**RULES**
**OF**
**THE TENNESSEE DEPARTMENT OF HEALTH**

**CHAPTER 1145-01**
**COMMISSIONER'S CONTROLLED SUBSTANCE MONITORING DATABASE RULES**

**TABLE OF CONTENTS**



**1145-01-.01 DEFINITIONS.**

The following definitions shall be applicable to this chapter:

(1) "Commissioner" means the Commissioner of Health.

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

(3) "Controlled substance(s)" means a drug, substance, or immediate precursor in Schedules I through VI as defined or listed in the Tennessee Drug Control Act, compiled in T.C.A., Title 39, Chapter 17, part 3.

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

(5) "Department" means the Department of Health.

(6) "Dispense" means to physically deliver a controlled substance covered by this chapter to any person, institution or entity with the intent that it be consumed away from the premises from which it is dispensed. It does not include the act of writing a prescription by a practitioner to be filled at a pharmacy. For purposes of this part, physical delivery includes mailing controlled substances into this state.

(7) "Dispenser" means the entity or individual that has the authority to and actually physically delivers a controlled substance to any person with the intent that it be consumed away from the premises from which it is dispensed. For purposes of reporting, "dispenser" as used in this section means a pharmacy where a controlled substance is dispensed from a licensed pharmacy and means an authorized individual when a controlled substance is dispensed outside a licensed pharmacy.

(8) "Healthcare practitioner," for the purposes of this part only, means:

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

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

(c) A certified registered nurse anesthetist (CRNA) as described in T.C.A. § 63-7-103.

(Rule 1145-01-.01, continued)

(9) "Law enforcement personnel" means agents of the Tennessee bureau of investigation, agents of a judicial district drug task force, drug enforcement administration agents, and certified law enforcement officers certified pursuant to T.C.A. § 38-8-107, and certified law enforcement officers by other states.

***Authority:*** *T.C.A. §§ 53-10-303(f), 53-10-305(e), 53-10-310(e), and 53-10-311(b).* ***Administrative History:*** *New rules filed October 28, 2021; effective January 26, 2022.*

**1145-01-.02 REPORTING TO THE DATABASE.**

(1) Dispensing healthcare practitioners or their agents 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.

(c) Veterinarians shall not be required to use a computerized system in order to submit required information to the Database. Instead, veterinarians may elect to submit information to the Database by any appropriate method set forth in the Tennessee Controlled Substance Database Data Collection Manual.

(2) The information to be included in the Database shall be submitted each business day and no later than the close of business on the business day after dispensing for all controlled substances as set forth in the Prescription Safety Act of 2016. Consistent with the Prescription Safety Act of 2016, veterinarians shall only be required to submit information to the Database every fourteen days.

(3) The dispensing healthcare practitioner or its agent, excluding a veterinarian, shall transmit or enter into the data collection application 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). Beginning on July 1, 2022, the dispensing healthcare practitioner or its agent, excluding a veterinarian, shall transmit or enter into the data collection application the data that is required pursuant to T.C.A. § 53-10-305 in the June 2017 version 4.2A of the Telecommunications Format for Controlled Substances established by the ASAP. The committee shall have the power to grant a waiver of the requirement to report or submit data in the June 2017 version 4.2A of the Telecommunications Format for Controlled Substances established by the ASAP upon a showing of hardship. Such waiver shall be good for up to two (2) years. The dispenser shall report, at minimum, all required fields even when reporting using alternative method as per waiver.

(4) Each controlled substance prescription required to be reported to the database shall be serially numbered by the unique dispenser.

(5) Each dispenser or dispenser's agent shall, regarding each controlled substance in Schedules II-V dispensed, submit to the database all of the following information in accordance with the guidance in the CSMD Data Collection Manual:

(a) Dispenser Information:

1. Dispenser NPI Number, if available;

(Rule 1145-01-.02, continued)

2. Either an NCPDP or NABP Provider ID, if available, as set forth in the CSMD Data Collection Manual;

3. DEA Number;

4. Dispenser's Name including the name of the Dispensing Organization or Individual where applicable;

5. Dispenser's Address (Street, City, State, Zip);

6. Dispenser's Phone Number;

7. Dispenser's Contact Person's Name;

8. Dispenser's Chain Site ID, if available; and

9. For Pharmacy Dispensers, the Pharmacy's Tennessee License Number; and

(b) Patient Information:

1. ID qualifier of Patient Identifier (assigning authority);

2. ID qualifier (identifies what type), as set forth in the CSMD Data Collection Manual ID of Patient;

3. Patient's Name, including First, Last, and Middle names as well as Name Prefixes and Suffixes. Prefixes and Suffixes shall not be included in the First, Last, or Middle name fields. For non-human patients the last name of the patient shall be the owner's family name. The first name shall be the name of the animal;

4. Patient Address including street address, city, state, and zip code. For non-US residents or others without an address information may be collected pursuant to the instructions in the CSMD Data Collection Manual;

5. Patient Phone Number;

6. Patient's Date of Birth;

7. Patient's Gender;

8. Patient's Species; and

9. Patient Location Code, if available; and

(c) Dispensing Information:

1. Reporting Status in compliance with the CSMD Data Collection Manual;

2. Prescription Number;

3. Prescription Written Date;

4. Prescription Refills Authorized;

5. Prescription Fill Date;

6. Prescription Refill Number, if applicable;

7. Product ID Qualifier, as set forth in the CSMD Data Collection Manual; and

8. Product ID;

9. Quantity Dispensed;

10. Days' Supply (calculated or estimated number of days the medication will cover);

11. Drug Dosage Units Code;

12. Transmission Form of Prescription Origin Code;

13. Partial Fill Indicator;

14. Dispenser NPI Number, if available;

15. Classification Code for Payment Type;

16. Prescription Sold Date;

17. Electronic Prescription Reference and Electronic Order Number, if available;

18. Quantity Prescribed (on the original prescription); and

19. Whether a prescription contains a notation that it was written pursuant to a medical necessity Diagnosis Code (ICD-10), if available.

(d) Prescriber Information:

1. Prescriber's National Providers Identifier (NPI) Number, if available;

2. Prescriber DEA number;

3. Prescriber DEA suffix, if applicable;

4. Prescriber last name, first name, middle name;

5. Prescriber Phone Number; and

6. Prescriber XDEA Number, if applicable.

(e) Compound Drug Information. If a compound substance is dispensed, the Compound Segment of ASAP shall be used to report:

1. Ingredient Sequence Number;

2. Product ID Qualifier, as set forth in the Data Collection Manual;

3. Product ID;

4. Compound ingredient quantity; and

(Rule 1145-01-.02, continued)

5. Compound drug dosage units code.

(6) All the data fields in Rule 1145-01-.02(5) are taken directly from the June 2017 version 4.2A of the Telecommunications Format for Controlled Substances established by the ASAP. It is expected that new versions of the Telecommunications Format for Controlled Substances established by ASAP will remain consistent with these data fields. Guidance on the use of the fields consistent is provided in the CSMD Data Collection Manual. In cases where certain fields are not available processes for reporting are contained in the CSMD Data Collection Manual.

(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 or its designee. The waiver may be valid for up to two (2) years from ratification by the Committee or its designee.

(8) If the Committee or its designee grants the healthcare practitioner 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 or its designee, such as submitting the required data in writing on a form approved by the Committee.

(9) In reporting the appropriate payment type, the healthcare practitioner shall, where possible, report discount cards as code 99 in the Classification Code for Payment Type.

***Authority:*** *T.C.A. §§ 53-10-303(f), 53-10-305(e), and 53-10-311(b).* ***Administrative History:*** *New rules filed October 28, 2021; effective January 26, 2022.*

**1145-01-.03 REGISTRATION WITH THE DATABASE.**

(1) Each healthcare practitioner registered with the database shall register each of his or her Tennessee DEA Registration Numbers, including suffixes, as part of his or her CSMD profile.

(2) Each healthcare practitioner required by Title 63 to maintain a collaborating physician shall register each and every of his or her collaborating physicians who allow that healthcare practitioner to prescribe controlled substances within his or her CSMD profile. Each collaborating physician who allows a collaborating healthcare practitioner to prescribe controlled substances shall be registered with the database profile within thirty (30) days after such collaborative relationship begins. Any collaborative relationship which lasts less than thirty days in a calendar year is exempt from registration unless such registration is required for the healthcare practitioner to have the necessary access to the database.

(3) Each healthcare practitioner registered with the database must maintain a unique valid e-mail address that she or he has access to and keep such e-mail address associated with his or her user profile in the database.

***Authority:*** *T.C.A. §§ 53-10-303(f), 53-10-305(e), 53-10-310(e), and 53-10-311(b).* ***Administrative History:*** *New rules filed October 28, 2021; effective January 26, 2022.*

**1145-01-.04 DRUGS OF ABUSE.**

Pursuant to T.C.A. § 53-10-310(e)(4), in addition to opioids and benzodiazepines, the Commissioner finds, and the Committee has found at Rule 1140-11-.02, that Schedule II amphetamines demonstrate such a potential for abuse that when prescribing Schedule II amphetamines, all healthcare practitioners, unless otherwise exempted, shall check the controlled substance database prior to prescribing Schedule II amphetamines to a human patient in accordance with T.C.A. § 53-10-310(e)(1).

(Rule 1145-01-.04, continued)

***Authority:*** *T.C.A. §§ 53-10-303(f), 53-10-304(c), 53-10-305(e), 53-10-310(e), and 53-10-311(b).* ***Administrative History:*** *New rules filed October 28, 2021; effective January 26, 2022.*

**1145-01-.05 MAINTENANCE OF INFORMATION FROM THE CSMD BY LAW ENFORCEMENT OFFICERS.**

(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 or such officer or agent's disclosed supervisor, and may only be shared with law enforcement personnel from other law enforcement agencies where there is a reasonable belief the information is relevant to an investigation regarding a violation of criminal law relating to controlled substances.

(2) 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.

***Authority:*** *T.C.A. §§ 53-10-303(f), 53-10-305(e), and 53-10-311(b).* ***Administrative History:*** *New rules filed October 28, 2021; effective January 26, 2022.*

**1145-01-.06 SHARING OF INFORMATION.**

For any individual who can access CSMD data pursuant to T.C.A. § 53-10-306(a)(1), (2), (3), or (4), the Commissioner may provide any data related to any patient for whom that individual has access, including any information collected and shared by the Commissioner pursuant to T.C.A. § 68-11-314, through the CSMD in any format the Commissioner determines will best achieve the purpose of the CSMD as set forth in T.C.A. § 53-10-304(c). The data provided through the CSMD must be data that the Commissioner is otherwise authorized to release and the recipient is otherwise authorized to receive.

***Authority:*** *T.C.A. §§ 53-10-303(f), 53-10-305(e), and 53-10-311(b).* ***Administrative History:*** *New rules filed October 28, 2021; effective January 26, 2022.*