information from the database pursuant to this section shall comply with the requirements of this subsection (a):

(A)(i) Any law enforcement agency or judicial district drug task force that wants 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 director. The list of pre-approved applicants shall be sent to the district attorney general in the judicial district in which the agency or task force has jurisdiction;

(ii) 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)(i) If the Tennessee bureau of investigation (TBI) wants 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 by the director;

(ii) 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, but not be limited to the:

(i) 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 business email addresses; and

(ii) Signatures of the applicant, the applicants approving supervisor and the district attorney general of the judicial district in which the applicant has jurisdiction or the approving division head and the TBI director;

(D) It shall be a duty of the board, as part of its duties to maintain the database pursuant to § 53-10-305(c), to receive and verify the lists of authorized applications sent to it by the district attorneys general and the director of the TBI pursuant to this subsection (a); or

(9) The judge of a drug court treatment program, created pursuant to title 16, chapter 22, that is participating in the pilot project pursuant to this act to the extent the information relates specifically to a current participant in the drug court treatment program. Any judge or personnel of a drug court treatment program receiving information from the database pursuant to this subdivision (a)(9) shall comply with the requirements of this subsection (a) and the following:

(A) Any judge of a participating drug court requesting information from the database shall submit an application to the board pursuant to subdivision (a)(9)(B) that must include acknowledgment by the district attorney general of the judge's judicial district that the judge is seeking information from the database on a current participant in the drug court treatment program;

(B) An application submitted by the judge of a drug court treatment program shall include:

(i) The applicant's name, title, agency, agency address, and the business email address;

(ii) The signatures of the judge and the district attorney general of the judicial district in which the judge has jurisdiction; and

(iii) The names of any current participants in the drug court treatment program that the judge has a reasonable belief may not be in compliance with the guidelines or rules of participation in the drug court treatment program as they pertain solely to the participant's unauthorized use or misuse of controlled substances. Such information shall not be considered a public record as defined by § 10-7-503; and

(C) The board shall, as part of the duty to maintain the database pursuant to § 53-10-305(e), receive the authorized application sent by the judge of the participating drug court treatment program pursuant to this subsection (a); or

(10) 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, is

prescribing or dispensing, or considering prescribing or dispensing any controlled substance. Each authorized individual referenced under this subdivision (a)(10) shall have a separate identifiable authentication for access.

(b) When requesting information from the database, the board shall require law enforcement personnel to provide a case number as part of the process for requesting information from the database. The case number entered shall correspond with an official investigation involving controlled substances and information requested should directly relate to the investigation.

(c) The board of pharmacy shall by rule, establish a fee for providing information to a law enforcement agency, judicial district drug task force, TBI or a judge of a drug court treatment program pursuant to this section. In determining the fee and type of fee to be charged, the board shall consider options such as an annual fee or a per use, incremental cost basis fee.

(d)(1) Law enforcement personnel and judicial district drug task force agents who are authorized to request information from the database shall resubmit their identifying application information that was submitted pursuant to subdivision (a)(8)(C) to the appropriate district attorney by November 20 of each year. Such resubmitted applications shall be sent by the appropriate district attorney general to the board by December 1 of 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 shall immediately notify the board of any changes to the list submitted or in the information submitted for each officer or agent on the list application.

(2) TBI agents who are authorized to request information from the database shall resubmit their identifying application information that was submitted pursuant to subdivision (a)(8)(C) to the TBI director by November 20 of each year. Such resubmitted applications shall be sent by the TBI director to the board by December 1 of 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 TBI director shall immediately notify the board of any changes to the list submitted or in the information submitted for each officer or agent on the list application.

(e)(1) 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.

(2) Any information obtained from the data base that is sent to a law enforcement official or a 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.

(3) Information obtained from the database by the judge of a drug court treatment program may be shared with personnel of a drug court treatment program. For the purposes of this subdivision (e)(3), "personnel of a drug court treatment program" includes a judge of a drug court and any

person employed by the drug court and designated by the judge to require access to the information in order to efficiently administer the drug court treatment program.

(4) Any information obtained from the database that is sent to a judge of a drug court treatment program shall also be sent to the district attorney general of the judicial district in which the judge has jurisdiction.

(f)(1) To ensure the privacy and confidentiality of patient records, 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.

(2) To ensure the privacy and confidentiality of patient records, information obtained from the database by a drug court treatment program shall be retained by the program director of the drug court treatment program. The information obtained from the database shall not be made public record, notwithstanding the use of the information in court for prosecution purposes.

(g) Any information disseminated pursuant to subdivisions (a)(1)-(7) shall be released to the individual or entity requesting the information by the database manager or by password protected internet access.

(h) Any prescriber, dispenser or healthcare practitioner extender receiving patient-specific information pursuant to subdivision (a)(1), (a)(2), (a)(3), or (a)(4) shall not disclose the information to any person other than:

(1) The patient to whom the information relates for the purpose of adjusting the patient's treatment plans or counseling the patient to seek substance abuse treatment;

(2) Other dispensers or prescribers who are involved or have a bona fide prospective involvement in the treatment of the patient, or dispensers or prescribers identified by the information for the purpose of verifying the accuracy of the information; or

(3) Any law enforcement personnel to whom reporting of controlled substances being obtained in a manner prohibited by § 53-11-401, § 53-11-402(a)(3) or (a)(6) and required by § 53-11-309, or any agent of the prescriber who is directed by the prescriber to cause a report to law enforcement to be made in accordance with § 53-11-309(a) and (d).

(4) A prescriber, healthcare practitioner extender or dispenser who may place a copy of a patient’s report obtained from the database pursuant to this section in that patient’s medical records. Once placed in a patient’s medical records, any copy of a patient’s report obtained from the database pursuant to this section shall be subject to disclosure on the same terms and conditions as medical records defined under §§ 63-2-101 and 63-1-117.

(i) If a law enforcement officer, judicial district drug task force agent, TBI agent or a judge of a drug court treatment program 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, agent or judge shall consult with the board of pharmacy inspector's office if a pharmacist and the health related boards' investigations unit if a prescriber.

(j)(1) At least every six (6) months, the board 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 director of the TBI for all TBI agents making requests during the previous six (6) months.

(2) Each district attorney general and the TBI director shall use the list to perform an audit to determine if the database information requests made during the preceding six (6) month period correspond to specific cases under investigation in the applicable judicial district or by the bureau and if the information requested is relevant and pertinent to an investigation.

(3) Each district attorney general and the TBI director shall verify all database information requests contained on the list received and send it back to the board within sixty (60) days of receipt. If a database information request does not correspond to an investigation in the applicable jurisdiction or if the information requested was not relevant or pertinent to the information requested, the district attorney general or director shall so note on the verified list and shall investigate the discrepancy and make a report back to the board within a reasonable period of time.

(4) The results of the audit conducted pursuant to subdivision (j)(2) 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 licensure board, the results of the audit conducted pursuant to subdivision (j)(2) shall not be discoverable by the prescriber, dispenser or healthcare practitioner extender during either such period.

(k)(1) Any person who obtains or attempts to obtain information from the database by misrepresentation or fraud is guilty of a Class A misdemeanor.

(2) Any person who knowingly uses, releases, publishes, or otherwise makes available to any other person or entity any information submitted to, contained in, or obtained from the database for any purpose other than those specified in this part is guilty of a Class A misdemeanor.

(3) Intentional unauthorized use or disclosure of database information by law enforcement personnel, judicial district drug task force members or TBI agents shall be punishable as a Class A misdemeanor.

(4) Any law enforcement personnel, judicial district drug task force member or TBI agent charged with a violation of this section shall have such person's authorization to request information from the database suspended pending final disposition of any criminal prosecution. Any law enforcement personnel, judicial district drug task force member or TBI agent found guilty of a violation of this subsection (i) shall have such person's authorization to request information from the database permanently revoked.

(5) Where an individual authorized under subsection (a) acts in good faith in accessing or using information from the database in accordance with the limitations under this part, that person shall not incur any civil or criminal liability as a result of that use or access.

(l)(1) The following personnel of the department of mental health and substance abuse services actively engaged in analysis of controlled substances prescription information as a part of their assigned duties and responsibilities shall have access to the database for controlled substances prescription information for specific patients:

(A) The chief pharmacist;

(B) The state opioid treatment authority (SOTA) or SOTA designee; and

(C) The medical director.

(2) Aggregate controlled substances prescribing information from the database may be provided upon request by the following personnel of the department of mental health and substance abuse services, who are actively engaged in analysis of controlled substances prescription information as provided in this subsection (l), and may be shared with other personnel of the department of mental health and substance abuse services as needed to fulfill assigned duties and responsibilities:

(A) The chief pharmacist;

(B) The SOTA; or

(C) The medical director.

(m) Where an investigation is conducted under § 38-7-109, and information within the database is obtained pursuant to the requirements of this part, there exists a rebuttable presumption that the county medical examiner is acting in good faith.

(n) Prohibited access to, an inappropriate request for, or illegal disclosure of information from the database by a judge of a drug court treatment program shall be considered a violation of the canons of the code of judicial conduct, including Rules 1.2, 1.3 and 3.5.

(o) Authorized committee, board, or department personnel and any designee appointed by the committee engaged in analysis of controlled substances prescription information as a part of the assigned duties and responsibilities of their employment may publish, or otherwise make available to prescribers, dispensers and to the general public, aggregate unidentifiable personal data contained in or derived from the database for the purpose of educational outreach.

West's Tennessee Code Annotated (2014)
Title 53. Food, Drugs and Cosmetics
Chapter 10. Legend Drugs
Part 3. Tennessee Prescription Safety Act of 2012

§ 53-10-308. Release of confidential information

<Text of section effective until July 1, 2016. See, also, section effective July 1, 2016.>

(a) Notwithstanding any other provision of this part to the contrary, the committee or its designee:

(1) After consultation with the member of the committee who represents the board which has licensed the individual being considered for investigation, may release confidential information from the database regarding dispensers, prescribers, healthcare practitioner extenders, or patients, to a manager of any investigations or prosecution unit of an appropriate licensure board, committee, or other governing body that licenses or registers dispensers, prescribers or healthcare practitioner extenders and is engaged in an investigation, adjudication, or prosecution of a violation under any state or federal law that involves a controlled substance;

(2) May release confidential information from the database regarding patients to law enforcement personnel engaged in an investigation, adjudication, or prosecution of a violation under any state or federal law that involves a controlled substance, pursuant to the procedure established in § 53-10-306(a)(6);

(3) Shall release information from the database when ordered by a court to do so upon the court's finding that disclosure is necessary for the conduct of proceedings before the court regarding the investigation, adjudication, or prosecution of a violation under any state or federal law that involves controlled substances and after an appropriate protective order is issued regarding the information to be released to the court.

(b) Before the committee releases confidential information under this section, the applicant must petition the committee for the confidential information, particularly describe the information required, and demonstrate to the committee that the applicant has reason to believe that a violation under any state or federal law that involves a controlled substance has occurred and that the requested information is reasonably related to the investigation, adjudication, or prosecution of the violation.

(c) No information may be released under this section until it has been reviewed by the committee or its designee and the member of the committee who represents the board which has licensed the individual being considered for investigation, and certified that further investigation or prosecution is warranted and that release of the information is necessary to that continued investigation or prosecution.

West's Tennessee Code Annotated (2014)
Title 53. Food, Drugs and Cosmetics
Chapter 10. Legend Drugs
Part 3. Tennessee Prescription Safety Act of 2012

§ 53-10-310. Electronic access to controlled substance database; penalty

<Text of section effective until July 1, 2016. See, also, section effective July 1, 2016.>

(a) 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.

(b) This section shall not apply to any dispensers that are not required to report pursuant to § 53-10-304(d) or § 53-10-305(g).

(c) A violation of subsection (a) 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.

(d) Any prescriber, dispenser, individual or entity who is authorized to access the database by this part shall not be subject to a suit for civil damages or held civilly liable for the failure to register in, report to, or check the database, or for actions taken after reasonable reliance on information in the database, or accessing the database to determine whether or not the prescriber or dispenser's professional medical credentials are being inappropriately used or for reporting the same to the appropriate authorities, except as otherwise provided in this part.

(e)(1) All prescribers or their designated healthcare practitioner's extenders, unless otherwise exempted under this part, shall check the controlled substance database prior to prescribing one of the controlled substances identified in subdivision (e)(3) to a human patient at the beginning of a new episode of treatment and shall check the controlled substance database for that human patient at least annually when that prescribed controlled substance remains part of the 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 § 53-11-402.

(3) The controlled substances which trigger a check of the controlled substance database pursuant to subdivision (e)(1) include, but are not limited to, all opioids and benzodiazepines. By rule, the committee may require a check of the database for additional Schedule II-V controlled substances that are identified by the committee as demonstrating a potential for abuse.

(4) The board shall adopt rules in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, that establish standards and procedures to be followed by a dispenser regarding the review of patient information available through the database.

(5) Prescribers are not required to check the controlled substance database before prescribing or dispensing one of the controlled substances identified in subdivision (e)(3) 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;

(E) The controlled substance is prescribed for administration directly to a patient during the course of inpatient or residential treatment in a hospital or nursing home licensed under title 68 or a mental health hospital licensed under title 33.

(f) Each appropriate licensure board shall promulgate rules pursuant to the Uniform Administrative Procedures Act, to establish procedures, notice requirements, and penalties for prescribers and dispensers who fail to register in, report to, or check the controlled substance database as required.

(g) Notwithstanding any other provision of this part to the contrary, a prescriber, dispenser or healthcare practitioner extender shall not be in violation of this part during any time period in which the controlled substance database is suspended or not operational or the Internet is not operational or available as defined by rules promulgated by the commissioner after consultation with the committee.

West's Tennessee Code Annotated (2014)
Title 53. Food, Drugs and Cosmetics
Chapter 10. Legend Drugs
Part 3. Tennessee Prescription Safety Act of 2012

§ 53-10-311. Sharing and dissemination of data in database; agreements with other states and entities

Notwithstanding any other provision of this part to the contrary, the commissioner is authorized to enter into agreements with other states or other entities acting on behalf of a state for the purposes of sharing and dissemination of data and information in the database. Disclosure of such agreements shall be consistent with the provisions and limitations set forth in this part. All such agreements shall specifically provide which prescribers, dispensers, heathcare practitioner extenders or law enforcement personnel who are licensed, registered, or certified in other states shall have access to the database.

West's Tennessee Code Annotated (2014)
Title 53. Food, Drugs and Cosmetics
Chapter 11. Narcotic Drugs and Drug Control
Part 3. Regulations and Registration

§ 53-11-309. Controlled substances; attempt to obtain; report; immunity for health care providers

<Text of section effective until July 1, 2016. See, also, section effective July 1, 2016.>

(a) Any physician, dentist, optometrist, podiatrist, veterinarian, pharmacist, advanced practice nurse with a certificate of fitness issued under title 63, chapter 7, or physician assistant, hereinafter referred to collectively as "health care providers", who has actual knowledge that a person has knowingly, willfully and with intent to deceive, obtained or attempted to obtain controlled substances in the manner prohibited by § 53-11-402(a)(6) shall cause a report to be submitted regarding such activity within five (5) business days of obtaining such knowledge. The report should be submitted to the local law enforcement agency where the health care provider is located or, where one exists, to a judicial district or multi-judicial district drug task force. The controlled substance database advisory committee established by § 53-10-303 shall develop a form by no later than August 1, 2010, that health care providers may choose to use to make reports. The department of health shall make the form available on its web site.

(b) Any physician or advanced practice nurse with a certificate of fitness issued under title 63, chapter 7, or physician assistant who has actual knowledge that a person has knowingly, willfully and with the intent to deceive, obtained or attempted to obtain controlled substances in the manner prohibited by § 53-11-402(a)(6) and who is providing treatment to a person with a mental illness as defined in § 33-1-101 may, but is not required to, report as provided for under subsection (a).

(c) If the health care provider's actual knowledge of conduct prohibited by § 53-11-402(a)(6) is a result of the health care provider accessing the information available in the controlled substance database established in § 53-10-304, then notwithstanding the confidentiality provisions in § 53-10-306, the local law enforcement agency or, where one exists, a judicial district or multi-judicial district drug task force may receive from the health care provider only the pertinent information from the database for the thirty (30) days prior to the date of treatment leading to the alleged offense which ostensibly demonstrates non-compliance with § 53-11-402(a)(6). A report with information from the database not exceeding thirty (30) days prior to the date of treatment made under this provision to local law enforcement or, where one exists, to a judicial district or multi-judicial district drug task force is sufficient grounds for the production of complete or more detailed controlled substance database information for purposes of a criminal investigation or pending prosecution pursuant to the procedures established by § 53-10-306(b).

(d) A health care provider, or any person under the direction of the health care provider or any entity that assumes the responsibility of reporting for the provider who furnishes any information in good faith is immune from liability if a complaint, report, information, or record is furnished to a law enforcement agency.

(e) This section shall not apply in the case of a person who, on the date of treatment by the health care provider, is enrolled in or covered by TennCare.

Tennessee Rules and Regulations (2014)
0940. Department of Mental Health and Developmental Disabilities
0940-05. Office of Licensure
Chapter 0940-05-42. Minimum Program Requirements for Non-Residential Opioid Treatment Program Facilities

0940-05-42-.07 SERVICE RECIPIENT RECORD REQUIREMENTS.

(1) Facilities shall organize and coordinate service recipient records in a manner which demonstrates that all pertinent service recipient information is accessible to all appropriate staff and to the SOTA and TDMHSAS. The service recipient Central Registry I.D. Number shall be shown on each page of the service recipient's record.

(a) Records shall be preserved for not less than 10 years even if the Facility discontinues operations. The records may be generated, maintained, or transferred in whole or in part to any recording medium that assures accurate preservation of the record.

(b) The Facility shall discuss final storage or disposition of the Facility's records with TDMHSAS 90 days in advance of the closing of a Facility.

(2) The Facility shall document that the following assessments are completed prior to the development of the Individualized Program Plan (IPP).

(a) Screening. The sources and methods of verification shall have been recorded in the prospective service recipient's case folder. The screening process shall include:

1. Verification, to the extent possible, of a prospective service recipient's identity, including name, address, date of birth and other identifying data.

2. Drug history and current status, including determination and substantiation, to the extent possible, of the duration of substance dependence, determination by medical examination performed by a program physician of dependence on opium, morphine, heroin or any derivative or synthetic drug of that group, and determination of current Diagnostic and Statistical Manual (DSM) diagnosis.

3. Medical history, including past and family medical history, HIV status, pregnancy, a six-month history of prescriber medications, over-the-counter medications used frequently, and the patterns of specific usage of alcohol or other drugs for the past 30 days, and active medical problems.

4. Verification of other prescribed controlled medications through the PMP.

5. Psychiatric history and current mental status exam.

6. Within 14 days of admission, physical assessment and laboratory tests, including drug screens, HIV status, if the prospective service recipient consents to be tested, pregnancy, sexually transmitted diseases, Mantoux tuberculosis tests, Hepatitis C, and others as directed by the SOTA.

7. Pregnancy tests for females at admission and at least annually thereafter, unless otherwise indicated.

8. Determination if the prospective service recipient needs special services, such as treatment for alcoholism or psychiatric services, and determination that the Facility is capable of addressing these needs either directly or through referral.

9. If a prospective service recipient is 18 years of age or older, verification of dependence on opium, morphine, heroin or any derivative or synthetic drug of that group for a period of two years or verification of one year of opioid dependence and one documented unsuccessful attempt at clinical treatment. If clinically appropriate, the program physician may waive these dependency and detoxification requirements for service recipients released from penal institutions (within six months after release), for pregnant service recipients with a verified pregnancy and for previously treated service recipients.

10. If a prospective service recipient is under 18 years of age, verification of two documented unsuccessful attempts at detoxification within a twelve month period. Additionally, no person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian or responsible adult designated by the SOTA consents in writing to such treatment.

(3) A voluntary, written, program-specific informed consent to treatment from each service recipient at admission to include:

(a) Information about all treatment procedures, services and other policies and regulations throughout the course of treatment, including clinic charges in the form of a fee agreement signed by the service recipient;

(b) Consent to the individualized, prescribed therapy before dosing begins, including information about potential interactions with and adverse reactions to other substances, including those reactions that might result from interactions and adverse reactions to alcohol, other prescribed or over-the-counter pharmacological agents, other medical procedures and food;

(c) Information to each service recipient that the goal of opioid treatment is stabilization of functioning;

(d) Information that detoxification from opioids over 30 to 180 days is a treatment alternative to long-term maintenance;

(e) Acknowledgement that the service recipient has been informed of the Facility's rules regarding service recipient conduct and responsibilities and continuing documentation of the service recipient's compliance with the Facility's policies;

(f) Acknowledgement that the service recipient has been informed of his or her rights (0940-05-42-.27);

(g) Information that at regular intervals, in full consultation with the service recipient, the program shall discuss the service recipient's present level of functioning, course of treatment and future goals; and

(h) Information that the service recipient may choose to withdraw from or be maintained on the medication as s/he desires unless medically contraindicated;

(4) A narrative biopsychosocial history completed within 30 days of the service recipient's admission;

(5) Medical reports including results of the physical examination; past and family medical history; review of systems; laboratory reports, including results of required toxicology screens; and progress notes, including documentation of current dose and other dosage data. Information in the medical record shall be entered by physicians and other licensed health professionals;

(6) Dated case entries of all significant contacts with service recipients, including a record of each counseling session in chronological order;

(7) Dates and results of case conferences for service recipients;

(8) The initial treatment plan, any amendments to the plan, reviews of the plan and the long-term, individualized treatment plan, including any amendments to that document and reviews of the plan;

(9) Documentation that services listed in the plan are available and have been provided or offered;

(10) Documentation that the service recipient was informed about the process and factors considered in decisions impacting service recipient treatment (for example, take-home medication privileges, changes in counseling sessions, changes in frequency of toxicology screens) or any other significant change in treatment, both positive and negative;

(11) A record of correspondence with the service recipient, family members and other individuals and a record of each referral for services and its results;

(12) Documentation that the service recipient was provided a copy of the Facility's rules and regulations and a copy of the service recipient's rights and responsibilities and that these items were discussed with her or him;

(13) A closing summary, including reasons for discharge and any referral. In the case of death, the reported cause of death shall be documented;

(14) A written fee agreement as detailed in Rules Chapter 0940-05-42-.06 dated and signed by the service recipient (or the service recipient's legal representative) prior to provision of any services. This fee agreement shall include an explanation of the financial aspects of treatment and the consequences of nonpayment of required fees, including the procedures for medically supervised withdrawal in the event the service recipient (or service recipient's legal representative) becomes unable to pay for treatment;

(15) Documentation of Central Registry clearance as required under these rules; and

(16) All other information and documents as required by the SOTA and these rules.

Tennessee Rules and Regulations (2014)
0940. Department of Mental Health and Developmental Disabilities
0940-05. Office of Licensure
Chapter 0940-05-42. Minimum Program Requirements for Non-Residential Opioid Treatment Program Facilities

0940-05-42-.15 MEDICATION MANAGEMENT.

(1) Opioid Drugs. Facilities shall develop and implement written policies and procedures for prescription, dispensing and administration of opioid drugs and their security. No standardized routines or schedules of increases or decreases of medications may be established or used. These policies and procedures shall include the following:

(a) Administration.

1. A program physician shall perform a medical assessment to determine the service recipient's initial dose and schedule. The physician shall communicate the initial dose and schedule to the person supervising medication.

2. The proper initial dose shall be based on the clinical judgment of the program physician who has examined the service recipient and who has considered all available relevant information, including, but not limited to, drug screens, quantitative methadone levels, service recipient interview, and specific circumstances pertaining to the individual service recipient.

3. A physician may assign such dose and schedule by verbal order only on an emergency basis. If a verbal order is given, the physician shall examine the service recipient within 72 hours. Both the verbal order and the results of the physical examination shall be documented in the service recipient's record. Verbal orders must be taken by a licensed nurse or physician assistant, qualified by training and experience, and categorically approved by the medical staff of the Facility. Upon hearing the order, the receiver shall record the order in the service recipient's record, and then shall read back the written order to the issuing professional to assure that the order is understood clearly. “Oral” and “Telephone” orders must be documented as such and staff recording must sign their name and title. “Oral” and “Telephone” orders must be countersigned by the physician no later than 72 hours.

4. The initial dose of methadone may not exceed 30 milligrams. Only in extraordinary circumstances may the total dose for the first day exceed 40 milligrams. A transferring service recipient may receive an initial dosage of no more than the last daily dosage authorized at the former facility unless in the clinical judgment of the medical director, there are extenuating circumstances documented in the records which justify an initial dosage that is greater than the last daily dosage authorized at the former facility.

5. Subsequent doses shall be authorized by a prescriber, as defined by Rule 0940-05-42-.01(2)(x). Additional dosage may be dispensed in the first day where the prescriber documents that the initial dose does not suppress withdrawal symptoms. Service recipients are stabilized on

methadone when they are receiving a therapeutic dose that is sufficient to stop opioid use and sufficient to keep the service recipient comfortable for at least 24 hours with no need to resort to illicit opioids to satisfy opioid cravings.

6. No dosage increases shall occur on the days that the Facility is closed.

7. No methadone may be administered unless the prospective service recipient has undergone all of the screening and admission procedures required, unless there is an emergency situation that is fully documented in the records. In that case, intake procedures shall be completed on the next working day. No take-home medication may be given in such an emergency.

8. The administration of greater than 100 milligrams of methadone to a service recipient requires written notification to the SOTA within 10 working days, signed by the program physician, which details clinical justification for exceeding 100 milligrams.

9. No dose of methadone in excess of 120 milligrams may be ordered or administered without the prior approval of the SOTA.

10. Benzodiazepine Use. If a service recipient has a positive benzodiazepine screen:

(i) The treatment team shall meet with the service recipient within 14 days of receiving the results of the screen, to develop a benzodiazepine action plan in the service recipient's record. The plan shall be reviewed and signed by the medical director;

(ii) If the plan requires the service recipient to become clean from benzodiazepines, a time period for detoxification shall be established. The plan must contain a justification for any time period longer than 90 days;

(iii) The Facility shall provide detoxification treatment services either directly or through referral to another provider of detoxification treatment services;

(iv) If the plan calls for the continued use of benzodiazepines, the Facility shall coordinate the care with a qualified prescriber and document this coordination in the service recipient's record;

(v) The plan shall contain requirements for counseling, frequency of urine drug screens, and the consequences for failing to comply with the action plan on take-home privileges, and continued treatment at the OTP; and

(vi) The plan and weekly progress notes about plan implementation shall be documented in the service recipient's record.

(b) Any opioid drug prescribed and administered shall be documented on an individual medication administration record that is filed with the IPP. The record shall include:

1. Name of medication;

2. Date prescribed;

3. Dosage;

4. Frequency of administration;

5. Route of administration;

6. Date and time administered; and

7. Documentation of staff administering medication or supervising self-administration.

(c) Take-home doses of methadone or buprenorphine shall be handled in accordance with applicable rules of the Substance Abuse and Mental Health Administration or other applicable federal agency.

1. All requests for take-home exceptions shall be reviewed and approved by the SOTA and any other applicable federal agency.

2. The Facility shall check the PMP database prior to requesting any take-home or dosing exceptions and shall submit this report to the SOTA with the exception request.

3. The Facility shall provide counseling prior to providing take-home doses to any service recipient. Progress notes in the service recipient's record shall document the counseling provided.

4. The Facility shall document in the service recipient's record the basis for approving "take-home" medication for the service recipient. The following criteria shall be considered in determining the service recipient's eligibility for "take-home" medications.

(i) Cessation of illicit drug use;

(ii) Regularity of program attendance;

(iii) Length of time and level of treatment in medication therapy (ability to responsibly self-medicate);

(iv) Absence of known recent criminal activity (especially drug dealing);

(v) Absence of serious behavioral problems;

(vi) Absence of abuse of drugs including excessive use of alcohol;

(vii) Other special needs of the service recipient, such as split dosing, physical health needs, pain treatment, etc.;

(viii) Capacity to safely store “take-home” medication within the service recipient's home;

(ix) Stability of the home environment and social relationships;

(x) Service recipient's work, school, or other daily-life activity schedule; and

(xi) Hardship experienced by the service recipient in traveling to and from the Facility.

(d) Adverse drug reactions and errors shall be reported to a program physician immediately and corrective action initiated. The adverse reaction or error shall be recorded in the drug administration record, the nurse progress notes and the IPP, and all persons who are authorized to administer medication or supervise self-medication shall be alerted.

(e) All medications shall be stored in a locked safe when not being administered or self-administered.

(f) Medication orders and dosage changes shall be written or printed on a form which clearly displays the physician's signature. The dosage dispensed, prepared or received shall be recorded and accounted for by written or printed notation in a manner which achieves a perpetual and accurate inventory at all times. Every dose shall be recorded in the service recipient's individual medication record at the time the dose is dispensed or administered. If initials were used, the full signature and credentials of the qualified person administering or dispensing shall appear at the end of each page on the medication sheet. The perpetual inventory shall be totaled and recorded in milligrams daily.

(g) Computer-based Recording.

1. Any such computerized system shall have the capability of producing a hard-copy printout of any medical or dosing order data which the OTP is responsible for maintaining under the laws and/or regulations of this state and/or the federal government. Any computerized system shall, upon the request of the SOTA, send or provide such a printout within 48 hours excluding weekends.

2. In the event that an OTP which utilizes such a computerized system experiences system down-time, the OTP must have a written or readily retrievable auxiliary policy and procedure for documentation of all medical and dosing orders. The auxiliary procedure shall ensure that each medical or dosing order is authorized, and that all appropriate data are retained for on-line data entry as soon as the computer system is available for use again.

(h) The Facility shall check the PMP database upon admission of the service recipient, at least every six months to determine if controlled substances other than methadone are being prescribed for the service recipient, and thereafter as clinically indicated. The service recipient's record shall include documentation of the check of the PMP database and the date upon which it occurred.

(i) Guest Dosing.

1. Guest dosing shall be provided for a maximum of 14 days. Anything beyond 14 days shall be approved by the SOTA before dosing occurs.

2. Service recipients shall have been enrolled at the home clinic for a minimum of 30 days before being eligible for a guest dose. Service recipients enrolled less than 30 days at the home clinic shall be eligible for guest dosing only if approved by the SOTA.

3. Service recipients shall have two consecutive clean urine drug screens before being eligible for a guest dose unless the medical director determines that the benefits of guest dosing outweigh the risks and documents the justification for granting guest dosing privileges in the service recipient's record.

Tennessee Rules and Regulations (2014)
0940. Department of Mental Health and Developmental Disabilities
0940-05. Office of Licensure
Chapter 0940-05-42. Minimum Program Requirements for Non-Residential Opioid Treatment Program Facilities

0940-05-42-.17 DRUG SCREENS.

(1) Random urine drug screening and other adequately tested toxicological procedures shall be used for the purposes of assessing the service recipient's abuse of drugs and evaluating a service recipient's progress in treatment.

(2) Drug screening procedures shall be individualized and shall include at least weekly random drug screens for newly admitted service recipients during the first 30 days of treatment and at least monthly thereafter.

(3) Service recipients on a monthly schedule whose drug screen reports indicate drug abuse shall be returned to a weekly schedule for at least two weeks, or longer, if clinically indicated.

(4) More frequent collection and analysis of samples during medically-supervised or other types of withdrawal may occur.

(5) Collection of observed specimens on an unannounced basis when using urine as a screening mechanism may occur if the staff believes that observation is necessary based on service recipient behavior or need.

(6) Each sample collected shall be screened to include, but not be limited to:

(a) Opioids including synthetics at common levels of dosing;

(b) Methadone or any other medication used by the Facility's program as an intervention for that service recipient;

(c) Benzodiazepines;

(d) Cocaine;

(e) Meth-amphetamine/amphetamines;

(f) Tetrahydrocannabinol (THC); and

(g) Other drugs as indicated by individual service recipient use patterns, community standards, regional variation or clinical indication (e.g., carisoprodol, barbituates) or drugs that are heavily used in the locale of the service recipient or as directed by the SOTA.

(7) Collection and testing shall be done in a manner that assures that urine collected from service recipients is unadulterated. Such collection and testing may include random direct observation conducted professionally, ethically and in a manner which respects service recipients' privacy.

(8) Positive Test. Any refusal to participate in a random drug test shall be considered a positive test. A positive test is a test that results in the presence of any drug or substances listed in section (6) of this rule that is illegal or for which the service recipient cannot provide a valid prescription or any drug or substance prohibited by the opioid treatment program or SOTA; the presence of medication which is documented as part of the service recipient's treatment plan shall not be considered a positive test.

(9) A positive drug test result after the first six months in an opioid treatment program shall result in the following:

(a) Upon the first positive drug test result, the opioid treatment program shall:

1. Provide mandatory and documented weekly counseling, which shall include weekly meetings with a counselor who is qualified by training, education and/or two years' experience in addiction treatment under appropriate clinical supervision; and

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days;

(b) Upon a second positive drug test result within six months of the first positive drug test result, the opioid treatment program shall:

1. Provide mandatory and documented weekly counseling which shall include weekly meetings with a counselor who is qualified by training, education and/or two years' experience in addiction treatment under appropriate clinical supervision;

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days; and

3. Provide mandatory documented treatment team meetings with the service recipient;

(c) Upon a third positive drug test result within six months of the second positive drug test result, the opioid treatment program shall:

1. Provide mandatory and documented weekly counseling, which shall include weekly meetings with a counselor who is qualified by training, education and/or two years' experience in addiction treatment under appropriate clinical supervision;

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days; and

3. Provide mandatory and documented treatment team meetings with the service recipient which shall include, at a minimum: the need for continuing treatment; a discussion of other treatment

alternatives; and documentation that the service recipient has been advised that the service recipient may be discharged for continued positive drug tests; and

(d) Upon a fourth positive drug test result within six months of the third positive drug test result, opioid treatment program shall:

1. Through an assessment of the service recipient's IPP, address the on-going multi-drug use through increased group and individual counseling, intensive outpatient and residential clinical treatment. The treatment team shall consider each service recipient's condition and address the situation from an individualized clinical perspective;

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days; and

3. If the service recipient refuses recommended, more intensive levels of care, the service recipient shall be immediately enrolled in an individualized, medically supervised detoxification plan for up to two weeks, followed by immediate discharge from the opioid treatment program.

(10) The Facility shall document both the results of toxicological tests and the follow-up therapeutic action taken in the service recipient record.

(11) Treatment programs shall work carefully with toxicology laboratories to ensure valid, appropriate results of toxicological screens. Workplace testing standards are not appropriate for urine testing.

(12) The Facility shall ensure that its physicians demonstrate competence in interpretation of "false negative" and "false positive" laboratory results as they relate to physiological issues, differences among laboratories, and factors that impact absorption, metabolism and elimination of opioids.

(13) The program physician shall thoroughly evaluate a positive toxicological screen for any potentially licit substance such as benzodiazepines, carisoprodol, barbiturates and amphetamines. The Facility shall verify with appropriate releases of information that:

(a) The service recipient has been prescribed these medications by a licensed prescriber for a legitimate medical purpose; and

(b) The prescribing physician is aware that the service recipient is enrolled in an opioid treatment program.

(14) If the service recipient refuses the release of information to contact his or her physician but can produce prescriptions and/or other evidence of legitimate prescription (such as current medication bottles, fully labeled), the team shall consider the service recipient's individual situation and the possibility that he or she may be dismissed from the care of his or her physician if the physician discovers that the service recipient is in medication-assisted treatment. The

program physician shall make the ultimate decision as to the service recipient's continuing care in the clinic and the circumstances of that care.

(15) Absence of methadone or other medications prescribed by the Facility for the service recipient shall be considered evidence of possible medication diversion and evaluated by the physician accordingly.

(16) As appropriate and necessary, the SOTA shall develop guidelines for frequency of toxicological screening for alternative treatment modalities such as buprenorphine.

(17) The Facility shall access the PMP:

(a) Upon admission of a service recipient;

(b) Before the initial administration of methadone or other treatment in an opioid treatment program;

(c) After any positive drug test for prescription medication;

(d) Every six months to determine if controlled substances other than methadone are being prescribed for the service recipient. The service recipient's record shall include documentation of the check of the PMP database and the date upon which it occurred; and

(e) Each PMP access shall confirm that the service recipient is not seeking prescription medication from multiple sources.

(18) Nothing contained in this rule shall preclude any opioid treatment program from administering any additional drug tests it determines necessary.

Tennessee Rules and Regulations (2014)
1140. Board of Pharmacy
Chapter 1140-11. Controlled Substance Monitoring Database

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.

(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.

Tennessee Rules and Regulations (2014)
1140. Board of Pharmacy
Chapter 1140-11. Controlled Substance Monitoring Database

1140-11-.04 SUBMISSION OF INFORMATION.

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

(a) Prescriber identifier;

(b) Dispensing date of controlled substance;

(c) Patient identifier and/or client identifier;

(d) Controlled substance dispensed identifier;

(e) Quantity of controlled substance dispensed;

(f) Strength of controlled substance dispensed;

(g) Estimated number of days' supply;

(h) Dispenser identifier;

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

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

(7) If the dispenser does not have an automated recordkeeping system capable of producing an electronic report of the required data in the format established by the ASAP, or for whom electronic reporting would cause an undue hardship as determined by the Committee, then that dispenser may request a waiver from the electronic reporting requirement from the Committee. The waiver may be valid for two (2) years from ratification by the Committee.

(8) If the Committee grants the dispenser a waiver from the electronic reporting requirement, then the dispenser shall comply with an alternative method of reporting the data as determined by the Committee, such as submitting the required data in writing on a form approved by the Committee.

Tennessee Rules and Regulations (2014)
1140. Board of Pharmacy
Chapter 1140-11. Controlled Substance Monitoring Database

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.

Tennessee Rules and Regulations (2014)
1200. Department of Health, Department of Environment and Conservation, and Department of Finance and Administration
1200-34. Division of Pain Management Clinics
Chapter 1200-34-01. Pain Management Clinics

1200-34-01-.07 MEDICAL DIRECTOR RESPONSIBILITIES.

(1) Clinic Operation and Personnel.

(a) The medical director of a pain management clinic shall:

1. oversee all of the pain management services provided at the clinic;

2. be on-site at the clinic at least twenty percent (20%) of the clinic's weekly total number of operating hours;

3. ensure that each supervising physician for each of the health care providers working at the clinic complies with the supervision requirements contained in Tenn. Comp. Rules and Regulations Chapter 0880-03 and Chapter 0880-06, or Rule 1050-02-. 15, as applicable. Should the medical director of the clinic serve as a health care provider's supervising physician, the medical director must ensure that he or she complies with Chapter 0880-03 and Chapter 0880-06. or Rule 1050-02-. 15, as applicable;

4. ensure that all health care providers employed by or working at the pain management clinic comply with applicable state and federal laws and rules relative to the prescribing of controlled substances in the pain management clinic;

5. ensure the establishment of protocols for the health care providers employed by or working at the pain management clinic as provided in Tenn. Comp. Rules and Regulations Chapter 0880-03 and Chapter 0880-06 and ensure that providers comply with such protocols, as well as any other established policies and procedures;

6. ensure that, in the event that the medical director for the clinic is unable to fulfill his or her duties on a temporary basis because of illness, vacation, or unavailability, there is an alternate or substitute medical director meeting the same qualifications as a medical director under 1200-34-01-.09;

7. establish quality assurance policies and procedures, which, at a minimum, include, but are not limited to:

(i) documentation of the background, training, licensure, and certifications for all pain management clinic staff providing patient care;

(ii) a written drug screening policy and compliance plan for patients to include random urine drug screening as clinically indicated, but at a minimum, upon each new admission and once every six (6) months thereafter;

(iii) use of substance abuse risk assessment tools upon new patient admission and periodic review or re-assessment;

(iv) evaluating and monitoring the quality and appropriateness of patient care, the methods of improving patient care as well as identifying and correcting deficiencies, and the opportunities to improve the clinic's performance and quality of care;

(v) medication counts for any controlled substances prescribed by the clinic to the clinic's patients;

(vi) use of patient agreements and periodic review of such agreements;

(vii) health care provider access to and review of patient information contained in the controlled substance monitoring database in accordance with T.C.A. §§ 53-10-301 - 53-10-309, as clinically indicated, but at a minimum upon each new admission and once every six (6) months thereafter;

(viii) documentation of requests for records from other health care providers;

8. establish an infection control program to provide a sanitary environment for the prevention, control, and investigation of infections and communicable diseases, including, but not limited to:

(i) written infection control policies and procedures;

(ii) techniques and systems for identifying, reporting, investigating and controlling infections at the clinic;

(iii) written policies and procedures relative to the use of aseptic techniques;

(iv) training for clinic staff providing direct patient care relative to infection control and aseptic techniques; and

(v) a log of incidents related to infectious and communicable diseases and the corrective action taken;

9. establish written policies and procedures for health and safety requirements at the clinic;

10. ensure compliance with the patient safety standards established by the licensing boards for each health care provider;

11. establish written policies and procedures to assure patient access to their medical records and continuity of care should the pain management clinic close.

(2) Records, Reporting Requirements, and Patient Billing Procedures.

(a) The medical director shall ensure that each health care provider employed by or working at a certified pain management clinic shall maintain complete and accurate medical records of patient consultation, examination, diagnosis, and treatment, which shall include, but not be limited to the following:

1. patient medical history;

2. physical examination;

3. diagnostic, therapeutic, and laboratory results;

4. evaluations and consultations;

5. treatment objectives;

6. documentation of informed consent and discussion of risks and benefits of treatment provided;

7. treatments and treatment options;

8. medications prescribed (including date, type, dosage and quantity prescribed);

9. instructions and agreements;

10. periodic reviews;

11. reason for prescribing or dispensing more than a seventy-two (72) hour dose of controlled substances for the treatment of chronic nonmalignant pain;

12. a notation indicating whether the controlled substance monitoring database had been accessed for a particular patient;

13. copies of records, reports, or other documentation obtained from other health care providers;

14. results of urine drug screens to be performed as clinically indicated, but at a minimum upon each new admission and once every six (6) months thereafter.