

Tennessee Rules and Regulations [Currentness](#)

1140. Board of Pharmacy

665 MAINSTREAM DRIVE

NASHVILLE, TN 37243

ADMINISTRATIVE HISTORY

Original chapter 1140-01 was certified on June 7, 1974, under Chapter 491 of the Public Acts of 1974 as Rules in effect when Chapter 491 became effective. The Administrative History following each rule gives the date on which the rule was certified, or the date on which the rule was filed and its effective date, if promulgated after March 11, 1974. The Administrative History following each rule also shows the dates of any amendments or repeals.

Rules 1140-01-.04 and 1140-01-.31 filed June 7, 1974; effective July 7, 1974.

Amendments to rules 1140-01-.02, 1140-01-.07, 1140-01-.10, 1140-01-.12 through 1140-01-.15, 1140-01-.18, 1140-01-.20, 1140-01-.25, and 1140-01-.27 through 1140-01-.30 filed June 7, 1974; effective July 7, 1974.

Amendment to rule 1140-01-.14(3) filed June 25, 1975; effective July 25, 1975.

Amendment to rules 1140-01-.14(2), 1140-01-.18(1)(b), 1140-01-.29(2), 1140-01-.31(5), and 1140-01-.3 through 1140-01-.37 filed September 23, 1975; effective October 23, 1975.

Repeal of rules 1140-01-.02(h) and 1140-01-.07(g) filed January 11, 1977; effective February 10, 1977.

Amendment to rules 1140-01-.04(1), 1140-01-.14, 1140-01-.16, 1140-01-.19(6), and 1140-01-.28(1), (2), (4), (8), (9), (10) and (11)(b) filed January 11, 1977; effective February 10, 1977.

Rules 1140-01-.28(13), 1140-01-.31(2) and (7), and 1140-01-.38 filed January 11, 1977; effective February 10, 1977.

Amendments to rules 1140-01-.10, 1140-01-.24(1), 1140-01-.25, 1140-01-.30(1) and 1140-01-.31(5) filed December 15, 1977; effective January 16, 1978.

Rule 1140-01-.39 filed December 15, 1977; effective January 16, 1978.

Amendments to rules 1140-01-.28 and 1140-01-.31 filed April 27, 1978; effective July 14, 1978.

Amendments to rule 1140-01-.10 filed September 26, 1978; effective December 29, 1978.

Rules 1140-01-.40 and 1140-01-.41 filed September 26, 1978; effective December 29, 1978.

Original chapter 1140-01 filed November 22, 1978; effective January 8, 1979.

Amendments to rules 1140-01-.02, 1140-01-.07, and 1140-01-.31 filed April 11, 1979; effective July 30, 1979.

Repeal of chapter 1140-01 and new rules 1140-01-1-.01 through 1140-01-1-.10 filed February 7, 1983; effective March 9, 1983.

Original rules 1140-01-03-.01 through 1140-01-03-.24 and 1140-01-04-.01 through 1140-01-04-.21 filed February 7, 1983; effective March 9, 1983.

Amendments to rules 1140-01-.03, 1140-01-.04 and 1140-04-.12 filed December 17, 1984; effective March 16, 1985.

Amendment to rule 1140-01-.08 filed September 30, 1985; effective October 30, 1985.

Amendment to rule 1140-03-.11 filed November 25, 1985; effective February 12, 1986.

Amendment to rule 1140-01-.10 filed May 23, 1986; effective August 12, 1986.

Amendment to 1140-01-.07 and original chapter 1140-06 filed January 26, 1987; effective April 29, 1987.

Original chapter 1140-07-.01 through 1140-07-.07 filed October 1, 1987; effective November 15, 1987.

Amendment to rule 1140-03-.16 filed October 1, 1987; effective November 15, 1987.

Amendments to rule 1140-01-.10 filed October 1, 1987; effective January 27, 1988.

Amendments to rule 1140-03-.24 filed January 19, 1988; effective March 4, 1988.

Amendments to rules 1140-01-.02, 1140-01-.04 and 1140-01-.08 filed January 19, 1988; effective April 27,

1988.

Amendment to rule 1140-01-.10 filed November 18, 1988; effective February 28, 1989.

Amendment to rule 1140-01-.08 filed August 25, 1989; effective October 9, 1989.

Original chapter 1140-08 and amendments to rules 1140-01-.06, 1140-03-.18 and 1140-03-.21 filed November 15, 1989; effective December 30, 1989.

Amendment to rule 1140-01-.09 filed April 12, 1990; effective July 29, 1990.

Amendment to rule 1140-01-.10 filed October 18, 1990; effective January 29, 1991.

Amendment to rule 1140-01-.10 filed May 3, 1991; effective August 28, 1991.

Original rule 1140-03-.25 filed August 2, 1991; effective September 16, 1991.

Amendment to rules 1140-04-.12 and 1140-04-.13 filed August 30, 1991; effective November 27, 1991.

Amendment to rules 1140-01-.03, 1140-01-.08, 1140-03-.06, 1140-03-.18 and original rule 1140-01-.11 filed October 30, 1991; effective December 14, 1991.

Original chapter 1140-09 filed January 7, 1992; effective February 22, 1992.

Amendments to rules 1140-03-.03, 1140-03-.06, 1140-03-.22, 1140-04-.05 and 1140-07-.04 filed November 16, 1992; effective January 8, 1993.

Amendment to rule 1140-01-.10 filed December 22, 1992; effective March 31, 1993.

Amendment to rule 1140-01-.10 filed June 25, 1993; effective September 28, 1993.

Amendments to rules 1140-03-.04, 1140-03-.05, 1140-03-.18, 1140-03-.24, 1140-07-.01, 1140-07-.03, 1140-07-.04, 1140-07-.05, 1140-07-.06, and 1140-07-.07; original rules 1140-07-.08, 1140-07-.09, 1140-07-.10; original chapter 1140-10 filed March 30, 1994; effective June 13, 1994.

Amendment to rules 1140-01-.08, 1140-01-.09, 1140-05-.02 through 1140-05-.05 filed November 17, 1993; effective March 30, 1995.

Amendment to rule 1140-03-.25 filed January 30, 1995; effective May 31, 1995.

Amendment to rule 1140-01-.10 filed October 19, 1996; effective February 28, 1996.

Repeal of and new chapter 1140-01 through 1140-10 filed May 11, 1998; effective July 25, 1998.

Amendment to rules 1140-01-.10, 1140-01-.14, 1140-02-.02, 1140-03-.04, 1140-03-.14, 1140-04-.09, and 1140-05-.02 filed August 19, 2002; effective November 2, 2002.

Original chapter 1140-11 filed December 22, 2005; effective March 7, 2006.

Public necessity rule filed 1140-12 filed February 16, 2007; expired July 31, 2007.

Public necessity rules 1140-13-.01 through 1140-13-.08 filed November 25, 2008; effective through May 9, 2009.

New rule 1140-03-.16, and amendments to rules 1140-01-.01, 1140-01-.05, 1140-01-.14, 1140-03-.15, 1140-05-.01, and 1140-06-.03 filed November 24, 2008; effective February 7, 2009.

New rule 1140-13-.01 through 1140-13-.08 filed February 24, 2009; effective May 10, 2009.

Amendments to rules 1140-01-.01, .09, and .14 and 1140-02-.01 and .02 filed December 23, 2009; effective March 23, 2010.

Amendments to rules 1140-01-.03 and 1140-02-.02 filed January 4, 2012; effective April 3, 2012.

Emergency rules 1140-11-.01, .02, .04, .05 and .06 filed January 4, 2013; effective through July 3, 2013.

Repeal and new rules 1140-11-.01, .02, .04, .05 and .06 filed April 2, 2013; effective July 1, 2013.

Tenn. Comp. R. & Regs. 1140. Refs & Annos, TN ADC 1140. Refs & Annos

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-01. Introductory Rules \(Refs & Annos\)](#)**→→ 1140-01-.01 DEFINITIONS.**

- (1) “ACPE” means the Accreditation Council for Pharmaceutical Education.
- (2) “Alternate or alternative infusion pharmacy practice site” means a pharmacy practice site where parenteral, enteral or respiratory therapies, and ancillary supplies, medications and equipment are provided to patients in a non-institutional setting.
- (3) “Accreditation Council for Pharmacy Education (ACPE)” means the national organization for accreditation of professional degree programs in pharmacy and for accreditation of providers of continuing pharmacy education.
- (4) “Blood” means whole blood collected from a single donor and processed either for transfusion or further manufacturing.
- (5) “Blood fraction/component” means that part of blood separated by physical or mechanical means.
- (6) “Centralized Prescription Processing” is the filling or refilling of a lawful prescription order written by the patient's authorized prescriber by one (1) pharmacy licensed by the State of Tennessee at the request of another pharmacy licensed by the State of Tennessee for the delivery of the prescription drugs to the patient or patient's agent.
- (7) “Certified pharmacy technician” means an individual who is certified by a national or state agency that offers a certification program that is recognized by the board.
- (8) “Consultant pharmacist” means a pharmacist retained on a routine basis to consult with organizations, institutional facilities or patients in areas that pertain to the practice of pharmacy.
- (9) “Contact hour” means any hour of completed continuing pharmaceutical education programming which is:
 - (a) accredited by ACPE (including, but not limited to, live programs, independent study courses, home correspondence courses, and audio or video cassettes); or

- (b) approved by the board (including, but not limited to, attendance at state, district, or local pharmacy association meetings).
- (10) "Continuing education unit" means ten (10) hours of participation in an ACPE approved or board-approved continuing pharmaceutical education program under responsible sponsorship, capable direction, and qualified instruction.
- (11) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the prescription drug.
- (12) "Electronic medical or prescription order" means a medical or prescription order which is transmitted by computer technology other than by electronic image transmission.
- (13) "Facsimile (FAX) medical or prescription order" means a medical or prescription order which is transmitted by an electronic image transmission.
- (14) "Foreign pharmacy graduate" means a person whose undergraduate pharmacy degree was conferred by any college or school of pharmacy not accredited by the ACPE but which is listed in the World Health Organization World Directory of Colleges and Schools of Pharmacy, or otherwise approved by the Foreign Pharmacy Graduate Examination Committee (FPGEC) certification program as established by the National Association of Boards of Pharmacy.
- (15) "Hazardous product" means any substance that may be cytotoxic, genotoxic, oncogenic, mutagenic, teratogenic, or otherwise pose a potential health hazard.
- (16) "Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, and where patients spend a majority of their time within the facility, including but not limited to a(n) :
 - (a) adult care facility;
 - (b) assisted living facility;
 - (c) correctional facility;
 - (d) developmental disability center;
 - (e) hospital;

- (f) inpatient psychiatric center;
 - (g) intermediate care facility for the mentally retarded;
 - (h) mental health facility;
 - (i) nursing facility;
 - (j) personal care home;
 - (k) rehabilitation center;
 - (l) residential drug or alcohol treatment center;
 - (m) rest home;
 - (n) retirement center;
 - (o) sub-acute care facility; and
 - (p) university health center.
- (17) “Institutional pharmacy practice site” means a pharmacy practice site serving patients within an institutional facility.
- (18) “Medication order” means a prescription order for any prescription drug or device or related material issued by an authorized prescriber to authorized healthcare personnel in an institutional facility or institutional pharmacy practice site.
- (19) “National Association of Boards of Pharmacy (NABP)” means the professional organization that represents the individual state boards of pharmacy.
- (20) “Nuclear pharmacy practice site” means a pharmacy practice site providing radiopharmaceutical services.
- (21) “Patient counseling” means communication by the pharmacist of information to the patient or caregiver in order to improve therapeutic outcome.

- (22) "Pharmaceutical care" is the responsible provision of drug therapy through, among other things, pharmacists identifying potential and actual drug-related problems and resolving and preventing drug-related problems, for the purpose of achieving definite outcomes that improve a patient's quality of life. The outcomes include but are not limited to cure of a disease, elimination or reduction of a patient's symptomatology, arresting or slowing of a disease process and the preventing of a disease or symptomatology.
- (23) "Pharmacy internship" is a period of practical pharmacy experience under the direct supervision of a licensed pharmacist and pursuant to the rules of the board.
- (24) "Pharmacy practice site" means any place within this state where prescription drugs or prescription devices are dispensed and where pharmaceutical care is provided, and any place outside of the state where prescription drugs or prescription devices are dispensed and pharmaceutical care is provided to persons residing in this state.
- (25) "Preceptor" means an individual who is currently licensed as a pharmacist and who meets the qualifications of a preceptor under the rules of the board and participates in the education of pharmacy interns.
- (26) "Prescription department" means the area of a pharmacy practice site in which prescription drugs and devices and related materials are stocked and medical and prescription orders are compounded and dispensed.
- (27) "Quality assurance" means a system for identifying problems in patient care that are resolved via administrative, clinical, or educational actions to ensure that final products and outcomes meet applicable specifications.
- (28) "Radiopharmaceutical service" means, but is not limited to:
- (a) the compounding, dispensing, labeling, and delivering of radiopharmaceuticals;
 - (b) the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews;
 - (c) the proper and safe storage and distribution of radiopharmaceuticals;
 - (d) the maintenance of radiopharmaceutical quality assurance;
 - (e) the responsibility for advising, where necessary or where regulated, of the diagnostic and therapeutic value, hazards, and use of radiopharmaceuticals; and

- (f) the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a nuclear pharmacy practice site.
- (29) “Reciprocity” means to issue a license to an applicant who furnishes satisfactory proof of licensing by examination in another state or territory pursuant to the rules of the board.
- (30) “Shall” means that compliance is mandatory.
- (31) “Third party pharmacy program” means any system of providing for the reimbursement of medical or prescription orders and/or pharmaceutical care services under a contractual arrangement or agreement between a provider of such services and the third party program administrator who is not the consumer of those services.
- (32) “Third party pharmacy program administrator” means, but is not limited to, insurance companies, managed care organizations, health maintenance organizations, preferred provider organizations, pharmacy benefit managers, and pharmacy services administrative organizations.
- (33) “Unit dose packaging” means that packaging which is designed to hold a quantity of a drug product intended for administration as a single dose.

Authority: *T.C.A. §§ 63-10-101, 63-10-102, 6-10-404(5), (6), (14), (22), (26), (28), and (29), 63-10-304, 63-10-304(b)(1), 63-10-504(b)(1), and Chapter 966 of the Public Acts of 2008 §1.*
Administrative History: *Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed November 24, 2008; effective February 7, 2009. Amendment filed December 23, 2009; effective March 23, 2010.*

Tenn. Comp. R. & Regs. 1140-01-.01, TN ADC 1140-01-.01

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[Chapter 1140-01.](#) Introductory Rules ([Refs & Annos](#))

→→ **1140-01-.02 VIOLATIONS CONSTITUTE UNPROFESSIONAL CONDUCT.**

Any person who violates any rule of the board may be deemed guilty of dishonorable, immoral, unethical or unprofessional conduct within the meaning of [T.C.A. § 63-10-505\(6\)](#).

Authority: [T.C.A. §§ 63-10-101, 63-10-102, 63-10-202, 63-10-504\(b\)\(1\), and 63-10-505\(6\)](#). **Administrative**

History: Original rule certified June 7, 1974. Amendment filed August 14, 1974; effective September 13, 1974. Repeal filed January 11, 1977; effective February 10, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed January 19, 1988; effective April 27, 1988. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

Tenn. Comp. R. & Regs. 1140-01-.02, TN ADC 1140-01-.02

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-01. Introductory Rules \(Refs & Annos\)](#)**→→ 1140-01-.03 APPLICATION FOR A PHARMACIST LICENSE.**

- (1) An applicant for a license to engage in the practice of pharmacy shall submit the following to the Board office at time of application:
 - (a) A completed application on a form approved by the Board;
 - (b) Application and registration fees established in rule 1140-01-.10; and
 - (c) The result of a criminal background check, which the applicant shall pay for and cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's licensure application materials.
 - (d) Any application submitted which lacks required information or reflects a failure to meet any of the requirements for licensure will be returned to the applicant with written notification of the information that is lacking or the reason(s) the application does not meet the requirements for licensure and will be held in "pending" status until satisfactorily completed within a reasonable period of time, not to exceed sixty (60) days from date of written notification.
- (2) For the purpose of [T.C.A. § 63-10-506\(d\)](#), a "recognized" college or school of pharmacy is a college or school of pharmacy which meets the minimum standards of the ACPE and appears in the ACPE "Annual Directory of Accredited Professional Programs of Colleges and Schools of Pharmacy."
- (3) No applicant shall be eligible for a license if the applicant has engaged in conduct or suffers a condition which would constitute grounds for revocation or suspension of a license under [T.C.A. § 63-10-505](#), unless the applicant can show cause why a license should be issued.
- (4) No license shall be issued to a reciprocal applicant from a state which denies reciprocal privileges to a pharmacist currently licensed and in good standing in Tennessee.
- (5) It shall be unlawful for any person to procure or attempt to procure a license or certificate of registration for such person or for any other person by making any false representations.

- (6) An applicant initially licensed in another state and who wishes to obtain a Tennessee license may, in the discretion of the board, transfer to Tennessee the applicant's score on NAPLEX taken in another state. Provided, however, if the applicant has been licensed for twelve (12) or more months in another state, then the applicant shall apply for a license in Tennessee by reciprocity. No license shall be issued to a score transfer applicant from a state which denies score transfer privileges to a pharmacist currently licensed and in good standing in Tennessee.

Authority: *T.C.A. §§ 63-10-101, 63-10-102(a), 63-1-116, 63-10-202, 63-10-304, 63-10-306, 63-10-404(2), (13), (17), and (26), 63-10-404(2), (13), (17), and (26), 63-10-504(b)(1), 63-10-506, and 63-10-508.*
Administrative History: *Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed December 17, 1984; effective March 16, 1985. Amendment filed October 30, 1991; effective December 14, 1991. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed January 4, 2012; effective April 3, 2012.*

Tenn. Comp. R. & Regs. 1140-01-.03, TN ADC 1140-01-.03

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-01. Introductory Rules \(Refs & Annos\)](#)**→→ 1140-01-.04 PHARMACY INTERNSHIP.**

(1) An applicant for an initial pharmacist license by examination must show, on affidavit forms prescribed by the board, that the applicant has acquired a minimum of one thousand five hundred (1,500) hours of pharmacy internship (practical pharmacy experience) under the instruction of a pharmacist in good standing, subject to all of the following conditions.

(a) The one thousand five hundred (1,500) hours must be acquired after enrollment in a recognized college or school of pharmacy; one thousand one hundred (1,100) of these hours may be acquired in pharmacy programs or demonstration projects structured by the college or school of pharmacy.

(b) Pharmacy internship may be acquired in another state, provided that the preceptor's qualifications are certified by the appropriate authorities of such state.

(c) Four hundred (400) of these hours may be acquired in non-traditional pharmacy internship programs which have received prior approval of the board.


(d) Foreign pharmacy graduates shall complete five hundred (500) hours of pharmacy internship in Tennessee within a period of six (6) consecutive months.

Authority: *T.C.A. §§ 63-10-101, 63-10-102, 63-10-202, 63-10-404(29), and 63-10-504(b)(1).* **Administrative History:** *Original rule filed June 7, 1974; effective July 7, 1974. Amendment filed September 23, 1975; effective October 23, 1975. Amendment filed January 11, 1977; effective February 10, 1977. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed December 17, 1984; effective March 16, 1985. Amendment filed January 19, 1988; effective April 27, 1988. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-01-.04, TN ADC 1140-01-.04

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-01. Introductory Rules \(Refs & Annos\)](#)**→→ 1140-01-.05 LICENSING EXAMINATIONS.**

- (1) An applicant for an initial license to engage in the practice of pharmacy in the State of Tennessee shall take the National Association of Boards of Pharmacy (NABP) Multistate Pharmacy Jurisprudence Examination (MPJE®) and the NABP North American Pharmacy Licensing Examination (NAPLEX®), which shall be administered on the dates scheduled by the NABP. An applicant shall also meet the minimum acceptable passing scores on the NAPLEX® and MPJE® as established and nationally accepted.
- (2) An applicant to obtain a pharmacy license by reciprocity shall successfully complete the MPJE®.
- (3) In addition to completing the requirements in paragraph (1) of this rule, a pharmacy foreign graduate shall successfully complete the foreign pharmacy equivalency examination, the Test of Spoken English (TSE®) examination and any other requirements established by the NABP.
- (4) Any applicant who fails either the NAPLEX® or MPJE® may retake the examinations at any of the next examination dates scheduled by the NABP. If an applicant fails the NAPLEX® or MPJE® three (3) consecutive times, then the Board may require that applicant to take review courses prior to any following reexamination.

Authority: *T.C.A. §§ 63-10-304 and 63-10-306.* **Administrative History:** *Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed November 24, 2008; effective February 7, 2009.*

Tenn. Comp. R. & Regs. 1140-01-.05, TN ADC 1140-01-.05

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1140. Board of Pharmacy

☐ [Chapter 1140-01.](#) Introductory Rules ([Refs & Annos](#))

➔➔ **1140-01-.06 SUMMARY SUSPENSION OF LICENSE.**

Pursuant to [T.C.A. § 4-5-320](#), if the board finds that public health, safety or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, summary suspension of a license may be ordered pending proceedings for revocation or other action.

Authority: [T.C.A. §§ 4-5-320, 63-10-101, 63-10-102, 63-10-504\(b\)\(1\), 63-10-504\(b\)\(2\), and 63-10-505.](#)

Administrative History: Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed November 15, 1989; effective December 30, 1989. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

Tenn. Comp. R. & Regs. 1140-01-.06, TN ADC 1140-01-.06

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-01. Introductory Rules \(Refs & Annos\)](#)**→→ 1140-01-.07 INACTIVE LICENSES AND LICENSE REINSTATEMENT.**

- (1) A pharmacist may apply for an inactive license by:
- (a) Completing the biennial license renewal application form; and
 - (b) Paying the biennial renewal fee for an inactive license.
- (2) A pharmacist maintaining an active license to practice pharmacy in another state or jurisdiction is ineligible for inactive license status in Tennessee.
- (3) A pharmacist seeking active status for an inactive, delinquent, suspended or revoked license must fulfill the following minimum requirements.
- (a) If the license has been inactive, delinquent, suspended or revoked for less than one (1) year, the pharmacist shall:
 - 1. Provide written notice to the board requesting an active license;
 - 2. Satisfy all past due continuing pharmaceutical education as required by the board; and
 - 3. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked.
 - (b) If the license has been inactive, delinquent, suspended or revoked from one (1) year to not more than five (5) consecutive years, the pharmacist shall:
 - 1. Provide written notice to the board requesting an active license;
 - 2. Satisfy all past due continuing pharmaceutical education as required by the board;
 - 3. Successfully complete the jurisprudence examination;

4. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked; and
5. Complete a period of pharmacy internship in Tennessee as follows.
 - (i) If the license has been inactive, delinquent, suspended or revoked from one (1) year to not more than three (3) consecutive years, one hundred sixty (160) hours within ninety (90) consecutive days.
 - (ii) If the license has been inactive, delinquent, suspended or revoked for more than three (3) consecutive years but not more than five (5) consecutive years, three hundred twenty (320) hours within one hundred eighty (180) consecutive days.
- (c) If the license has been inactive, delinquent, suspended or revoked for more than five (5) consecutive years, the pharmacist shall:
 1. Provide written notice to the board requesting an active license;
 2. Satisfy all past due continuing pharmaceutical education as required by the board;
 3. Successfully complete the NAPLEX and jurisprudence examinations;
 4. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked; and
 5. Complete a period of pharmacy internship of three hundred twenty (320) hours within one hundred eighty (180) consecutive days.
- (d) Fulfill any other requirements which may be contained in any order of the board suspending or revoking the applicant's license.
- (e) The board shall consider a written notice requesting reinstatement of an inactive, delinquent, suspended or revoked license within ninety (90) days of the notice being received by the director.
- (f) The board shall consider a waiver upon request.

Authority: *T.C.A. §§ 63-10-101, 63-10-102, 63-10-210, 63-10-404(17), and 63-10-504(b)(1).* **Administrative**

History: *Original rule certified June 7, 1974. Amendment filed June 7, 1974; effective July 7, 1974. Amendment filed September 23, 1975; effective October 23, 1975. Amendment filed January 11, 1977; effective February 10,*

1977. Amendment filed April 11, 1979; effective July 30, 1979. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed January 26, 1987; effective April 29, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

Tenn. Comp. R. & Regs. 1140-01-.07, TN ADC 1140-01-.07

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy**[Chapter 1140-01. Introductory Rules \(Refs & Annos\)](#)**→→ 1140-01-.08 APPLICATION FOR PHARMACY PRACTICE SITE, MANUFACTURER AND WHOLESALE LICENSES.**

- (1) Application for a license to operate as a pharmacy practice site, manufacturer or wholesaler within the state of Tennessee shall be submitted to the office of the board at least thirty (30) days prior to the scheduled opening date. No pharmacy practice site, manufacturer or wholesaler may open within the state of Tennessee until a license has been obtained; and such license will not be issued until an inspection by an authorized representative of the board has been made.
- (2) An application for an existing pharmacy practice site, manufacturer or wholesaler physically located within the state of Tennessee must be filed when the pharmacy practice site, manufacturer or wholesaler changes name, location or ownership.
 - (a) Transactions constituting a change of ownership include, but are not limited to, the following:
 1. A sole proprietor becomes a member of a partnership or corporation, which succeeds him as the new operator;
 2. A partnership dissolves;
 3. One partnership is replaced by another through the removal, addition or substitution of a partner;
 4. Two (2) or more corporations merge and the originally-licensed corporation does not survive; and
 5. Transfers between levels of government.
 - (b) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
 1. Changes in the membership of a corporate board of directors or board of trustees;
 2. Two (2) or more corporations merge and the originally-licensed corporation survives; and

3. Corporate stock transfers or sales, even when a controlling interest.

(3) No out-of-state pharmacy practice site, manufacturer or wholesaler shall conduct business in the state of Tennessee until such pharmacy practice site, manufacturer or wholesaler obtains the required license from the board. In order to obtain a license for a pharmacy practice site, manufacturer or wholesaler physically located out-of-state the following standards must be met.

(a) Pharmacy practice site.

1. Submit an application for a license, which shall include the address of the pharmacy practice site, name of owner if a sole proprietorship, names of partners if a partnership or names and titles of all officers if a corporation and names of all pharmacists who practice at the site, together with the appropriate application fee. The director shall be notified in writing within thirty (30) days of any change in the information contained on the original application for a license, including names of pharmacists practicing at the site.
2. Comply with all statutorily authorized directions and requests for information from the board.
3. Maintain at all times a current permit, license or registration to conduct the pharmacy practice site in compliance with the laws of the state in which the site is physically located.
4. Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located. Thereafter, the pharmacy practice site shall submit to the director a copy of any subsequent inspection report conducted by the regulatory or licensing agency of the state in which the site is physically located.
5. Maintain records of prescription orders dispensed to persons residing in Tennessee.
6. All records of prescription orders prepared and dispensed to persons residing in Tennessee shall be readily retrievable from other records.
7. During regular hours of operation, but not less than six (6) days per week nor for a minimum of forty (40) hours per week provide access to a pharmacist by a toll-free telephone service. A toll-free number shall be placed on the label affixed to the dispensing container for each prescription dispensed to a person residing in Tennessee.
8. Designate a pharmacist in charge who shall be responsible for compliance with the provisions in this section, and who shall hold a current Tennessee pharmacist license.

9. All out-of-state pharmacy practice sites shall comply with the requirements for patient counseling, patient profiling, drug regimen review and pharmaceutical care as set forth at 1140-03-.01.

(b) Manufacturer or wholesaler.

1. Submit an application for a license, which shall include the address of the manufacturer or wholesaler, name of owner if a sole proprietorship, names of partners if a partnership or names and titles of all officers if a corporation, together with the appropriate application fee. The director shall be notified in writing within thirty (30) days of any change in the information contained on the original application for a license.
 2. Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the manufacturer or wholesaler is physically located. Thereafter, the manufacturer or wholesaler shall submit to the director a copy of any subsequent inspection report conducted by the regulatory or licensing agency of the state in which the manufacturer or wholesaler is physically located.
 3. Comply with the requirements contained in Chapter 1140-09 of the rules of the board.
- (4) Representatives of a manufacturer or wholesaler conducting business in the state of Tennessee and who possess and distribute controlled substances shall obtain a controlled substance registration from the board.
- (5) It shall be unlawful for any person to procure or attempt to procure a license or certificate of registration for such person or for any other person by making any false representations.
- (6) In determining whether to grant a license under this rule, the board shall require from the applicant proof satisfactory to the board that the:
- (a) Applicant is of good moral character, or, if the applicant is a partnership or corporation, that the managing officers are of good moral character; and
 - (b) That the applicant is equipped as to land, buildings and equipment necessary to conduct the business for which the application has been submitted.

Authority: *T.C.A. §§ 53-11-301, 53-14-104, 53-14-106, 53-14-107, 56-1-302(b)(1)(2), 63-10-101, 63-10-102(a), 63-10-203, 63-10-204, 63-10-210, 63-10-404(18), (28), and (37), 63-10-504(b)(1), § 63-10-504(b)(2), and 63-10-508.* **Administrative History:** *Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed September 30, 1985; effective October 30, 1985. Amendment filed January 19, 1988; effective April 27, 1988. Amendment filed August 25, 1989; effective October 9, 1989. Amendment filed October 30, 1991; effective December 14, 1991. Amendment filed November 17, 1994;*

effective March 30, 1995. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

Tenn. Comp. R. & Regs. 1140-01-.08, TN ADC 1140-01-.08

Current through rules effective December 2013

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C

Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy⌕ [Chapter 1140-01.](#) Introductory Rules ([Refs & Annos](#))➔➔ **1140-01-.09 RENEWAL OF LICENSES.**

- (1) All licenses and certificates of registration granted by the board shall be for a two (2) year period beginning on the date the license is initially granted. All licenses and certificates of registration shall be renewed on or before the last day of the two (2) year license cycle.
- (2) A pharmacist or pharmacy technician serving in the uniformed services of the United States shall not be required to pay license or registration renewal fees during the period of active duty and the pharmacist shall not be required to complete continuing pharmacy education requirements during the period of active duty.

Authority: *T.C.A. §§ 53-11-301, 53-11-302, 56-1-302(b)(1)(2), 63-10-102(a), 63-10-404(17), 63-10-504(1) and (2), 63-10-304(b)(1) and 63-10-508.* **Administrative History:** *Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed April 12, 1990; effective July 29, 1990. Amendment filed November 17, 1994; effective March 30, 1995. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed December 23, 2009; effective March 23, 2010.*

Tenn. Comp. R. & Regs. 1140-01-.09, TN ADC 1140-01-.09

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-01. Introductory Rules \(Refs & Annos\)](#)**→→ 1140-01-.10 FEES.**

- (1) An applicant for examination for a license as a pharmacist shall pay a fee of fifty dollars (\$50.00) plus cost of the examination and materials.
- (2) An applicant for a reciprocal license or NAPLEX score transfer shall pay a fee of three hundred dollars (\$300.00).
- (3) Each person becoming licensed as a pharmacist shall pay a registration fee of ninety six dollars (\$96.00). Each person licensed as a pharmacist who desires to continue in the practice of pharmacy shall biennially, on or before the last day of the month that the person's license shall expire, pay a renewal fee of ninety six dollars (\$96.00). Each person licensed as pharmacist and who wishes to obtain an inactive license shall biennially, on or before the last day of the month that the person's license shall expire, pay a renewal fee of forty eight dollars (\$48.00).
- (4) Each person becoming registered as a pharmacy technician shall pay a registration fee of fifty dollars (\$50.00). Each person who desires to continue to practice as a pharmacy technician shall biennially, on or before the last day of the month that the person's registration shall expire, pay a renewal fee of fifty dollars (\$50.00).
- (5) Any person, partnership, firm, corporation or agency owning or operating a pharmacy practice site or any establishment or institution where prescription drugs and devices and related materials are kept for the purpose of the compounding and dispensing of medical and prescription orders shall pay a registration fee of one hundred sixty eight dollars (\$168.00) biennially. Any new pharmacy practice site to be opened or established, or any change in location, name or ownership of any existing pharmacy practice site, shall before active operation obtain a license from the board and shall pay a fee of one hundred sixty eight dollars (\$168.00).
- (6) All manufacturers and wholesalers of prescription drugs and devices and related materials doing business in the state of Tennessee must be licensed by the board by paying a registration fee of four hundred eight dollars (\$408.00), and thereafter a biennial renewal fee of four hundred eight dollars (\$408.00).
- (7) The fee for the board's publication of Pharmacy Drug Laws, Rules and Regulations shall be ten dollars (\$10.00).

- (8) The charge for a roster of Tennessee pharmacies, pharmacists and printing of mailing labels of Tennessee pharmacies and pharmacists shall be determined by the administration of Commerce and Insurance.
- (9) The fee for certification of license examination grades shall be twenty five dollars (\$25.00).
- (10) The fee for a duplicate or revised pharmacist license wall certificate shall be twenty five dollars (\$25.00).
- (11) If any person fails to renew a license, such license may be reinstated upon complying with rule 1140-01-.07 and upon the payment of the appropriate renewal fee plus a penalty fee of ten dollars (\$10.00) for each month or fraction thereof that payment for renewal is delinquent. In the event such renewal is not procured within six (6) months from the date on which the last renewal became delinquent, the board may refuse to issue the renewal.
- (12) If any person fails to renew a license or registration certificate, such license or registration certificate may be reinstated upon complying with rule 1140-01-.07 and upon the payment of the appropriate renewal fee plus a penalty fee of ten dollars (\$10.00) for each month or fraction thereof that payment for renewal is delinquent. In the event such renewal is not procured within six (6) months from the date on which the last renewal became delinquent, the board may refuse to issue the renewal.
- (13) A penalty of fifty dollars (\$50.00) may, in the discretion of the board, attach to each failure of a licensee or registration certificate holder to provide any required notice to the director as may be required by the rules of the board.
- (14) Any licensee who wishes to modify the terms or conditions of a license to manufacture, obtain, possess, administer or dispense a prescription drug or device or controlled substance for the purpose of scientific research, chemical analysis, instruction or training of detection animals shall file those modifications with a non-refundable fee of five dollars (\$5.00).
- (15) Any person who holds a license to manufacture, obtain, possess, administer or dispense a prescription drug or device or controlled substance for the purpose of scientific research, chemical analysis, instruction or training of detection animals shall pay a renewal fee of sixty dollars (\$60.00) biennially from the date of issuance.

Authority: *T.C.A. §§ 4-5-202, 63-10-102(a), 63-10-216, 63-10-404(17), 63-10-504(b)(1), 63-10-504(b)(2), and 63-10-508.* **Administrative History:** *Original rule certified June 7, 1974. Amendment filed June 7, 1974; effective July 7, 1974. Amendment filed December 15, 1977; effective January 16, 1978. Amendment filed September 26, 1978; effective December 29, 1978. Repeal and new rule file February 7, 1983; effective March 9, 1983. Amendment filed May 23, 1986; effective August 12, 1986. Amendment filed January 26, 1987; effective April 29, 1987. Amendment filed October 1, 1987; effective January 27, 1988. Amendment filed November 18, 1989; effective February 28, 1989. Amendment filed October 18, 1990; effective January 29, 1991. Amendment filed May 3, 1991; effective August 28, 1991. Amendment filed December 22, 1992; effective March 31, 1993.*

Amendment filed June 25, 1993; effective September 28, 1993. Amendment filed October 19, 1996; effective February 28, 1996. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002.

Tenn. Comp. R. & Regs. 1140-01-.10, TN ADC 1140-01-.10

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy [Chapter 1140-01.](#) Introductory Rules ([Refs & Annos](#))**→→ 1140-01-.11 CONTROLLED SUBSTANCE REGISTRATION.**

No licensee may obtain, possess, administer, dispense, distribute, or manufacture any controlled substance in this state, and no representative of a manufacturer or wholesaler may distribute any controlled substance in this state, without obtaining a controlled substance registration from the board. Application for such registration shall be submitted on a form prescribed by the board, and shall be accompanied by a fee of forty dollars (\$40.00) and thereafter a biennial renewal fee of forty dollars (\$40.00).

Authority: *T.C.A. §§ 53-10-303, 63-10-102(a), 63-10-404(6), 63-10-504(b)(1), 63-10-504(b)(1) and (2), and 63-10-508.* **Administrative History:** *Original rule filed October 30, 1991; effective December 14, 1991. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-01-.11, TN ADC 1140-01-.11

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy [Chapter 1140-01.](#) Introductory Rules ([Refs & Annos](#))**→→ 1140-01-.12 STANDARDS FOR PHARMACIES AND PRESCRIPTION DEPARTMENT SECURITY.**

A license to operate a new or remodeled pharmacy practice site, or an existing pharmacy practice site which changes location or ownership, will not be issued unless the pharmacy practice site meets the following standards.

- (1) The pharmacy practice site and equipment therein shall be maintained in a clean, sanitary, orderly and well-lighted condition, and all persons working in the pharmacy practice site shall be required to keep themselves and their apparel in a clean and sanitary condition.
- (2) All new or relocated pharmacies opening after July 1, 1998 shall provide a consultation area which offers sufficient privacy to the patient before a license will be issued. All existing pharmacies shall be in compliance with this requirement on or before January 1, 2000.
- (3) The prescription department at the pharmacy practice site shall meet the following standards.
 - (a) The department shall have necessary counters and storage space.
 - (b) The department shall have a representative stock of prescription drugs and devices and related materials sufficient to compound and dispense medical and prescription orders as indicated by experience.
 - (c) The department shall have the apparatus and equipment needed to compound and dispense medical and prescription orders properly.
 - (d) The department shall occupy a space of not less than one hundred eighty (180) square feet.
 - (e) The department shall have hot and cold running water and immediate area refrigeration.
 - (f) The department shall have a physical barrier sufficient to protect against unauthorized entry and pilferage of prescription drugs and devices and related materials.

- (g) Keys or other access devices to the physical barriers shall be subject to the following standards.
1. Only pharmacists practicing at the pharmacy and pharmacists authorized by the pharmacist in charge shall be in possession of any keys or other access devices.
 2. The pharmacist in charge shall place a key or other access device in a sealed envelope bearing the signature of the pharmacist in charge affixed across the seal and placed in a safe or vault in a secured place outside of the department. The key or access device may be used to allow emergency entrance to the department.
- (h) Access to the department is restricted to pharmacists, pharmacy interns and pharmacy technicians who are practicing at the pharmacy. Other persons designated by the pharmacist in charge may be allowed access but only during hours that a pharmacist is on duty.
- (i) Notwithstanding any rule or regulation to the contrary, a pharmacy which was established before June 6, 1945, and which serves food, and which has continuously had a soda fountain, may allow a customer to go through the pharmacy area to the restroom, and not be required to have a gate or door to separate the pharmacy from the restroom or other parts of the establishment.
- (4) All licenses and certificates of registration for a pharmacy practice site shall at all times be conspicuously displayed at the practice site.
- (5) If a pharmacy practice site is located in a mercantile establishment (such as a discount store, grocery store, department store, or other similar establishment), then such pharmacy practice site shall be:
- (a) open for business during the same hours as the mercantile establishment, unless the pharmacy practice site is capable of being closed-off by physical barrier from floor to ceiling; and
 - (b) under the supervision of a pharmacist at all times; except as provided in rule 1140-03-.07.
- (6) The pharmacist shall not at any time be denied access to the prescription department of a pharmacy practice site located in a mercantile establishment; provided, however, that entry of the pharmacist at times when the pharmacy is closed to the public may be subject to reasonable and prudent conditions.
- (7) A pharmacy practice site where prescription drugs and devices and related materials are received, stored, compounded and dispensed shall not be opened for business or any other reason unless a licensed pharmacist is present. Furthermore, no medical or prescription order shall be dispensed except during the presence and under the direct supervision of a pharmacist.

(8) Nothing in this rule applies to a pharmacy practice site or prescription department operating in an institutional facility.

(9) In cases of practical difficulty or undue hardship, the board may permit exceptions to the standards specified in this rule.

Authority: *T.C.A. §§ 63-10-404(28), 63-10-504(b)(1), and 63-10-504(b)(1) and (2).* **Administrative History:** *Original rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-01-.12, TN ADC 1140-01-.12

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1140. Board of Pharmacy

⌕ [Chapter 1140-01.](#) Introductory Rules ([Refs & Annos](#))

➡➡ **1140-01-.13 STANDARDS FOR MANUFACTURERS AND WHOLESALERS.**

No license to operate a new or remodeled manufacturer or wholesaler location within the state of Tennessee, or an existing manufacturer or wholesaler location which changes location or ownership, will be issued unless the manufacturer or wholesaler meets the standards set forth in Chapter 1140-09 of the rules of the board.

Authority: *T.C.A. §§ 63-10-404(18) and (37), and 63-10-504(b)(1).* **Administrative History:** *Original rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-01-.13, TN ADC 1140-01-.13

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Tennessee Rules and Regulations [Currentness](#)

1140. Board of Pharmacy

⌕ [Chapter 1140-01.](#) Introductory Rules ([Refs & Annos](#))

➡➡ **1140-01-.14 PRESCRIPTION DRUGS DISPENSED BY HEALTH DEPARTMENTS.**

For purposes of [T.C.A. § 63-10-405](#), the following drugs are hereby approved as not subject to abuse:

(1) Tuberculosis Control Agents:

- (a) Capreomycin Injection
- (b) Cycloserine Capsules
- (c) Ethambutol Tablets
- (d) Ethionamide Tablets
- (e) Isoniazid Tablets
- (f) Para-Aminosalicyclate Tablets
- (g) Pyrazinamide Tablets
- (h) Rifampin Capsules
- (i) Streptomycin Injection
- (j) Tuberculin Skin Test (Mantoux only)
- (k) Rifampin/Isoniazid
- (l) Ofloxacin

(m) Rifampin-isoniazid-pyrazinamide

(2) Venereal Disease Control Agents:

(a) Ampicillin Capsules

(b) Doxycycline Capsules

(c) Erythromycin Tablets

(d) Penicillin

1. Benzathine Penicillin G Injection

2. Procaine Penicillin G Injection

(e) Probenecid Tablets

(f) Spectinomycin Injection

(g) Tetracycline Capsules

(h) Ceftriaxone

(i) Ciprofloxacin

(j) Lidocaine Injection

(k) Azithromycin

(l) Acyclovir Tablets, Ointments

(m) Trichloroacetic Acid

(n) Salicylic Acid

(o) Podophyllin/Salicylic Acid

(p) Aldara (Imiquimod)

(3) Biologicals/Immunizations:

(a) Antiserums

(b) Antitoxins

(c) Immune Serum Globulin

(d) Toxoids

(e) Vaccines

(f) Antigens

(4) Reproductive Health Agents:

(a) Metronidazole Tablets

(b) Oral Contraceptives

(c) Podophyllin

(d) Prenatal Vitamins

(e) Triple Sulfa Vaginal Cream/Tabs

(f) Vaginal Antifungal Cream/Tabs

1. Clotrimazole

2. Miconazole

3. Nystatin

4. Terconazole (Terazole)

(g) Amino-Cerv

(h) Nitrofurantoin

(i) Ibuprofen, 600 mg Tablets

(j) Metronidazole (vaginal jelly)

(k) Fluconazole Tablets

(l) Clindamycin Vaginal Cream

(m) Premarin Tablets (for use in estrogen trials for the evaluation of atypical cells in certain inflammatory atrophic pap smears)

(n) Medroxyprogesterone Acetate Injectable (Depo Provera®)

(o) Norelgestromin/ethinyl estradiol transdermal system (Ortho Evra®)

(p) Etonogestrel/ethinyl estradiol vaginal ring (Nuvaring®)

(5) Child Health Agents:

(a) Fluoride Tablets and Drops

(b) Lindane Cream, Lotion, Shampoo

(c) Mebendazole Tablets

(d) Pyrantel Pamoate Liquid

(e) Sulfadiazine Tablets

(f) Trimethoprim and Sulfamethoxazole

(g) Permethrin

(h) Crotamiton

(i) Nystatin Oral Suspension

(j) Nystatin Triamcinolone Cream

(k) Ibuprofen, Suspension Liquid

(6) Emergency Agents:

(a) Aminophylline Injection

(b) Benztropine Injection

(c) Diphenhydramine Injection

(d) Epinephrine Injection

(e) Glucagon Injection

(f) Hydralazine Injection

(g) Hydrocortisone Sodium Succinate

(h) Insulin, Regular

(i) Intravenous Fluids

(j) Oxygen

(k) Phenylephrine Injection

(l) Sodium Bicarbonate Injection

(m) Atropine Injection

(n) Nitroglycerin Sublingual Tablets

(o) Dexamethasone Injection

(p) Norepinephrine

(7) Antihypertensive Agents:

(a) Methyldopa

(b) Reserpine

(c) Hydrochlorothiazide

(d) Hydralazine

(e) Propranolol

(f) Potassium Supplements

(g) Nicotine Patches

Authority: *T.C.A. §§ 63-10-404(14), 63-10-205, 63-10-304, 63-10-304(b)(1), 63-10-405, 63-10-504(b), 63-10-504(b)(1), and 63-10-504(b)(2).* **Administrative History:** *Original rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002. Amendment filed November 24, 2008; effective February 7, 2009. Amendment filed December 23, 2009; effective March 23, 2010.*

Tenn. Comp. R. & Regs. 1140-01-.14, TN ADC 1140-01-.14

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy**[Chapter 1140-02. Professional Conduct and Responsibilities \(Refs & Annos\)](#)**→→ 1140-02-.01 PHARMACISTS AND PHARMACY INTERNS.**

- (1) A pharmacist shall hold the health and safety of patients to be the first consideration and shall render to each patient the full measure of the pharmacist's ability as an essential health practitioner.
- (2) A pharmacist shall not knowingly condone or assist in the dispensing, promoting, or distributing of drugs or devices which are not of good quality, which do not meet standards by law, or which lack therapeutic value for the patient.
- (3) A pharmacist shall always strive to perfect and enlarge the pharmacist's professional knowledge and shall utilize and make available this knowledge as may be required in accordance with the pharmacist's best professional judgment.
- (4) A pharmacist shall observe the law, uphold the dignity and honor of the profession, and accept its ethical principles. A pharmacist shall not engage in any activity that will bring discredit to the profession, and shall expose, without fear or favor, illegal or unethical conduct in the profession.
- (5) A pharmacist shall seek at all times only fair and reasonable remuneration for the pharmacist's services. A pharmacist shall never agree to or participate in transactions with practitioners of other health professions or any other person under which fees are divided, or which may cause financial or other exploitation in connection with the rendering of the pharmacist's professional services.
- (6) A pharmacist shall respect the confidential and personal nature of professional and patient records. Except where the best interest of a patient requires or the law demands, a pharmacist shall not disclose such information to anyone without proper patient authorization.
- (7) A pharmacist shall not agree to practice under terms or conditions which tend to interfere with or impair the proper exercise of professional judgment and skill, which tend to cause a deterioration of the quality of professional service and patient care, or which require the pharmacist to consent to unethical conduct.
- (8) A pharmacist shall not make publication or circulation of any statement tending to deceive, misrepresent, or mislead anyone, nor be a party or accessory to any fraudulent or deceptive practice or transaction in pharmacy.

- (9) A pharmacist shall not enter into any agreement with anyone for the compounding of secret formula or coded medical or prescription orders.
- (10) A pharmacist shall, by utilizing education, skill, experience, and professional judgment, make every reasonable effort to prevent the abuse of drugs which the pharmacist dispenses.
- (11) A pharmacist shall provide pharmaceutical service:
 - (a) which is as complete as the public may reasonably expect;
 - (b) without discriminating in any manner between patients or groups of patients; and
 - (c) without compromising the kind or extent of services or facilities made available.
- (12) A pharmacist shall recognize the Tennessee Board of Pharmacy as the governing body of the practice of pharmacy in the State of Tennessee, and report to the board any violations of pharmacy laws or rules which may come to the pharmacist's attention. The pharmacist at all times shall refrain from discussing these matters with nonmembers of the profession.
- (13) The following functions must be performed personally by a pharmacist or by a pharmacy intern under the personal supervision and in the presence of a pharmacist:
 - (a) Certification of medical and prescription orders;
 - (b) Performance of final verification of the product prior to dispensing;
 - (c) Initialing of medical and prescription orders noting appropriate comments;
 - (d) Providing patient counseling;
 - (e) Providing direct patient care services;
 - (f) Providing drug information to patients, care givers, and health care providers;
 - (g) Supervision of compounding;
 - (h) Evaluation and establishment of criteria for selection of drug product(s) and supplier(s); and

- (i) Daily opening and closing of a pharmacy practice site.
- (14) A pharmacist and pharmacy intern shall wear appropriate identification showing name and appropriate title.
- (15) A pharmacist shall immediately notify the board office in writing of a change in location of primary practice site and permanent residence.
- (16) A pharmacist shall conspicuously display the pharmacist's license and certificate of registration at the pharmacist's primary practice site, unless it is an institutional pharmacy practice site, in which case, the pharmacist's license and certificate of registration shall be maintained at the site.
- (17) A pharmacist convicted of any crime, including driving under the influence of alcohol or controlled substances, shall report such conviction to the board within ten (10) days of the conviction becoming final. For purposes of this reporting requirement, a conviction includes pretrial or judicial diversion.
- (18) A pharmacist shall comply with lawful order(s) of the board.

Authority: *T.C.A. §§ 63-10-404(26), (27), and (29), 63-10-304(b)(1) and (c), 63-10-504(b)(1), and 63-10-504(b)(1)(C).* **Administrative History:** *Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed December 23, 2009; effective March 23, 2010.*

Tenn. Comp. R. & Regs. 1140-02-.01, TN ADC 1140-02-.01

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy**[⌕ Chapter 1140-02. Professional Conduct and Responsibilities \(Refs & Annos\)](#)**→→ 1140-02-.02 PHARMACY TECHNICIANS.**

- (1) Any person acting as a pharmacy technician shall register with the Board by submitting a complete application on a form prescribed by the Board accompanied by the following:
 - (a) An affidavit signed by both the applicant and employer attesting that the applicant has read and understands the laws and rules relative to pharmacy technicians and the practice of pharmacy in Tennessee. (A copy of this affidavit shall be retained at the applicant's place of employment);
 - (b) Registration fee established in rule 1140-01-.10; and
 - (c) The result of a criminal background check, which the applicant shall pay for and cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's registration application materials.
 - (d) Any application submitted which lacks required information or reflects a failure to meet any of the requirements for registration will be returned to the applicant with written notification of the information that is lacking or the reason(s) the application does not meet the requirements for registration and will be held in "pending" status until satisfactorily completed within a reasonable period of time, not to exceed sixty (60) days from date of written notification.
- (2) The following individuals are exempt from registration as a pharmacy technician:
 - (a) Any individual performing tasks that may be performed by a pharmacy technician who is classified by the employer as a probationary employee. The exemption shall not exceed ninety (90) days from the date of employment.
 - (b) A student enrolled in a formal pharmacy technician training program while performing experiential rotations as a part of the academic curriculum. The student shall wear a school-issued identification badge.
- (3) The pharmacist in charge at each pharmacy practice site is responsible for compliance with the provisions of this chapter by pharmacy technicians at that pharmacy practice site.

- (4) A registered pharmacy technician may, in the presence of and under the supervision of a pharmacist, perform those tasks associated with the preparation and dispensing process except those tasks identified in Rule 1140-02-.01(13) that must be personally performed by a pharmacist or pharmacy intern under the personal supervision and in the presence of a pharmacist.
- (5) Certified pharmacy technicians may also:
- (a) Receive new or transferred oral medical and prescription orders;
 - (b) Receive and transfer copies of oral medical and prescription orders between pharmacy practice sites; and
 - (c) Verify the contents of unit dose carts prepared by other registered technicians when an additional verification by use of bar code technology or a licensed health care professional is performed prior to administration to the patient.
- (6) No prescription drugs and devices and related materials may be released to a patient without verification by a pharmacist of the functions performed by a pharmacy technician.
- (7) Pharmacy Technician to Pharmacist Ratio
- (a) The pharmacy technician to pharmacist ratio shall not exceed 2:1; however the ratio may be increased up to a maximum of 4:1 by the pharmacist in charge based upon public safety considerations but only if the additional pharmacy technicians are certified pharmacy technicians. However, the pharmacist in charge may request a modification of the ratio from the Board in writing which addresses:
 - 1. the pharmacy technician's experience, skill, knowledge and training; and
 - 2. the workload at the practice site; and
 - 3. detailed information regarding the numbers of pharmacy technicians and the specific duties and responsibilities of each of the pharmacy technicians; and
 - 4. justification that patient safety and quality of pharmacy services and care can be maintained at the pharmacy.
 - (b) Requested modifications of the established ratios may not be implemented until the written request is considered and approved by the Board.

- (8) Pharmacy technicians must wear appropriate identification showing name and appropriate title (e.g. pharmacy technician, certified pharmacy technician).
- (9) All pharmacy technician functions shall be performed under the supervision of a pharmacist, who shall direct and verify the accuracy of all pharmacy technician functions.
- (10) A registered technician shall maintain his or her registration certificate at the pharmacy practice site; additionally, all certified technicians shall display in like manner evidence of certification. Pharmacy technicians shall possess at all times, while on duty, proof of registration and proof of certification, if applicable.
- (11) All registered technicians shall immediately notify the board in writing of any change of address or employer.
- (12) For purposes of this rule, a pharmacy intern is not considered to be a pharmacy technician.

Authority: *T.C.A. §§ 63-1-116, 63-10-304, 63-10-304(b)(1), (e), and (j), 63-10-306, 63-10-404(30), 63-10-504(b)(1), 63-10-504(b)(1)(C), 63-10-506, and 63-10-508.* **Administrative History:** *Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002. Amendment filed December 23, 2009; effective March 23, 2010. Amendment filed January 4, 2012; effective April 3, 2012.*

Tenn. Comp. R. & Regs. 1140-02-.02, TN ADC 1140-02-.02

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1140. Board of Pharmacy

☞ [Chapter 1140-02.](#) Professional Conduct and Responsibilities

227 FRENCH LANDING, SUITE 300

HERITAGE PLACE, METRO CENTER

NASHVILLE, TN 37243

ADMINISTRATIVE HISTORY

Original chapter 1140-01 was certified on June 7, 1974, under Chapter 491 of the Public Acts of 1974 as Rules in effect when Chapter 491 became effective. The Administrative History following each rule gives the date on which the rule was certified, or the date on which the rule was filed and its effective date, if promulgated after March 11, 1974. The Administrative History following each rule also shows the dates of any amendments or repeals.

Rules 1140-01-.04 and 1140-01-.31 filed June 7, 1974; effective July 7, 1974.

Amendments to rules 1140-01-.02, 1140-01-.07, 1140-01-.10, 1140-01-.12 through 1140-01-.15, 1140-01-.18, 1140-01-.20, 1140-01-.25, and 1140-01-.27 through 1140-01-.30 filed June 7, 1974; effective July 7, 1974.

Amendment to rule 1140-01-.14(3) filed June 25, 1975; effective July 25, 1975.

Amendment to rules 1140-01-.14(2), 1140-01-.18(1)(b), 1140-01-.29(2), 1140-01-.31(5), and 1140-01-.3 through 1140-01-.37 filed September 23, 1975; effective October 23, 1975.

Repeal of rules 1140-01-.02(h) and 1140-01-.07(g) filed January 11, 1977; effective February 10, 1977.

Amendment to rules 1140-01-.04(1), 1140-01-.14, 1140-01-.16, 1140-01-.19(6), and 1140-01-.28(1), (2), (4), (8), (9), (10) and (11)(b) filed January 11, 1977; effective February 10, 1977.

Rules 1140-01-.28(13), 1140-01-.31(2) and (7), and 1140-01-.38 filed January 11, 1977; effective February 10, 1977.

Amendments to rules 1140-01-.10, 1140-01-.24(1), 1140-01-.25, 1140-01-.30(1) and 1140-01-.31(5) filed December 15, 1977; effective January 16, 1978.

Rule 1140-01-.39 filed December 15, 1977; effective January 16, 1978.

Amendments to rules 1140-01-.28 and 1140-01-.31 filed April 27, 1978; effective July 14, 1978.

Amendments to rule 1140-01-.10 filed September 26, 1978; effective December 29, 1978.

Rules 1140-01-.40 and 1140-01-.41 filed September 26, 1978; effective December 29, 1978.

Original chapter 1140-01 filed November 22, 1978; effective January 8, 1979.

Amendments to rules 1140-01-.02, 1140-01-.07, and 1140-01-.31 filed April 11, 1979; effective July 30, 1979.

Repeal of chapter 1140-01 and new rules 1140-01-1-.01 through 1140-01-1-.10 filed February 7, 1983; effective March 9, 1983.

Original rules 1140-01-03-.01 through 1140-01-03-.24 and 1140-01-04-.01 through 1140-01-04-.21 filed February 7, 1983; effective March 9, 1983.

Amendments to rules 1140-01-.03, 1140-01-.04 and 1140-04-.12 filed December 17, 1984; effective March 16, 1985.

Amendment to rule 1140-01-.08 filed September 30, 1985; effective October 30, 1985.

Amendment to rule 1140-03-.11 filed November 25, 1985; effective February 12, 1986.

Amendment to rule 1140-01-.10 filed May 23, 1986; effective August 12, 1986.

Amendment to 1140-01-.07 and original chapter 1140-06 filed January 26, 1987; effective April 29, 1987.

Original chapter 1140-07-.01 through 1140-07-.07 filed October 1, 1987; effective November 15, 1987.

Amendment to rule 1140-03-.16 filed October 1, 1987; effective November 15, 1987.

Amendments to rule 1140-01-.10 filed October 1, 1987; effective January 27, 1988.

Amendments to rule 1140-03-.24 filed January 19, 1988; effective March 4, 1988.

Amendments to rules 1140-01-.02, 1140-01-.04 and 1140-01-.08 filed January 19, 1988; effective April 27, 1988.

Amendment to rule 1140-01-.10 filed November 18, 1988; effective February 28, 1989.

Amendment to rule 1140-01-.08 filed August 25, 1989; effective October 9, 1989.

Original chapter 1140-08 and amendments to rules 1140-01-.06, 1140-03-.18 and 1140-03-.21 filed November 15, 1989; effective December 30, 1989.

Amendment to rule 1140-01-.09 filed April 12, 1990; effective July 29, 1990.

Amendment to rule 1140-01-.10 filed October 18, 1990; effective January 29, 1991.

Amendment to rule 1140-01-.10 filed May 3, 1991; effective August 28, 1991.

Original rule 1140-03-.25 filed August 2, 1991; effective September 16, 1991.

Amendment to rules 1140-04-.12 and 1140-04-.13 filed August 30, 1991; effective November 27, 1991.

Amendment to rules 1140-01-.03, 1140-01-.08, 1140-03-.06, 1140-03-.18 and original rule 1140-01-.11 filed October 30, 1991; effective December 14, 1991.

Original chapter 1140-09 filed January 7, 1992; effective February 22, 1992.

Amendments to rules 1140-03-.03, 1140-03-.06, 1140-03-.22, 1140-04-.05 and 1140-07-.04 filed November 16, 1992; effective January 8, 1993.

Amendment to rule 1140-01-.10 filed December 22, 1992; effective March 31, 1993.

Amendment to rule 1140-01-.10 filed June 25, 1993; effective September 28, 1993.

Amendments to rules 1140-03-.04, 1140-03-.05, 1140-03-.18, 1140-03-.24, 1140-07-.01, 1140-07-.03,

1140-07-.04, 1140-07-.05, 1140-07-.06, and 1140-07-.07; original rules 1140-07-.08, 1140-07-.09, 1140-07-10; original chapter 1140-10 filed March 30, 1994; effective June 13, 1994.

Amendment to rules 1140-01-.08, 1140-01-.09, 1140-05-.02 through 1140-05-.05 filed November 17, 1993; effective March 30, 1995.

Amendment to rule 1140-03-.25 filed January 30, 1995; effective May 31, 1995.

Amendment to rule 1140-01-.10 filed October 19, 1996; effective February 28, 1996.

Repeal of and new chapter 1140-01 through 1140-10 filed May 11, 1998; effective July 25, 1998.

Amendment to rules 1140-01-.10, 1140-01-.14, 1140-02-.02, 1140-03-.04, 1140-03-.14, 1140-04-.09, and 1140-05-.02 filed August 19, 2002; effective November 2, 2002.

Original chapter 1140-11 filed December 22, 2005; effective March 7, 2006.

Public necessity rule filed 1140-12 filed February 16, 2007; expired July 31, 2007.

Public necessity rules 1140-13-.01 through 1140-13-.08 filed November 25, 2008; effective through May 9, 2009.

New rule 1140-03-.16, and amendments to rules 1140-01-.01, 1140-01-.05, 1140-01-.14, 1140-03-.15, 1140-05-.01, and 1140-06-.03 filed November 24, 2008; effective February 7, 2009.

New rule 1140-13-.01 through 1140-13-.08 filed February 24, 2009; effective May 10, 2009.

Amendments to rules 1140-01-.01, .09, and .14 and 1140-02-.01 and .02 filed December 23, 2009; effective March 23, 2010.

Amendments to rules 1140-01-.03 and 1140-02-.02 filed January 4, 2012; effective April 3, 2012.

Tenn. Comp. R. & Regs. Ch. 1140-02, Refs & Annos, TN ADC Ch. 1140-02, Refs & Annos

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy[Chapter 1140-03.](#) Standards of Practice ([Refs & Annos](#))**→→ 1140-03-.01. RESPONSIBILITIES FOR PHARMACEUTICAL CARE.**

(1) Patient counseling

- (a) Upon the receipt of a medical or prescription order and following a review of the patient's record, a pharmacist shall personally counsel the patient or caregiver “face-to-face” if the patient or caregiver is present. If the patient or caregiver is not present, a pharmacist shall make a reasonable effort to counsel through alternative means.
- (b) Alternative forms of patient information may be used to supplement, but not replace, face-to-face patient counseling.
- (c) Patient counseling, as described herein, shall also be required for outpatients of hospitals or other institutional facilities dispensing medical and prescription orders and for patients when medications are dispensed on discharge from the hospital or other institutional facility.
- (d) Patient counseling as described in this rule shall not be required for inpatients of an institutional facility.
- (e) Patient counseling shall cover matters, which in the exercise of the pharmacist's professional judgement, the pharmacist deems significant including:
 - 1. the name and description of the medication;
 - 2. the dosage form, dose, route of administration, and duration of drug therapy;
 - 3. special directions and precautions for preparation, administration, and use by the patient;
 - 4. common side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
 - 5. techniques for self-monitoring drug therapy;

6. proper storage;

7. prescription refill information; and

8. action to be taken in the event of a missed dose.

(f) Upon the receipt of a request for a refill of a medical or prescription order, a pharmacist or a person designated by the pharmacist shall offer for the pharmacist to personally counsel the patient or caregiver. Counseling as described in (e) above is not required unless requested by the patient or deemed necessary in the professional judgment of the pharmacist.

(g) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such counseling.

(2) Patient Profiling.

(a) A patient's record system shall be maintained by all pharmacy practice sites for patients for whom medical and prescription orders are dispensed. The patient's record system shall provide for the immediate retrieval of information necessary for the pharmacist to identify previously dispensed medical and prescription orders at the time a medical or prescription order is presented.

(b) In order to effectively counsel patients, the pharmacist or a person designated by the pharmacist shall, through communication with the patient, caregiver, or agent make a reasonable effort to obtain, record, and maintain the following information for each patient of the individual pharmacy practice site.

1. Name, address, telephone number.

2. Date of birth (age), gender.

3. An individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

4. Pharmacist's comments as deemed relevant. This may be done manually or by computer.

(3) Drug Regimen Review.

(a) A pharmacist shall be responsible for a reasonable review of a patient's record prior to dispensing each medical or prescription order. The review shall include evaluating the medical and prescription order for:

1. over-utilization or under-utilization;
2. therapeutic duplication;
3. drug-disease contraindication;
4. drug-drug interactions;
5. incorrect drug dosage or duration of drug treatment;
6. drug-allergy interactions;
7. clinical abuse/misuse.

(b) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem.

(4) Implementation of Pharmaceutical Care.

(a) As a necessary health care provider, pharmacists shall carry out, in addition to the responsibilities in paragraphs (1) through (3) of this rule, those professional acts, professional decisions and professional services necessary to maintain a patient's pharmacy-related care and to implement and accomplish the medical and prescription orders of licensed practitioners, including but not limited to:

1. Developing relationships with licensed practitioners to enable the pharmacist to accomplish comprehensive management of a patient's pharmacy related care and to enhance a patient's wellness, quality of life and optimize outcomes; and
2. Communicating to the health care provider any knowledge of unexpected or adverse response to drug therapy, or resolving unexpected or adverse response; and
3. Having a pharmacist accessible at all times to patients and healthcare providers to respond to their questions and needs.

Authority: *T.C.A. §§63-10-404(19),(22),(23),(26), and (34), 63-10-504(b)(1) and (2), 63-10-504(j), and 63-10-504(c).* **Administrative History:** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-03-.01, TN ADC 1140-03-.01

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy[Chapter 1140-03.](#) Standards of Practice ([Refs & Annos](#))**→→ 1140-03-.02. LOCATION OF PRACTICE.**

A pharmacist may compound and dispense prescription drugs and devices and related materials only in a pharmacy practice site which is duly licensed by the board and which operates in compliance with Tennessee and federal laws and rules governing the practice of pharmacy. The practice of the knowledge skills of pharmacy is not pharmacy practice site dependent. However, any person practicing any aspect of the art and science of pharmacy must be licensed by the board.

Authority: *T.C.A. §§63-10-404(4),(8),(11),(14),(26), and (28), 63-10-504(b)(1) and (2).* **Administrative History:** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-03-.02, TN ADC 1140-03-.02

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy**[Chapter 1140-03. Standards of Practice \(Refs & Annos\)](#)**→→ 1140-03-.03. MEDICAL AND PRESCRIPTION ORDERS.**

- (1) To the extent that a medical order contains an order for the compounding, dispensing or administration of a prescription drug or device or related material, the medical order shall be treated as a prescription order. Written medical and prescription orders must be signed by the prescriber. Verbal medical and prescription orders must be immediately reduced to writing (by hand or other means), dated, and initialed by the authorized individual accepting the medical and prescription orders.
- (2) Each medical and prescription order when dispensed shall be serially numbered, filed numerically and maintained so as to be readily retrievable at the pharmacy practice site for at least two (2) years from the date the medical and prescription order was last dispensed. Institutional pharmacies shall not be required to serially number medical and prescription orders dispensed for administration to inpatients of that institution.
- (3) A pharmacist upon initial dispensing of a medical or prescription order shall record on that medical or prescription order: the date such medical or prescription order was dispensed, the pharmacist's initials, and the amount of any product dispensed. If the pharmacist merely initials and dates a medical or prescription order the pharmacist shall be deemed to have dispensed the full face amount of the medical or prescription order.
- (4) A pharmacist upon refilling a medical or prescription order shall enter on the back of that medical or prescription order: the date such medical or prescription order was refilled, the pharmacist's initials, and the amount of any product dispensed on such refill. If the pharmacist merely initials and dates the back of the medical or prescription order the pharmacist shall be deemed to have dispensed a refill for the full face amount of the medical or prescription order. As an alternative to recording refill information on the back of medical and prescription orders, an automated data processing system may be used for the storage and retrieval of refill information for medical and prescription orders, subject to the following conditions:
 - (a) Any such computerized system must provide on-line retrieval (via CRT display or hard-copy printout) of the original medical or prescription order information and the complete refill history of all medical and prescription orders which are currently authorized for refilling. This shall include all the information contained in and required to be entered on each such medical or prescription order. This data must include at least the medical or prescription order serial number; date of issuance of the medical or prescription order; patient's name (and address on controlled substance medical and prescription orders); prescriber's name (and address and DEA registration number on controlled substance medical and prescription orders); product name, strength, dosage form, and quantity prescribed; directions for use, and labeling instructions; refill instructions; and the date of dispensing, quantity dispensed, and identity (name, initials,

or identification code) of the dispensing pharmacist for the original dispensing and each refill.

- (b) Each individual pharmacist using a computerized system in the refilling of a medical or prescription order shall certify that the information entered into the computer for such a refill is correct by verifying, dating, and signing a hard-copy printout of each day's medical or prescription order refill data, or in lieu of such a printout, by signing a statement in a book or file each day attesting that the refill information entered that day has been reviewed by the pharmacist and is correct as shown. Such documentation shall be separately maintained at the pharmacy practice site for at least two (2) years from the date of the last dispensing.
 - (c) Any such computerized system shall have the capability of producing a hard-copy printout of any medical or prescription order refill data which the pharmacy practice site is responsible for maintaining under the laws and/or regulations of this state and/or the federal government. (This would, for example, furnish a medical or prescription order-by-medical or prescription order, refill-by-refill audit trail for any specified strength and dosage form of any prescription drug and device, by either brand or generic name or both.) Such a printout must include: the medical or prescription order serial number; patient's name (and address on controlled substance medical and prescription orders); name of prescriber; name, strength, and dosage form of the product; and the date of each refill, quantity dispensed on each refill, and the name or identification code of the dispensing pharmacist. Controlled substance data contained on such a printout must be separated, asterisked, or in some other manner visually identifiable apart from other items appearing on the printout. Any computerized system employed by a pharmacy practice site must, upon the request of an authorized representative of the board, send or provide such a printout to the pharmacy practice site within forty eight (48) hours excluding weekends (Saturdays and Sundays) and legal holidays.
 - (d) In the event that a pharmacy practice site which utilizes such a computerized system experiences system down-time, the pharmacy practice site must have a written or readily retrievable auxiliary policy and procedure which will be used for documentation of refills of all medical and prescription orders. This auxiliary procedure must ensure that each refill is authorized, and that all appropriate data is retained for on-line data entry as soon as the computer system is available for use again.
 - (e) Each pharmacy practice site and pharmacist using such a computerized system must comply with the provisions of paragraphs one (1) and two (2) of this rule. In addition, the requirements of paragraph three (3) of this rule shall apply, unless this initial dispensing data is included on the printout required by subparagraph four (4)(b) of this rule, and is identified as pertaining to the initial dispensing.
- (5) A pharmacist may dispense an appropriately authorized refill of a medical or prescription order by referral to a patient profile (medication record) instead of the original medical or prescription order on file at that pharmacy practice site, subject to the following conditions:
- (a) The patient profile must contain all the information contained in and required to be entered on the original medical or prescription order, including the complete refill history of that medical or prescription

order. This data includes the medical or prescription order serial number; date of issuance of the medical or prescription order; name of patient; name of the prescriber; product name; strength; dosage form, and quantity prescribed; directions for use, and labeling instructions; refill instructions; and the date of dispensing, quantity dispensed, and initials of the dispensing pharmacist for the original dispensing and each refill. Dispensing data must be identified as to whether it pertains to the original dispensing or to a refill.

- (b) Controlled substance data contained on the patient profile must be asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the profile.
 - (c) The patient profile system must contain a complete and accurate record of the refill history of all medical and prescription orders dispensed at the pharmacy practice site. (This record will constitute compliance with the provisions of paragraph four (4) of this rule.)
 - (d) Each such profile must be maintained so as to be readily retrievable at the pharmacy practice site for at least two (2) years from the date of the last dispensing recorded on the profile.
 - (e) A pharmacist dispensing a medical or prescription order by referral to a patient profile in so doing certifies as to the accuracy and validity of the information contained on the patient profile.
 - (f) Each pharmacy practice site and pharmacist using such a patient profile system must comply with the provisions of paragraphs one (1) and two (2) of this rule. In addition, the requirements of paragraph three (3) of this rule shall obtain, unless the patient profile system contains a record of this initial dispensing information for all medical and prescription orders dispensed at the pharmacy practice site.
- (6) No pharmacist, or pharmacy intern or pharmacy technician under the supervision of a pharmacist, shall compound or dispense any medical or prescription order except upon the following conditions:
- (a) All medical and prescription orders shall be compounded and dispensed in strict conformity with any directions of the prescriber. Nothing in this rule shall prohibit a pharmacist from substituting a therapeutically equivalent prescription drug or device or related material containing the same active ingredient or ingredients, dosage form and strength;
 - (b) No medical or prescription order shall be refilled if it contains a statement over the signature of the prescriber that it is not to be refilled, and a medical or prescription order shall not be refilled unless so authorized by the prescriber;
 - (c) If any medical or prescription order contains a statement that it may be refilled a specified number of times within or during any particular period, such order shall be refilled in strict conformity with such statement; and

(d) If a prescription contains a statement that during any particular time it may be refilled at will, the order shall be refilled in strict conformity to dosage directions, with the exception that it may not be refilled after the expiration of the time specified or one (1) year from the date the order was originally issued or dispensed, whichever comes first.

(e) At a rate, based on the actual number of medical and prescription orders compounded and dispensed per hour or per day, that does not pose a danger to the public health, safety or welfare.

(7) Copies of Medical and Prescription Orders.

(a) Copies of medical and prescription orders issued directly to the patient by the pharmacy practice site where the order was originally compounded and dispensed pursuant to the receipt of the order shall bear on the face thereof, in letters red in color and equal in size to those describing the prescription drug or device or related material, the statement: "Copy for Information Only." Presentation of an informational written copy or label of a dispensing container shall be for information purposes only and have no legal status as a valid medical or prescription order. The recipient pharmacist of such copy or label shall contact the prescriber or transferor pharmacy practice site and obtain all information required by this rule, which is the same as obtaining an original medical or prescription order;

(b) Medical and prescription orders shall be transferred between pharmacy practice sites for the purpose of compounding and dispensing provided that the transferee, upon receiving such order directly from the transferor, records the following:

1. The name, address and original medical or prescription order serial number at the pharmacy practice site from which the order was transferred;

2. The name of the transferor; and

3. All information constituting a medical or prescription order including the following:

(i) Date of original dispensing;

(ii) Original number of refills authorized on the original order;

(iii) Date of last dispensing; and

(iv) Number of valid refills remaining.

(c) The transferee informs the patient that the original medical or prescription order has been canceled at the

pharmacy practice site from which it was obtained.

(d) Computerized systems must satisfy all information requirements.

(e) The transfer of schedule III, IV, V, controlled substances are subject to the conditions set forth in C.F.R. 1306.26.

(8) It is unlawful for any pharmacy practice site, pharmacist, or pharmacy intern or pharmacy technician under the supervision of a pharmacist, or any other place of business engaged in compounding and dispensing prescription drugs and devices and related materials for human consumption to receive from any patient or other person the return of any portion of an order that has been taken from the premises of the pharmacy practice site or other place of business, except pursuant to 1140-4-.10.

(9) Medical and prescription orders cannot be accepted, solicited, collected or advertised at a location other than a pharmacy practice site for which a license has been issued by the board, and such pharmacy practice site shall be actively engaged in compounding and dispensing medical and prescription orders.

(10) Medical and prescription orders typed or printed must be signed by the prescriber. Oral medical and prescription orders shall be initialed by the authorized individual accepting the order.

Authority: *T.C.A. §§63-10-404(4),(11),(14),(19),(26),(29),(30), and (34), 63-10-504(b)(1), 63-10-504(j), and 63-10-504(b)(1) and (2). Administrative History: Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed November 16, 1992; effective January 8, 1993. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-03-.03, TN ADC 1140-03-.03

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy[Chapter 1140-03.](#) Standards of Practice ([Refs & Annos](#))**→→ 1140-03-.04. FACSIMILE AND ELECTRONIC MEDICAL AND PRESCRIPTION ORDERS.**

(1) Facsimile Orders

- (a) The transmission of a facsimile medical or prescription order shall be to a pharmacy practice site of the patient's choice and shall occur only at the option of the patient.
- (b) Medical and prescription orders may be transmitted to a pharmacy practice site by a facsimile device. Medical and prescription orders for controlled substances may be transmitted by facsimile devices in compliance with 21 C.F.R. 21306.11, [1306.21](#) and [1306.31](#).
- (c) A pharmacist may dispense medical and prescription orders transmitted by facsimile devices only when transmitted by an authorized prescriber or the prescriber's designated agent.
- (d) A facsimile medical or prescription order which meets the requirements of this rule shall be deemed the original medical or prescription order for purposes of filing. The facsimile medical or prescription order must either be photocopied or the original medical or prescription order should be of such quality to not fade within the legal requirements of medical or prescription order record keeping.
- (e) Wholesalers, manufacturers, pharmacists and pharmacy practice sites are prohibited from supplying facsimile devices or supplies to any authorized prescriber under any conditions.
- (f) An original medical or prescription order that indicates that it has been faxed to a pharmacy practice site, consistent with the provisions of this rule, may only be dispensed as an original medical or prescription order by the pharmacy practice site to which it was faxed, consistent with the notation on the medical or prescription order to be made in accordance with the requirements contained in this rule.

(2) Electronic Orders.

- (a) Prescription or medical orders transmitted electronically shall meet the following criteria:
 - 1. All prescription or medical orders shall be transmitted directly from an authorized prescriber or prescriber's agent to a licensed pharmacist or to an area in a licensed pharmacy of the patient's choice

that is under the direct supervision of a licensed pharmacist, with no intervening person or entity having access to the order for purposes other than transmission of the order. Subject to the provisions of this rule, a prescriber or prescriber's agent may electronically transmit medical or prescription orders to a pharmacist within an institutional facility for inpatients and/or outpatients currently under treatment at that facility. Nothing in this subsection shall apply to distributors of medical gases.

2. The transmission shall include:

- (i) The telephone number of the authorized prescriber to allow verbal confirmation of the validity and accuracy of the order;
 - (ii) The correct time and date of the transmission;
 - (iii) The name of the pharmacy to which the order is being transmitted; and
 - (iv) The prescribing practitioner's electronic signature or other secure method of validation. "Electronic Signature" is defined as the process that secures the user authentication (proof of claimed identify, such as by biometrics, fingerprints, retinal scans, hand written signature verification, etc.) at the time the signature is generated and creates the logical manifestation of a signature.
 - (v) If the transmission is delegated by the prescriber to an agent of the prescriber, the identity of the agent shall be included in the transmission.
- (b) A hard copy or exact image of the transmitted order shall be maintained in the pharmacy and shall be deemed the original prescription or medical order meeting all requirements of rule 1140-03-.03 of the rules of the board.
- (c) The Pharmacist receiving any transmitted order shall not knowingly participate in any system that restricts the patient's choice of pharmacy.
- (d) The pharmacist may not provide financial or other remuneration to the prescriber for any prescription transmitted to the dispensing pharmacy. No person or entity, including but not limited to wholesalers, distributors, manufacturers, pharmacists, and pharmacies, shall supply electronic equipment, software, devices, or modems to any prescriber in exchange for transmitting orders.
- (e) The pharmacist shall not use the electronic transmission of orders to circumvent or violate any provision of state or federal drug laws, or the Tennessee Pharmacy Practice Act, or the regulations of the board.
- (f) This rule shall not apply to medical or prescription orders electronically transmitted between pharmacies

or medical or prescription orders transmitted by facsimile.

Authority: *T.C.A. §§63-10-404(19),(26),(29),(30), and (34), 63-10-504, 63-10-504(b)(1) and (2), and 63-10-504(j).* **Administrative History:** *Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002.*

Tenn. Comp. R. & Regs. 1140-03-.04, TN ADC 1140-03-.04

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1140. Board of Pharmacy

⌕ [Chapter 1140-03.](#) Standards of Practice ([Refs & Annos](#))

➡➡ **1140-03-.05. AREAS OF RECEIPT AND DISPENSING.**

All medical and prescription orders shall be received or accepted and compounded and dispensed from a pharmacy practice site which is in a building permanently located and non-mobile in nature. In case of emergency, the board may waive this rule upon request.

Authority: *T.C.A. §§63-10-404(4),(11),(19),(28), and (34), and 63-10-504(b)(1) and (2)(j).* **Administrative History:** *Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-03-.05, TN ADC 1140-03-.05

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy [Chapter 1140-03.](#) Standards of Practice ([Refs & Annos](#))**→→ 1140-03-.06. LABELING REQUIREMENTS.**

The dispensing label for a medical or prescription order shall bear at least the following information: name and address and telephone number of pharmacy practice site; the medical or prescription order serial number, name of prescriber; name of patient; directions for use; date medical or prescription order originally dispensed, and/or refill date; “poison”, “shake”, “caution”, or other appropriate advisory label; name of product (unless otherwise required by the prescriber); and expiration date of the product (if applicable). This rule shall not apply to medical and prescription orders dispensed by an institutional pharmacy for administration to inpatients of that institution.

Authority: *T.C.A. §§63-10-404(11), (15), and (19), and 63-10-504(b)(1) and (2)(j).* **Administrative History:** *Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed October 30, 1991; effective December 14, 1999. Amendment filed November 16, 1992; effective January 8, 1993. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-03-.06, TN ADC 1140-03-.06

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy[Chapter 1140-03.](#) Standards of Practice ([Refs & Annos](#))**→→ 1140-03-.07. TEMPORARY ABSENCE OF PHARMACIST.**

A pharmacist is permitted one (1) temporary absence for a period not exceeding one (1) hour per day. During the absence of a pharmacist from the pharmacy practice site, a sign containing the words “pharmacist not on duty” must be conspicuously displayed in the pharmacy practice site. It shall be unlawful to fail or refuse to display the required sign in a conspicuous place when a pharmacist is absent. No medical or prescription order may be compounded or dispensed during the absence of a pharmacist. Additionally, during the absence of the pharmacist the prescription department shall be closed off by physical barrier from floor to ceiling.

Authority: *T.C.A. §§63-10-404(4),(11),(19),(26),(28), and (34), and 63-10-504(b)(1) and (2)(j).* **Administrative**

History: *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-03-.07, TN ADC 1140-03-.07

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-03. Standards of Practice \(Refs & Annos\)](#)**→→ 1140-03-.08. REPACKAGING.**

- (1) Any repackaging of prescription drugs and devices and related materials must be supervised and controlled by a pharmacist with in-process and end-process verification and documentation.
- (2) Prescription drugs and devices and related materials which are repackaged by an institutional pharmacy practice site for subsequent dispensing and use within the institution shall be labeled to include:
 - (a) the name, strength, and quantity of prescription drug or device or related material, if larger than one (1), in the container;
 - (b) the manufacturer's name, and lot or control number;
 - (c) the expiration date of the prescription drug or device or related material being repackaged; and
 - (d) cautionary notations (e.g., refrigerate, shake well, not for injection), if applicable.
- (3) A batch number assigned by the pharmacy practice site may be placed on the label in lieu of the manufacturer's name and lot number, provided that the pharmacy practice site maintains a readily retrievable record which identifies, by batch number, the manufacturer and lot number of the prescription drug or device or related material.
- (4) The pharmacy practice site shall have proper facilities, qualified personnel, effectual operational practices, suitable packaging material, and adequate control procedures to assure that the purity, integrity, safety, and effectiveness of the prescription drug or device or related material are not affected by such repackaging. All repackaging must be performed by a pharmacist or by a pharmacy intern or pharmacy technician under the supervision of a pharmacist.

Authority: *T.C.A. §63-10-404(8),(14),(26), and (28), and 63-10-504(b)(1) and (2). Administrative History: Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-03-.08, TN ADC 1140-03-.08

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1140. Board of Pharmacy

☞ [Chapter 1140-03.](#) Standards of Practice ([Refs & Annos](#))

➔➔ **1140-03-.09. LOSS OF PRESCRIPTION DRUGS, DEVICES AND RELATED MATERIALS.**

The pharmacist in charge shall immediately report to the board any robbery, embezzlement, theft, burglary, or fire or disaster resulting in a loss of prescription drugs, or controlled substances or medical devices or related materials. The report shall include a list, including amounts, of such prescription drugs or controlled substances or medical devices or related materials lost or damaged.

Authority: *T.C.A. §§63-10-404(6),(8),(14), and (27), 63-10-504(b)(1) and (2).* **Administrative History:** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-03-.09, TN ADC 1140-03-.09

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy[⌕](#) [Chapter 1140-03.](#) Standards of Practice ([Refs & Annos](#))**→→ 1140-03-.10. CONDITIONS FOR DELIVERY OR SALE.**

- (1) No package containing any prescription drug or device or related material damaged by fire, heat, smoke, water, or other causes shall be placed in stock, offered for sale or dispensed or otherwise sold. Any repossession proceedings must be performed with the approval of the board.
- (2) Under no circumstances shall any prescription drug or device or related material damaged by fire, heat, smoke, water, or other causes be delivered or handed over to any insurance company, adjustor, salvage company, or other person unless approved by the board prior to delivery.

Authority: *T.C.A. §§63-10-404(8),(11), and (14), and 63-10-504(b)(1) and (2).* **Administrative History:** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-03-.10, TN ADC 1140-03-.10

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⌕ [Chapter 1140-03.](#) Standards of Practice ([Refs & Annos](#))

➡➡ **1140-03-.11. OUTDATED AND DETERIORATED DRUGS.**

The owner or pharmacist in charge of a pharmacy practice site shall immediately return or destroy all outdated, defective, or deteriorated prescription drugs and devices and related materials; except that the destruction of controlled substances listed in any schedule shall be performed by a board approved agent or vendor.

Authority: *T.C.A. §§63-10-404(6), (8), (14), (27), and (28), and 63-10-504(b)(1) and (2).* **Administrative History:** *Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed November 25, 1985; effective February 12, 1986. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-03-.11, TN ADC 1140-03-.11

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy**[Chapter 1140-03. Standards of Practice \(Refs & Annos\)](#)**→→ 1140-03-.12. STORAGE, SALE AND DELIVERY.**

- (1) All prescription drugs and controlled substances and devices and related materials shall be stored in an area not accessible to the public.
- (2) A controlled substance which is not a prescription drug under the Federal Food, Drug, and Cosmetic Act may be dispensed by a pharmacist without a prescription to a patient provided the pharmacist complies with the provisions of [21 CFR §1306.32](#) and any other applicable law.
- (3) Instruments and/or devices intended for the injection of any substance through the skin shall be stored in an area not accessible to the public, and shall be sold only on proof of medical need by a pharmacist or a pharmacy intern or pharmacy technician under the direct supervision of a pharmacist.
- (4) All insulin preparations must be stored in an area not accessible to the public, and shall be sold only by a pharmacist or a pharmacy intern or pharmacy technician under the direct supervision of a pharmacist.
- (5) Nothing in this section prohibits delivery of a prescription to a patient's home or business by an agent of the pharmacy practice site.

Authority: *T.C.A. §§63-10-404(6),(8),(14),(26), and (28), and 63-10-504(b)(1) and (2). Administrative History: Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-03-.12, TN ADC 1140-03-.12

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy⌕ [Chapter 1140-03.](#) Standards of Practice ([Refs & Annos](#))➔➔ **1140-03-.13. AUTOMATED DISPENSING DEVICES FOR AMBULATORY PHARMACY PRACTICE.**

The following procedures shall be observed in the use and operation of automated dispensing devices used for storing and dispensing capsules or tablets:

- (1) The lot number of each drug contained therein must be listed or posted on the device.
- (2) After each lot number is used, the portion of the device where the drug was contained must be thoroughly cleaned to remove all residue before refilling.
- (3) Lot numbers may not be mixed.
- (4) The device may be loaded by a pharmacist; or a pharmacy intern or a pharmacy technician under the supervision of a pharmacist.

Authority: *T.C.A. § 63-10-404(8),(14),(26),(29), and (30), and 63-10-504(b)(1) and (2).* **Administrative History:** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-03-.13, TN ADC 1140-03-.13

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-03. Standards of Practice \(Refs & Annos\)](#)**→→ 1140-03-.14. PHARMACIST IN CHARGE.**

- (1) The board shall maintain a current record of all pharmacists who have been designated “pharmacist in charge” of a pharmacy practice site in the state of Tennessee.
- (2) It shall be the responsibility of the person, partnership, firm, or corporation holding a pharmacy practice site license issued pursuant to [T.C.A. § 63-10-506](#) to notify the board immediately of:
 - (a) the resignation, removal, or death of the pharmacist in charge named in the application for license (or successor pharmacist in charge); or
 - (b) the disability for a period exceeding thirty (30) days of the pharmacist in charge named in the application for license (or successor pharmacist in charge).
- (3) The notice required by paragraph two (2) of this rule shall contain:
 - (a) the name and (except in the case of death or disability) signature of the outgoing pharmacist in charge;
 - (b) the effective date of the appointment (whether temporary or permanent) of the new pharmacist in charge;
 - (c) the name and signature of the new pharmacist in charge; and
 - (d) the name and address of the pharmacy practice site.
- (4) Except in case of death or incapacity, the outgoing pharmacist in charge shall, prior to departure, conduct with the successor pharmacist in charge a joint inventory of all controlled substances. In case of failure of the outgoing pharmacist in charge to comply with this requirement, the successor pharmacist in charge shall conduct such inventory alone.
- (5) In the event of death of a pharmacist in charge, the successor pharmacist in charge shall, immediately upon assuming the appointment as pharmacist in charge, conduct an inventory of all controlled substances.

- (6) In the event of disability for a period exceeding thirty (30) days of a pharmacist in charge, the successor pharmacist in charge (temporary or permanent) shall conduct an inventory of all controlled substances. Should the disabled pharmacist in charge return, the disabled pharmacist in charge and successor pharmacist in charge shall immediately conduct a joint inventory of all controlled substances.
- (7) A record of any inventory required by this rule shall be signed by the pharmacist(s) in charge conducting it and maintained at the pharmacy practice site with other controlled substance records for at least two (2) years. The inventory record shall indicate:
- (a) the name and address of the pharmacy practice site;
 - (b) the name, strength, dosage form, and quantity of each controlled substance on hand;
 - (c) the date of inventory; and
 - (d) whether the inventory was taken as of the opening or close of business on that date.
- (8) The pharmacist in charge shall immediately notify the board in writing in the event of termination of business by the pharmacy practice site at which the pharmacist in charge practices. Such notice shall include a complete statement concerning the disposition by the pharmacy practice site of controlled substances and all prescription drugs and devices and related materials, invoices, records, and files.
- (9) In a transaction involving the purchase of a pharmacy practice site or its stock of prescription drugs and devices and related materials, both the pharmacist in charge, except in case of death or incapacity, of the pharmacy practice site selling and the pharmacist in charge of the pharmacy practice site buying the stock, or the new owner of the pharmacy practice site if no pharmacist in charge has been appointed, shall jointly inventory all controlled substances and both shall sign and date that inventory and mail a copy of that inventory to the board within thirty (30) days of the completion of the sale.
- (10) The pharmacist in charge shall maintain a current registry of individuals employed at the pharmacy practice site performing the functions of a pharmacy technician.
- (11) This rule does not relieve other pharmacists or persons from their responsibility to comply with state laws and regulations.
- (12) No pharmacist shall be designated pharmacist in charge of more than one (1) pharmacy practice site except where the board determines that such is in the best interest of the public health.
- (13) The designated pharmacist in charge at a particular pharmacy practice site shall be on duty a minimum of

fifty percent (50%) of the hours that the pharmacy is in operation. Except, in any event, the pharmacist in charge shall not be required to be on duty more than an average of forty (40) hours per week.

- (14) The designated pharmacist in charge shall report to the board any situation in which a medical or prescription order has caused serious personal injury or death.

Authority: *T.C.A. §§63-10-404(2),(25),(26),(27), and (28), and 63-10-504(b)(1) and (2). Administrative History: Original rule filed February 7, 1983; effective March 9 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002.*

Tenn. Comp. R. & Regs. 1140-03-.14, TN ADC 1140-03-.14

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1140. Board of Pharmacy

⌕ [Chapter 1140-03.](#) Standards of Practice ([Refs & Annos](#))

➔➔ **1140-03-.15. REFERENCE BOOKS.**

Each pharmacy practice site shall maintain an adequate reference library (printed or electronic) consistent with its scope of practice. The reference library shall include a current edition of the Tennessee Pharmacy Laws issued by the Tennessee Board of Pharmacy and may include current material regarding the technical, clinical, and professional components of the practice of pharmacy, with particular emphasis in the area in which the pharmacy specializes.

Authority: [T.C.A. §§63-10-304](#). **Administrative History:** Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed November 24, 2008; effective February 7, 2009.

Tenn. Comp. R. & Regs. 1140-03-.15, TN ADC 1140-03-.15

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-03. Standards of Practice \(Refs & Annos\)](#)**→→ 1140-03-.16. AUTOMATED DISPENSING DEVICES FOR PHARMACY PRACTICE.**

Centralized Prescription Processing:

- (1) A pharmacy may perform or outsource centralized prescription processing services to another pharmacy, provided that the following criteria are satisfied:
 - (a) both pharmacies shall be licensed by the State of Tennessee;
 - (b) both pharmacies shall share a common electronic file or both shall have the appropriate technology to allow each other access to information that is necessary to fill or refill a prescription order; and
 - (c) both pharmacies shall have the same owner or in the event that the pharmacies do not have the same owner, then the pharmacies shall enter a written contract stating the services that will be provided by each pharmacy as well as the responsibilities of each pharmacy in fulfilling the terms of the contract and in complying with federal and state laws and rules.
- (2) The pharmacy performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual stating how prescription orders will be filled or refilled through centralized prescription processing. The pharmacies shall provide the Board with a copy of the manual and appropriate documentation of the processes for the Board's review, upon the Board's request. The pharmacies shall ensure that the manual includes, but is not limited to the following:
 - (a) a description of how the pharmacies will comply with federal and state law and rules;
 - (b) the maintenance of records to identify the responsible pharmacist(s) in the dispensing process;
 - (c) the maintenance of a mechanism for tracking the prescription order during each step of the dispensing process:
 1. the maintenance of a mechanism to identify all of the pharmacies involved in dispensing the prescription order on the prescription label;

2. adequate security measures to protect the confidentiality and integrity of the patient information; and
3. the maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality of patient care, the identification of problems with patient care and the resolution of any identified problems with patient care.

(d) The pharmacies that are not physically located in the State of Tennessee shall comply with Tenn. Code Ann Title 63, Chapter 10 and the rules of the State of Tennessee Board of Pharmacy.

Authority: Chapter 966 of the Public Acts of 2008, §1, and [T.C.A. §63-10-304](#). **Administrative History:** New rule filed November 24, 2008; effective February 7, 2009.

Tenn. Comp. R. & Regs. 1140-03-.16, TN ADC 1140-03-.16

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1140. Board of Pharmacy

☞ [Chapter 1140-04.](#) Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites ([Refs & Annos](#))

➡➡ **1140-04-.01. APPLICABILITY.**

A pharmacy providing products and services to any institutional facility, and alternate or alternative infusion pharmacy practice site, shall be subject to all rules of the board dependent upon services provided.

Authority: *T.C.A. §§63-10-404(2) and (28) and 63-10-504(b)(1) and (2).* **Administrative History:** *Original rule filed February 7, 1983; effective March 9, 1983.*

Tenn. Comp. R. & Regs. 1140-04-.01, TN ADC 1140-04-.01

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☞ [Chapter 1140-04. Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites \(Refs & Annos\)](#)

➔➔ **1140-04-.02. PERSONNEL.**

- (1) Pharmacist in charge. The practice of pharmacy and the performance of pharmacists and supportive pharmacy personnel associated with any institutional facility shall be under the direction, supervision and responsibility of the pharmacist in charge. The pharmacist in charge shall also be responsible for the dispensing, distribution, compounding, storage and the procurement of prescription and nonprescription drugs used throughout the institutional facility. Policies and procedures defining the scope of pharmacy practice and the responsibilities of the pharmacists and supportive personnel, and the safe use and management of drugs, devices and related materials shall be established by the pharmacist in charge. The pharmacist in charge or designee shall participate in the institution's drug policy committees which serve to ensure rational drug use, patient care evaluation processes relating to drug utilization and effectiveness, drug delivery device selection and evaluation systems, and educational activities for the safe and appropriate use of drugs which will assess the quality of services and products provided and document actions taken. Policies and procedures as indicated in this chapter shall be written and shall be made available to the board.
- (2) Pharmacists. The pharmacist in charge shall be supported by a sufficient number of pharmacists to provide appropriate practice of pharmacy for the patients served by the institutional facility. Employment of pharmacists by the institutional facility shall be determined by the pharmacist in charge.
- (3) Institutional consultant pharmacist. An institutional facility may utilize a consultant pharmacist who may or may not be independent of the pharmacy practice site, who shall provide patient care service which includes, but is not limited to:
 - (a) development, interpretation, and communication of drug, device and related materials orders and health information;
 - (b) providing consultation on matters pertaining to efficient drug distribution systems, proper drug selection, rational and safe drug use, and drug therapy assessment;
 - (c) evaluation of a patient's drug therapy to maximize outcome(s), including effective communication with prescribing practitioners and other healthcare professionals;
 - (d) effective counseling of a patient or a patient's attorney for healthcare or other caregiver;

(e) service on committees or governing bodies; and

(f) providing in service educational programs for members of the healthcare team.

(4) Supportive personnel. The pharmacist in charge shall be assisted by a sufficient number of pharmacy technicians, as defined in 1140-2-.02 pharmacy interns, and other supportive personnel as may be required to operate the pharmacy competently, safely, and adequately to meet the needs of the patients served by the institution.

(5) Supervision. All of the activities associated with the practice of pharmacy and the operations of the pharmacy at a specific institutional pharmacy practice site shall be supervised by a sufficient number of pharmacists to ensure that all functions and activities are performed competently, safely and without risk of harm to patients.

Authority: *T.C.A. §§63-10-404(4), (8), (11), (14), (21), (26), (27), (28), and (30) and 63-10-504(b)(1) and (2).*

Administrative History: *Original rule filed February 7, 1983; effective March 9, 1983.*

Tenn. Comp. R. & Regs. 1140-04-.02, TN ADC 1140-04-.02

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☞ [Chapter 1140-04. Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites \(Refs & Annos\)](#)

➔➔ **1140-04-.03. PHYSICAL REQUIREMENTS.**

- (1) Area. An institutional or alternative infusion pharmacy practice site shall have sufficient floor space allocated to it to ensure that medical and prescription orders are prepared and dispensed in sanitary, well lighted, and enclosed spaces. The institutional pharmacy shall also have sufficient counter space or other suitable work module to ensure that medical and prescription orders are prepared and dispensed in an orderly manner.
- (2) Equipment and Materials. The pharmacy practice site shall have sufficient equipment and physical facilities for the practice of pharmacy. This shall include but not be limited to:
 - (a) hot and cold running water;
 - (b) refrigerated storage space;
 - (c) frozen storage space as appropriate; and
 - (d) adequate information systems.
- (3) Storage. All prescription drugs and devices and related materials shall be stored in designated areas within the pharmacy practice site which are sufficient to ensure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security.
- (4) Alcohol and Flammables. Alcohol and flammables shall be stored in an area that shall, at a minimum, meet basic local building code requirements for the storage of volatiles, and such other laws, ordinances, or regulations that may apply.
- (5) Security. A pharmacy practice site shall be capable of being locked to prevent access by unauthorized personnel. A pharmacist must be accessible within the institutional facility where an institutional pharmacy practice site is located; and when no pharmacist is present at the institution, the pharmacy practice site must be kept closed and securely locked except as provided in 1140-4-.14.

Authority: *T.C.A. §§63-10-404(8), (14), and (28) and 63-10-504(b)(1) and (2). Administrative History: Original rule filed February 7, 1983; effective March 7, 1983.*

Tenn. Comp. R. & Regs. 1140-04-.03, TN ADC 1140-04-.03

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☞ [Chapter 1140-04.](#) Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites ([Refs & Annos](#))

➔➔ **1140-04-.04. PRESCRIPTION ORDERS.**

A pharmacist shall review all prescription orders before the drug is first dispensed. In the event that medications available in the institutional facility are ordered and administered before the pharmacist's review, the order shall be reviewed by a pharmacist in a timely manner. The pharmacist shall have access to the patient's medical record. The original order must be maintained in a readily retrievable manner according to the pharmacy practice site policy for at least two (2) years from the date of its issuance.

Authority: *T.C.A. §§63-10-404(1), (11), (14), (26), and (28) and 63-10-504(b)(1) and (2). Administrative*

History: *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-04-.04, TN ADC 1140-04-.04

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☞ [Chapter 1140-04. Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites \(Refs & Annos\)](#)

➔➔ **1140-04-.05. DISTRIBUTION AND CONTROL OF DRUGS.**

The pharmacist in charge or designee, in conjunction with appropriate committees of the facility, shall be responsible for approving policies for the distribution and control of drugs within the facility. The process shall be established to provide for the safe and efficient distribution of drugs and for the provision of pharmaceutical care, and shall include but not be limited to:

- (1) A drug dispensed from the pharmacy for subsequent administration to a patient shall be appropriately identified with the name and location of the patient and the name and strength of the drug.
- (2) The pharmacist in charge is responsible for the development and maintenance of an audit trail on drugs dispensed.
- (3) The prescription order shall be recorded on a patient medication profile that will be maintained during the patient's treatment. This profile shall include the date of the prescription order, the name and dosage form of the drug and the dose and administration frequency.
- (4) The facility distribution system may be based on a combination of processes that will ensure compliance with federal and state guidelines such as emergency kits/crash carts, floorstock systems, automated dispensing devices, medication carts, and/or after-hours procedures for pharmacy site access.

Authority: *T.C.A. §§63-10-404(11), (14), and (27) and 63-10-504(b)(1) and (2). Administrative History: Original rule filed February 7, 1983; effective March 9, 1983. Amendment to rule filed November 16, 1992; effective January 8, 1993. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-04-.05, TN ADC 1140-04-.05

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⌕ [Chapter 1140-04.](#) Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites ([Refs & Annos](#))

➡➡ **1140-04-.06. MEDICATION CARTS.**

Drugs distributed from the pharmacy to other areas of the institutional facility may be stored in medicine cabinets or drug carts which shall be kept secured unless in use by the nursing staff or other authorized personnel. Access to the medication cart shall be defined by facility policies. It is recommended that drugs be dispensed in unit dose packaging and medications for each patient shall be distributed and stored in separate trays, drawers, compartments, or containers assigned to that resident and bearing the resident's name and location.

Authority: *T.C.A. §§63-10-404(11), (14), and (28) and 63-10-504(b)(1) and (2).* **Administrative History:** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-04-.06, TN ADC 1140-04-.06

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☞ [Chapter 1140-04.](#) Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites ([Refs & Annos](#))

➔➔ **1140-04-.07. FLOORSTOCK DRUGS.**

The pharmacist in charge or designee, in conjunction with appropriate committees, shall be responsible for approving policies and procedures for floorstock at the institutional facility. The policies shall include specific drugs, quantities, prescription order review, storage requirements, and replenishment of drugs, devices, or related materials which are supplied to the institutional facility as floorstock.

Authority: *T.C.A. §§63-10-404(8), (14), and (27) and 63-10-504(b)(1) and (2).* **Administrative History:** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-04-.07, TN ADC 1140-04-.07

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☞ [Chapter 1140-04. Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites \(Refs & Annos\)](#)

➔➔ **1140-04-.08. CONTROLLED DRUGS.**

(1) Controlled substances (and those drugs deemed by the pharmacist in charge to have a potential for abuse) which are issued as floorstock shall be accounted for by providing documentation of:

- (a) the drug name, strength, and dosage form;
- (b) the date and time of administration;
- (c) the quantity/dose administered;
- (d) identification of the patient;
- (e) identification of the prescriber; and
- (f) identification of the authorized personnel administering the controlled substance.

(2) A record of the destruction of controlled substances previously dispensed to or for patients shall be maintained so as to be readily retrievable for at least two (2) years, and such records shall include:

- (a) the identification of patient;
- (b) drug name, strength, dosage form, and quantity;
- (c) the date and method of destruction; and
- (d) the identification of authorized personnel witnessing the destruction and its record.

(3) Schedule II controlled substances which are kept within a pharmacy practice site shall be stored in a secured, substantially constructed cabinet, safe, or other structure which provides a double locked secured system.

- (4) Nothing in this rule shall be interpreted to authorize the destruction of controlled substance floorstock or pharmacy stock. Such drugs shall upon request, be destroyed or returned to the pharmacy for destruction by a board approved agent or vendor.

Authority: *T.C.A. §§53-11-302, 63-10-404(11), (14), (27), and (28) and 63-10-504(b)(1) and (2)(j).*

Administrative History: *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-04-.08, TN ADC 1140-04-.08

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📖 [Chapter 1140-04. Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites \(Refs & Annos\)](#)

➡➡ **1140-04-.09. EMERGENCY AND HOME CARE KITS.**

Drugs and devices and related materials may be provided by emergency kits as defined by policies and procedures provided that such kits meet the following requirements:

(1) Emergency Kits.

(a) Drugs and devices and related materials may be provided by emergency kits as defined by policies and procedures, provided that such kits meet the following requirements:

1. Emergency kit drugs are those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients. Drugs in this kit are to be used only for emergency orders.
2. The policies and procedures to implement the requirements of this subsection and to approve the contents of the emergency kit will be determined by a committee composed of representatives of the medical and nursing staff and the pharmacist in charge or his/her designee.
3. The emergency kit shall be provided sealed or electronically secured by authorized personnel in accordance with established policies. The expiration date of the kit shall be clearly marked on the exterior of the kit to represent the earliest expiration date of any drug, device, or related materials contained in the kits.
4. Emergency kits shall be stored in a secured area at the institutional facility or patient care site to prevent unauthorized access. To ensure a proper environment for preservation of the drugs contained therein, appropriate policies and procedures shall be written to include storage at the site of patient care.
5. Only authorized individuals may obtain drugs, devices or related materials from the emergency kit in accordance with established policies and state and federal laws and regulations.
6. A list of the emergency kit contents shall be readily accessible and it shall include the drugs, devices, and related materials contained therein and include the name (trade and/or generic), strength, and quantity of the products contained therein.

7. A mechanism must be in place to ensure that the emergency kits are not in use after the expiration date.
8. Drugs contained within the emergency kit shall be properly labeled according to the United States Food and Drug Administration (FDA) labeling requirements for the drug or device and with additional information that may be required by the staff to prevent misunderstanding or risk of harm to the patients.
9. Removal of any drug, device, or related material from the emergency kit shall be pursuant to a valid medical or prescription order and must be documented by established policy which may include patients identification, name of the drug, strength, amount, date, time, and identification of the authorized individual removing the drug.
10. When an emergency kit is opened for any reason, the pharmacy practice site shall be notified, and the kit shall be restocked and resealed within a reasonable time so as to prevent risk of harm to patients.

(2) Home Care Kits.

- (a) A home care kit is a kit containing certain drugs, as determined by the board, to be kept in the home of the patient for use by a healthcare professional engaged in home healthcare of a patient as necessary to meet the therapeutic needs of patients and which are not available from any other source in sufficient time to prevent risk of harm to patients.

1. A home care kit may contain:

- (i) Sodium Chloride for Injection 0.9% Bacteriostatic
- (ii) Sterile Water for injection Bacteriostatic or Preservative Free
- (iii) Epinephrine injection 1mg/ml
- (iv) Diphenhydramine
- (v) Heparin Flush < or = 100units/ml
- (vi) Naloxone
- (vii) Sodium Chloride for Irrigation

(viii) Sterile Water for Irrigation

(ix) Dextrose 50%

(x) Urokinase 5000units

(xi) Any other legend drug as approved by the board.

(b) Drugs contained in home care kits are to be used for emergencies only. Maintenance of a central venous catheter is considered an emergency if confirmed with the patient's physician or his/her designee.

(c) Policies and procedures for the dispensing, use, storage at the patient care site, security and expiration date review, and reconciliation of drug contents shall be determined as in section (1)(a)2 of this rule. Additional policies or protocols for treating anaphylactic reaction, maintaining patency of intravenous or central venous catheters, or flushing of intravenous devices shall be established, in the same manner.

(d) Removal of any drug from the Home Care Kit shall be pursuant to a valid medical or prescription order and/or protocol and must be documented in the patient's medical record.

(e) When a home care kit is opened for any reason, the pharmacy practice site shall be notified and the kit shall be restocked and resealed within a reasonable time so as to prevent risk of harm to patients.

Authority: *T.C.A. §§63-10-504 and 63-10-504(b)(1) and (2). Administrative History: Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002.*

Tenn. Comp. R. & Regs. 1140-04-.09, TN ADC 1140-04-.09

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➔➔ **1140-04-.10. UNUSED DRUGS, DEVICES, AND RELATED MATERIALS.**

Discontinued, outdated, defective, or deteriorated drugs, devices, or related materials and containers with worn, illegible, or missing labels shall be returned to the pharmacy practice site for proper disposition. All such drugs, devices or related materials returned to the pharmacy practice site must be destroyed unless in unit dose packaging, unopened commercially prepackaged containers and in the professional judgment of the pharmacist in charge or designee, the medications or related materials meet all federal and state board standards for product integrity.

Authority: *T.C.A. §§63-10-404(8), (14), (16), (28) and 63-10-504(b)(1) and (2).* **Administrative History:** *Original rule filed February 7, 1983; effective March 9, 1983; effective March 9, 1983. Repeal and rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-04-.10, TN ADC 1140-04-.10

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☞ [Chapter 1140-04. Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites \(Refs & Annos\)](#)

→→ 1140-04-.11. TAKE-HOME AND LEAVE OF ABSENCE DRUGS, DEVICES, AND RELATED MATERIALS.

- (1) All prescription drugs prescribed for and dispensed to patients who are on leave of absence from the institutional facility must be dispensed in accordance with the institution's policies and procedures.
- (2) All prescription drugs prescribed for and dispensed to patients who are being discharged from the institutional facility must be dispensed with labeling in accordance with 1140-3-.06.
- (3) The pharmacist in charge in coordination with the medical and nursing staff committees of the facility shall establish policies and procedures to assure that this process meets state and federal guidelines appropriate for the facility.

Authority: *T.C.A. §§63-10-404(11), (14), (16), and (27) and 63-10-504(b)(1) and (2). Administrative History: Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-04-.11, TN ADC 1140-04-.11

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➔➔ **1140-04-.12. DRUGS BROUGHT INTO THE FACILITY.**

- (1) The pharmacist in charge shall establish policies to control any drugs brought into the institutional facility.
- (2) Administration of these drugs shall be pursuant to a medical or prescription order.
- (3) Drugs brought into the facility shall not be administered until properly identified.
- (4) Drugs which are not to be administered shall be packaged, sealed, and returned to an adult member of the patient's family for removal from the institutional facility or the drugs shall be securely stored and returned to the patient at discharge per facility policy.

Authority: *T.C.A. §§63-10-404(14), (19), (27), and (34) and 63-10-504(b)(1) and (2).* **Administrative History:** *Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed December 17, 1984; effective March 16, 1985. Amendment filed August 30, 1991; effective November 27, 1991.*

Tenn. Comp. R. & Regs. 1140-04-.12, TN ADC 1140-04-.12

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☞ [Chapter 1140-04.](#) Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites ([Refs & Annos](#))

➔➔ **1140-04-.13. RECALLS.**

The recall procedure shall be readily activated to ensure that all prescription drugs and devices and related materials included on the recall are returned to the pharmacy practice site for proper disposition. The pharmacist in charge shall develop and implement policies and procedures for recalls.

Authority: *T.C.A. §§63-10-404(8), (14), (27), and (28) and 63-10-504(b)(1) and (2).* **Administrative History:** *Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed August 30, 1991; effective November 27, 1991. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-04-.13, TN ADC 1140-04-.13

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⌕ [Chapter 1140-04. Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites \(Refs & Annos\)](#)

➔➔ **1140-04-.14. ABSENCE OF PHARMACIST.**

(1) Institutional pharmacy practice site.

(a) General. During such times as an institutional pharmacy practice site is closed, facility policy as approved by the pharmacist in charge shall provide a process for authorized personnel to obtain drugs necessary for the provision of patient care. This function may also be accomplished as outlined in the After Hours Drug Provision of this section. A pharmacist must be “on call” twenty four (24) hours per day, seven (7) days per week.

(b) After Hours Drug Provision. When an institutional pharmacy practice site is closed, access to prescription drugs shall be by locked cabinet(s), automated dispensing machines or other enclosure(s) constructed and located outside of the pharmacy practice site, to which only personnel authorized by the pharmacist in charge may obtain access. Access should be sufficiently secured to deny entry to unauthorized persons by force or otherwise. Those practice sites utilizing automated dispensing devices for after hours drug provision shall meet the requirements of rule 1140-4-.15. The pharmacist in charge shall develop an inventory listing of those drugs to be included in such after hours storage, and shall ensure that:

1. such prescription drugs are available therein, properly labeled;
2. such prescription drugs are prepackaged in amounts not to exceed a seventy-two (72) hour medication period; unless available in a commercially prepared package dictating multiple dose therapy (e.g., ophthalmic products, topical products, otic products);
3. all prescription drugs therein are inventoried at least once a month;
4. a record shall be made at the after hours storage location including the following elements:
 - (i) the date and time of removal of a drug;
 - (ii) the patient's name and location;

(iii) the name, strength, dosage form, and quantity of the prescription drug; and

(iv) the identification of the authorized personnel removing the drug.

5. the prescription order shall be verified by a pharmacist or designee in a timely manner.

6. the above record shall be used by authorized pharmacy personnel to replenish the after hours storage location, and this record shall be kept at the institutional pharmacy practice site so as to be readily retrievable for at least two (2) years;

7. policies and procedures shall be established to implement the requirements of this section.

(c) Access to the Pharmacy Practice Site within an Institutional Facility. Whenever any prescription drug is not available from floor supplies, emergency kits, or other approved distribution system for the facility, and such prescription drug or device or related material is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such prescription drug, device or related material may be obtained from the pharmacy practice site in accordance with the requirements of this paragraph. Only authorized personnel, accompanied by a security guard or other authorized employee of the institution may have access to the pharmacy practice site and may remove the required drug, device or related material. Such person(s) shall be designated through policies of the facility and shall receive appropriate education and training in the proper methods of access and removal of prescription drugs, records and procedures required prior to such person(s) being permitted to obtain access to the pharmacy practice site. Such education and training shall be conducted by the pharmacist in charge or designee, who shall require, at a minimum, the following records and procedures;

1. Removal of any prescription drug, device or related material from the pharmacy practice site by an authorized person(s) must be recorded in a suitable form at the pharmacy practice site showing:

(i) the date and time of removal of the drug;

(ii) patient identification and location;

(iii) the name, strength, dosage form, and quantity of the drug, device or related material removed; and

(iv) the signatures of the authorized personnel and the accompanying witness;

2. The above record shall be maintained at least two (2) years at the pharmacy practice site in a separate file or log book;

3. The medication or prescription order shall be verified by a pharmacist or authorized personnel; and
 4. The quantity of drug removed shall not exceed the amount needed plus one (1) dose until the pharmacy practice site reopens; unless available in a commercially prepared package dictating multiple dose therapy (e.g., ophthalmic products, topical products, otic products).
- (2) Alternate or Alternative Infusion pharmacy practice site.
- (a) During such times as an alternate or alternative infusion pharmacy practice site is closed, policies and procedures shall be established by the pharmacist in charge for the provision of prescription drugs, devices and related materials to patients on a twenty four (24) hours per day seven (7) days per week basis.
 - (b) A pharmacist must be “on call” during all absences.

Authority: *T.C.A. §§63-10-404(11), (14), (15), (19), (26), (27), (28), and (34) and 63-10-504(b)(1) and (2).*

Administrative History: *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-04-.14, TN ADC 1140-04-.14

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⌕ [Chapter 1140-04. Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites \(Refs & Annos\)](#)

➡➡ **1140-04-.15. AUTOMATED DISPENSING DEVICES IN INSTITUTIONAL PRACTICE SITES.**

No prescription drug or device or related material shall be distributed or issued by the use of any automated dispensing device unless the device and the method of operation have been found by the board to ensure the purity, potency, and integrity of the prescription drug or device or related material, and to protect the prescription drug or device or related material from diversion.

- (1) A pharmacist shall be designated to be accountable for this automated dispensing system.
 - (a) Individuals authorized by the facility policies and the pharmacist in charge will stock this device under the supervision of a pharmacist, if a pharmacist is not stocking the device.
 - (b) The pharmacist will work collaboratively with healthcare professionals to ensure that appropriate controls and monitors are utilized to provide information that drugs dispensed were for the correct patient and that pilferage is identified and resolved.
- (2) All persons authorized to have access to these automated devices shall have documentation that they have successfully completed a training program that teaches them to perform the functions they perform with the automated device.
- (3) Automated dispensing systems shall be used only for the furnishing of drugs and devices and related materials or other products related to the care of patients of that institution or facility; and
- (4) At the time of removal of any drug or device or related material from the device, it shall automatically make a record, to be retained by the pharmacy for a minimum of two (2) years, indicating:
 - (a) the date and time of removal of the drug or device or related material;
 - (b) the name, strength, dosage form, and quantity of drugs or devices or related material removed;
 - (c) the identification of the patient for whom the drug or device or related material was ordered; and

- (d) the identification of the person authorized to remove the drug or device or related material from the device.
- (5) The pharmacist in charge or designee is responsible for determining how access codes or other methods of access to automated devices are assigned.
- (6) The facility shall have policies and procedures approved by the pharmacist in charge in coordination with members of the nursing and medical staff for the points outlined in this section for automated dispensing devices.

Authority: *T.C.A. §§63-10-404(8), (11), (14), (26), and (27) and 63-10-504(b)(1) and (2). Administrative*

History: *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-04-.15, TN ADC 1140-04-.15

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☞ [Chapter 1140-04. Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites \(Refs & Annos\)](#)

➔➔ **1140-04-.16. EMERGENCY ROOMS.**

If prescription drugs, devices and related materials in an emergency room are to be dispensed (other than by pharmacy staff) rather than administered, the drugs, devices or related materials must be dispensed by the physician or an emergency room nurse or certified physician assistant at the direction of a physician. If the physician in an emergency room does not personally dispense, then prescription drugs, devices and related materials for outpatient use must be packaged in containers from the pharmacy practice site in amounts not to exceed a twelve (12) hour period or with products commercially prepared for multiple dose therapy (e.g., ophthalmic products, topical products, otic drops) in the smallest available package. These prescription drugs, devices or related materials shall be dispensed only after a medical or prescription order has been issued and recorded in the emergency room and shall be labeled with appropriate labeling.

Authority: *T.C.A. §§63-10-404(1), (8), (11), (15), (19), (28), and (34) and 63-10-504(b)(1) and (2).*

Administrative History: *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-04-.16, TN ADC 1140-04-.16

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☞ [Chapter 1140-04.](#) Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites ([Refs & Annos](#))

➔➔ **1140-04-.17. INVESTIGATIONAL DRUGS.**

The pharmacist in charge in coordination with the institutional facility, medical and nursing staff and, if appropriate, the pharmaceutical manufacturer, shall develop policies and procedures for the approval, management, distribution and control of investigational drug studies. The process shall ensure that such studies contain safeguards for the patient, for the institution and for the scientific integrity of the study. Each patient or the patient's legal guardian must freely consent, in writing, to treatment with the drugs, unless otherwise not required by federal law. The pharmacist is responsible to the institution and to the principal investigator for seeing that procedures for the control of investigational drugs are developed and implemented when needed.

Authority: *T.C.A. §§63-10-404(14) and (26) and 63-10-504(b)(1) and (2).* **Administrative History:** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-04-.17, TN ADC 1140-04-.17

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☞ [Chapter 1140-04. Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites \(Refs & Annos\)](#)

➔➔ **1140-04-.18. MONTHLY INSPECTIONS.**

The pharmacist in charge shall be responsible (personally or by qualified designee) for documented monthly inspections of all drugs, devices and related materials kept at nursing stations, surgery, delivery rooms, emergency rooms, clinics, and any other area of the facility. Records of such inspections shall be dated, signed and maintained so as to be readily retrievable at the pharmacy practice site for at least two (2) years. These inspections must assure the following:

- (1) test reagents, germicides, and disinfectants are stored separately from drugs, devices and related materials;
- (2) external drugs, devices and related materials are stored separately from internal drugs, devices and related materials;
- (3) thermolabile drugs are stored at the proper temperature;
- (4) drugs, devices and related materials requiring special storage conditions to ensure their stability are properly stored;
- (5) there are no outdated or deteriorated drugs, devices or related materials;
- (6) all drugs, devices and related materials are properly labeled;
- (7) emergency drugs, devices and related materials are stored in accordance with rule 1140-4-.10;
- (8) medicine cabinets, carts and storage areas are accessible to authorized personnel only;
- (9) dispensing of controlled substances is properly and adequately documented;
- (10) telephone numbers of regional poison control centers and other emergency assistance organizations are posted;

(11) metric-apothecaries' weight and measure conversion tables and charts are available; and

(12) adequate pharmaceutical references for the drugs administered in that location are available.

Authority: *T.C.A. §§63-10-404(8) (14), and (28) and 63-10-504(b)(1) and (2).* **Administrative History:** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-04-.18, TN ADC 1140-04-.18

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-05. Continuing Education \(Refs & Annos\)](#)**→→ 1140-05-.01. REQUIREMENTS FOR PHARMACIST LICENSE RENEWAL.**

- (1) Every person licensed as a pharmacist shall complete at least thirty (30) hours of continuing pharmaceutical education during each two (2) year license cycle. The required thirty (30) hours shall consist of at least fifteen (15) hours obtained through live contract programs. In order to fulfill the fifteen (15) live contact hour requirement, a pharmacist shall obtain the hours from a program designated as “live” by the ACPE-approved provider, from a program that is approved by the Board prior to the expiration of the pharmacist's license or from an out-of-state program that is approved by the board of pharmacy in the state where the program was presented.
- (2) Notwithstanding paragraph one (1) of this rule, no pharmacist shall be required to complete any continuing pharmaceutical education during a two (2) year license cycle if that pharmacist presents proof that during all or part of the license cycle the pharmacist was enrolled in a recognized academic program pursuing a pharmacy degree, a doctor of medicine degree, a doctor of osteopathic medicine degree, a doctor of dental surgery degree, or an advanced or graduate degree in a health-related science; or participating in a pharmacy residency or fellowship program; or engaged in a course of study leading to certification as a nurse practitioner or a physician assistant.
- (3) The board may waive the requirements of this rule upon a showing of emergency, illness, or other good cause.

Authority: *T.C.A. §§63-10-204, 63-10-304, 63-10-306, 63-10-404(5) and (26), 63-10-504(b)(1) and 63-10-506(g).* **Administrative History:** *Original rule filed December 5, 1984; effective January 4, 1985. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed November 24, 2008; effective February 7, 2009.*

Tenn. Comp. R. & Regs. 1140-05-.01, TN ADC 1140-05-.01

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- (1) Each pharmacist shall submit to the board with the license renewal form, and on a form provided by the Tennessee Board of Pharmacy, a sworn statement indicating that the pharmacist has completed the required number of continuing pharmaceutical education hours.
- (2) The board shall not renew the license of any pharmacist until the applicant has submitted the required sworn statement indicating that the pharmacist has completed the required number of continuing pharmaceutical education contact hours during the previous license cycle.
- (3) The licensee shall produce proof of the completion of the required number of continuing pharmaceutical education hours upon the request of the board or its designee.
- (4) Falsification of the continuing pharmaceutical education sworn statement may result in the probation, suspension or revocation of the pharmacist's license and/or the imposition of a civil penalty not to exceed one thousand dollars (\$1,000.00) with the imposition of a requirement for additional continuing education if appropriate.

Authority: *T.C.A. §§56-1-308, 63-10-504(b)(1), and 63-10-506. Administrative History: Original rule filed December 5, 1984; effective January 4, 1985. Amendment filed November 17, 1994; effective March 30, 1995. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002.*

Tenn. Comp. R. & Regs. 1140-05-.02, TN ADC 1140-05-.02

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⌕ [Chapter 1140-05.](#) Continuing Education ([Refs & Annos](#))

➡➡ **1140-05-.03. RECOGNITION OF PROGRAMS.**

The board will recognize any continuing pharmaceutical education hours obtained from an ACPE-approved provider.

Authority: *T.C.A. §§63-10-404(5) and 63-10-504(b)(1).* **Administrative History:** *Original rule filed December 5, 1984; effective January 4, 1985. Amendment filed November 17, 1994; effective March 30, 1995. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-05-.03, TN ADC 1140-05-.03

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⌕ [Chapter 1140-05.](#) Continuing Education ([Refs & Annos](#))

➡➡ **1140-05-.04. FALSIFICATION OF RECORDS.**

Any pharmacist who alters, forges, or falsifies, or causes to be altered, forged, or falsified any information, documents, or records required to be kept or submitted by this Chapter shall be subject to disciplinary action by the board under [T.C.A. § 63-10-505\(6\)](#).

Authority: [T.C.A. §§63-10-404\(2\) and \(26\) and 63-10-504\(b\)\(1\)](#). **Administrative History:** Original rule filed December 5, 1984; effective January 4, 1985. Amendment filed November 17, 1994; effective March 30, 1995. Repeal and new rule filed May 11, 1998, effective July 25, 1998.

Tenn. Comp. R. & Regs. 1140-05-.04, TN ADC 1140-05-.04

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1140. Board of Pharmacy

⌕ [Chapter 1140-06.](#) Nuclear Pharmacy Practice Sites ([Refs & Annos](#))

➡➡ **1140-06-.01. APPLICABILITY.**

The provisions of this Chapter are in addition to, and not in substitution for, other applicable laws and rules administered by the board, the State Board of Radiological Health.

Authority: *T.C.A. § 63-10-504(b)(1).* **Administrative History:** *Original chapter filed January 26, 1987; effective April 29, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-06-.01, TN ADC 1140-06-.01

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy**[Chapter 1140-06. Nuclear Pharmacy Practice Sites \(Refs & Annos\)](#)**→→ 1140-06-.02. GENERAL REQUIREMENTS.**

- (1) A nuclear pharmacy practice site shall contain adequate space, commensurate with the scope of services required and provided. The board may, upon request, exempt a nuclear pharmacy practice site handling radioactive drugs exclusively from the minimum space requirements for pharmacy practice sites.
- (2) The compounding and dispensing area for radioactive drugs shall be separate from the compounding and dispensing area for non-radioactive drugs, and shall be secured from unauthorized personnel.
- (3) All pharmacy practice sites handling radiopharmaceuticals shall provide adequate radioactive storage and product decay area, preferably separate from and exclusive of the hot laboratory and the compounding, dispensing, quality assurance, and office areas.

A nuclear pharmacy practice site shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.

- (5) A pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with [T.C.A. 68-202-206](#). A nuclear pharmacy practice site may also furnish radiopharmaceuticals for office use to authorized practitioners for individual patient use.
- (6) In addition to any labeling requirements of the board for non-radioactive drugs, the immediate outer container of a radioactive drug to be dispensed shall also be labeled with:
 - (a) the standard radiation symbol;
 - (b) the words "Caution - Radioactive Material";
 - (c) the radionuclide;
 - (d) the chemical form;
 - (e) the amount of radioactive material contained, in millicuries or microcuries;

- (f) if a liquid, the volume;
 - (g) the calibration time for the amount of radioactivity contained;
 - (h) the expiration time; and
 - (i) the name, address, and telephone number of the nuclear pharmacy practice site.
- (7) The immediate container shall be labeled with:
- (a) the standard radiation symbol;
 - (b) the words “Caution - Radioactive Material”;
 - (c) the name of the drug; and
 - (d) the medical or prescription order number.
- (8) The amount of radioactivity shall be determined by radiometric methods for each product immediately prior to dispensing.
- (9) A nuclear pharmacy practice site shall conduct and keep proper records of appropriate internal test assessments on all radiopharmaceuticals, with interpretation of the resulting data to determine suitability for use in humans.
- (10) A nuclear pharmacy practice site shall conduct authentication of product history by identifying and keeping proper records of the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.


Authority: *T.C.A. § 63-10-404(4),(11),(16),(28), § 63-10-504(b)(1), § 63-10-504(b)(1),(2), § 63-10-504(j).*

Administrative History: *Original chapter filed January 26, 1987; effective April 29, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-06-.02, TN ADC 1140-06-.02

Current through rules effective December 2013

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy [Chapter 1140-06.](#) Nuclear Pharmacy Practice Sites ([Refs & Annos](#))**→→ 1140-06-.03. LIBRARY.**

Each nuclear pharmacy practice site shall maintain an adequate reference library (printed or electronic) consistent with its scope of practice. The reference library shall include a current edition of the Tennessee Pharmacy Laws issued by the Tennessee Board of Pharmacy and may include current material regarding the technical, clinical, and professional components of the practice of pharmacy, with particular emphasis in the area in which the pharmacy specializes.

Authority: [T.C.A. § 63-10-304](#). **Administrative History:** Original chapter filed January 26, 1987; effective April 29, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed November 24, 2008; effective February 7, 2009.

Tenn. Comp. R. & Regs. 1140-06-.03, TN ADC 1140-06-.03

Current through rules effective December 2013

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy**[Chapter 1140-06. Nuclear Pharmacy Practice Sites \(Refs & Annos\)](#)**→→ 1140-06-.04. EQUIPMENT.**

Each nuclear pharmacy practice site shall contain at least the following equipment:

- (1) Vertical laminar flow hood;
- (2) Dose calibrator;
- (3) Refrigerator;
- (4) Room monitor;
- (5) Portable survey meter;
- (6) Single or multiple channel scintillation counter;
- (7) Microscope;
- (8) Radio chemical exhaust hood and filter system, only if required for licensing by the State Board of Radiological Health.
- (9) Such other equipment as may be required by the State Board of Radiological Health.

Authority: *T.C.A. § 63-10-504(b)(1),(2). Administrative History: Original chapter filed January 26, 1987; effective April 29, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998*

Tenn. Comp. R. & Regs. 1140-06-.04, TN ADC 1140-06-.04

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1140. Board of Pharmacy

▢ [Chapter 1140-07.](#) Sterile Product Preparation in Pharmacy Practice ([Refs & Annos](#))

➔➔ **1140-07-.01. APPLICABILITY.**

The provisions of this Chapter shall apply to all pharmacy practice sites and pharmacists, pharmacy interns, pharmacy technicians and supportive personnel involved in the compounding and dispensing of sterile products.

Authority: *T.C.A. § 63-10-404(4),(11),(26),(28),(29),(30), § 63-10-504(b)(1),(2).* **Administrative History:** *Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-07-.01, TN ADC 1140-07-.01

Current through rules effective December 2013

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy [Chapter 1140-07.](#) Sterile Product Preparation in Pharmacy Practice ([Refs & Annos](#))**→→ 1140-07-.02. PERSONNEL.**

- (1) The pharmacist in charge or pharmacist designee shall be responsible for, at a minimum, the following:
 - (a) Procurement, storage, compounding, labeling, repackaging, dispensing, and distribution of all prescription drugs and devices and related materials necessary in compounding and dispensing sterile products;
 - (b) Establishment of policies and procedures for the compounding and dispensing of sterile products;
 - (c) Documentation of competency in aseptic techniques of all pharmacists, pharmacy interns and pharmacy technicians. The aseptic technique of each person compounding and dispensing sterile products shall be observed and evaluated as satisfactory during orientation and training and at least on an annual basis or whenever unacceptable techniques are observed or detected;
 - (d) Establishment of a quality assurance program;
 - (e) Reviewing and updating annually all policies and procedures; and
 - (f) Provision of sterile products on a twenty four (24) hour a day basis.
- (2) All pharmacists, pharmacy interns and pharmacy technicians as defined in 1140-2-.02 responsible for compounding or dispensing sterile products shall:
 - (a) Obtain practical and/or academic training in the compounding and dispensing of sterile products;
 - (b) Complete annual continuing education related to sterile product compounding and dispensing and utilization; and
 - (c) Maintain, in the pharmacy practice site, documentation of completion of the required training and continuing education.

- (d) Use proper aseptic technique in all sterile product compounding as defined by the pharmacy practice site's policies and procedures.
- (3) A pharmacist shall be available to respond to patients' and other health care practitioners' information needs on a twenty four (24) hour a day basis.
- (4) The pharmacist in charge shall be assisted by such additional pharmacists, pharmacy interns, pharmacy technicians as defined by 1140-2-.02 and supportive personnel necessary to operate the pharmacy practice site competently and safely and to provide services in a timely and appropriate manner.
- (5) All pharmacists, pharmacy interns and pharmacy technicians must be qualified through an appropriate combination of specific training and experience to operate or manipulate any item of equipment, apparatus, or device to which such pharmacists, interns and technicians will be assigned to use to compound and dispense sterile products.
- (6) A written record of initial and subsequent training and competency evaluations shall be maintained in the pharmacy practice site and contain the following information:
 - (a) Name of the person receiving the training or evaluation;
 - (b) Date(s) of the training or evaluation;
 - (c) General description of the topics covered; and
 - (d) Signature of the person receiving the training or evaluation and the pharmacist in charge or pharmacist designee of the pharmacist in charge.

Authority: *T.C.A. § 63-10-404(4),(5),(8),(11),(14),(16),(26),(27),(29),(30), § 63-10-504(b)(1),(2).*

Administrative History: *Original chapter filed October 1, 1987; effective November 15, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-07-.02, TN ADC 1140-07-.02

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy**[Chapter 1140-07. Sterile Product Preparation in Pharmacy Practice \(Refs & Annos\)](#)**→→ 1140-07-.03. PHYSICAL REQUIREMENTS.****(1) Area, Equipment and Materials.**

- (a) 1. The sterile product compounding area shall be enclosed from other pharmacy practice site operations in order to minimize the potential for sterile product contamination.
2. This area shall be designed as a limited access area to avoid unnecessary traffic and airflow disturbances.
3. The enclosure of the sterile product compounding area may be achieved through the utilization of partitions, plastic curtains, or similar washable solid surface dividers.
4. Entrances to the sterile product compounding area must contribute to the enclosure.
5. Materials utilized to define the enclosure must extend from the floor to a minimum of the top of the hood.
6. All surfaces of the sterile product compounding area shall be washable, non carpeted, and low particulate generating.
7. No new construction or remodeling will be approved that is not either:
 - (i) Fully enclosed as noted in paragraphs (3), (4) and (5) above; or
 - (ii) Has documented engineering studies validating that air flow in a partially opened design creates an atmosphere that is equal to a fully enclosed design.
- (b) For hand washing a sink with hot and cold running water shall be located in or adjacent to the area where sterile products are compounded.

- (c) There shall be appropriate refrigeration for storing supplies and sterile products requiring refrigeration after being prepared and before being dispensed or administered to patients.
 - 1. Documentation of refrigeration integrity shall be maintained in accordance with the pharmacy practice site's policies and procedures.
- (d) The storage of prescription drugs and devices and related materials shall be under appropriate conditions (e.g., controlled temperature, well lighted, dry, clean, secure, and well ventilated).
 - 1. Prescription drugs and devices and related materials shall not be stored in the sterile product compounding area in shipping containers (e.g., corrugated cardboard or other high particulate producing containers).
 - 2. After removal from shipping containers, unit packaging will be acceptable for storage in the sterile product compounding area.
- (e) All sterile product compounding must be performed within a Class 100 laminar flow hood, biologic-safety cabinet (Class II, Type A) or within a Class 100 clean room.
- (f) Laminar flow hoods, biologic safety cabinets (Class II, Type A) and Class 100 clean rooms shall be certified according to current federal standards for operational efficiency at least semi-annually.
- (g) The laminar flow hood, biologic safety cabinet (Class II, Type A) or Class 100 clean room shall be kept running continuously; however, if the hood is turned off, the hood shall be functioning at least thirty (30) minutes before being used to compound sterile products, or according to recommendations of the manufacturer to achieve appropriate air velocity and a complete cleaning of the inside works before being used to compound sterile products.
- (h) The sterile product compounding area shall be adequately ventilated so as not to interfere with laminar flow hood conditions and be used only for the compounding of sterile products.
- (i) Prefilters in laminar flow hoods shall be changed at least quarterly and a written record of such change shall be maintained.
- (j) The storage of prescription drugs, devices and related materials outside of the pharmacy shall be supervised and approved by the pharmacist in charge and inspected monthly to ensure that the products' safe storage is being maintained. These inspections shall be in accordance with rule 1140-4-.18.

Authority: *T.C.A. § 63-10-404(4),(8),(14), § 63-10-504(b)(1),(2).* **Administrative History:** *Original chapter filed*

October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

Tenn. Comp. R. & Regs. 1140-07-.03, TN ADC 1140-07-.03

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy**[Chapter 1140-07. Sterile Product Preparation in Pharmacy Practice \(Refs & Annos\)](#)**→→ 1140-07-.04. POLICY AND PROCEDURE MANUAL.**

(1) A policy and procedure manual related to sterile product compounding shall be available for inspection at the pharmacy practice site. The manual shall include policies and procedures for:

- (a) security;
- (b) equipment;
- (c) sanitation;
- (d) reference materials;
- (e) prescription drug and device and related material storage;
- (f) prescription drug and device and related material compounding and dispensing;
- (g) prescription drug and device and related material labeling and relabeling;
- (h) prescription drug and device and related material destruction and returns;
- (i) dispensing of sterile products;
- (j) record keeping;
- (k) quality assurance;
- (l) quality control;
- (m) duties for pharmacist(s), pharmacy intern(s), pharmacy technician(s) and supportive personnel;

(n) public safety relative to harmful sterile products;

(o) attire; and

(p) pharmacist, pharmacy intern, and pharmacy technician training.

Authority: *T.C.A. § 63-10-404(4),(8),(14),(26),(29),(30), § 63-10-504(b)(1),(2).* **Administrative History:** *Original rule filed October 1, 1987; effective November 15, 1987. Amendment filed November 16, 1992; effective January 8, 1993. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-07-.04, TN ADC 1140-07-.04

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-07. Sterile Product Preparation in Pharmacy Practice \(Refs & Annos\)](#)**→→ 1140-07-.05. LABELING.**

(1) At the time of dispensing of the sterile product, the dispensing container must bear a label which contains the following information:

- (a) patient's name (if for outpatient use);
- (b) prescriber (s) name (if for outpatient use);
- (c) pharmacy practice site name, address, and phone number (if for outpatient use);
- (d) identification of the pharmacist who compounded the sterile product;
- (e) when applicable, identification of the pharmacy intern or pharmacy technician who assisted in the compounding of the sterile product;
- (f) name and amount of drug added;
- (g) expiration date and, when applicable, expiration time;
- (h) date of compounding;
- (i) appropriate auxiliary label(s); and
- (j) directions for use (if for outpatient).

(2) Original medical or prescription orders for sterile products shall comply with applicable state and federal laws and regulations.

Authority: *T.C.A. §63-10-404(11),(14),(19),(26),(28),(29),(30),(32),(34), § 63-10-504(b)(1),(2).* **Administrative**

History: *Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30,*

1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

Tenn. Comp. R. & Regs. 1140-07-.05, TN ADC 1140-07-.05

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-07. Sterile Product Preparation in Pharmacy Practice \(Refs & Annos\)](#)**→→ 1140-07-.06. HAZARDOUS PRODUCTS.****(1) Physical Requirements.**

(a) If the pharmacy practice site is engaged in the compounding of hazardous sterile products, a suitable facility to prepare such products and minimize the risk associated with such products shall be provided.

(b) Such pharmacy practice site shall be designed and equipped for storage and have a procedure for disposal of materials containing hazardous residues in accordance with state and federal laws.

(1) A dedicated Class II, Type A contained vertical flow biohazard cabinet is the minimally acceptable compounding site for the routine compounding of hazardous sterile products.

(2) Hazardous sterile products shall be segregated within the pharmacy practice site and storage areas so identified.

(2) Dispensing.

(a) Prepared doses of hazardous sterile products for patients shall be placed in an appropriate outer wrap to minimize the risk exposure in case of accidental rupture of the primary container.

(b) Reasonable effort shall be made to assure that all hazardous sterile product primary containers and waste are removed from the site of use and disposed of as hazardous waste in accordance with applicable state and federal laws.

(3) Training.

(a) As part of the training for all pharmacists, pharmacy interns and pharmacy technicians involved in compounding of hazardous sterile products, an annual certification must be made by each pharmacist, pharmacy intern and pharmacy technician and the pharmacist in charge that each has read and understands the latest editions of:

1. Work Practice Guidelines for Personnel Dealing with Cytotoxic (Antineoplastic) Drugs (Occupational); and
 2. The American Society of Health-System Pharmacists (ASHP) technical assistance bulletin on handling cytotoxic and hazardous substances.
- (4) Hazardous sterile products dispensed shall bear a distinctive warning label with an appropriate caution statement thereon.
- (5) Gloving and gowning shall be required in the compounding of hazardous sterile products. Gloves should be rinsed frequently with a sanitizing agent (e.g., seventy percent (70%) isopropyl alcohol) and shall be changed when the integrity of the gloves is compromised.
- (6) In the compounding of hazardous sterile products, a protective disposable gown made of lint-free low permeability fabric with a closed front, long sleeves and elastic or knit closed cuffs with cuffs tucked under the gloves shall be worn. Gowns and gloves used in the compounding of hazardous sterile products shall not be worn outside the sterile product compounding area.

Authority: *T.C.A. § 63-10-404(4),(11),(26),(27),(28),(29),(30), § 63-10-504(b)(1),(2). Administrative History: Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-07-.06, TN ADC 1140-07-.06

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy [Chapter 1140-07.](#) Sterile Product Preparation in Pharmacy Practice ([Refs & Annos](#))**→→ 1140-07-.07. ATTIRE.**

- (1) All pharmacists, pharmacy interns and pharmacy technicians shall wear clean garments that generate low levels of particulate. Concerning clothing worn in a sterile product compounding area with a laminar flow hood or biologic safety cabinet (Class II, Type A), one (1) of the following must apply:
 - (a) Upon entering the sterile product compounding area, pharmacists, pharmacy interns and pharmacy technicians shall don an outer garment that generates a low level of particulate (e.g., clean laboratory jacket, disposable gown) before compounding sterile products. Upon leaving the sterile product compounding area, this outer garment shall be disposed of or left at the entrance of the sterile product compounding area and donned when re-entering the area.
 - (b) If scrubs or site specific clothing are donned for work in the sterile product compounding area, a laboratory jacket or outer covering shall be worn while outside the sterile product compounding area in order to protect the scrubs or site specific clothing from cross contamination. Upon entering the sterile product compounding area the lab jacket or outer covering shall be removed before compounding sterile products.
- (2) All pharmacists, pharmacy interns and pharmacy technicians with respiratory conditions that may result in contamination of sterile products shall wear a mask.
- (3) For the compounding of sterile products prior to receipt of specific medical or prescription orders and when the anticipated dispensing time may be greater than twenty eight (28) hours after preparation; clean, low particulate outer garments and gloves shall be required. Hair cover and a mask shall be required, unless a biologic safety cabinet (Class II, Type A) is utilized.
- (4) If utilizing a Class 100 clean room without a laminar flow hood, the attire shall include a jumpsuit or surgical scrubs and head coverings that generate low levels of particulate, mask, shoe covers, and gloves.
- (5) Attire specific to the compounding of hazardous sterile products is explained in rule 1140-7-.06.

Authority: *T.C.A. § 63-10-404(4),(26),(29),(30), § 63-10-504(b)(1),(2).* **Administrative History:** *Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994. Repeal and new*

rule filed May 11, 1998; effective July 25, 1998.

Tenn. Comp. R. & Regs. 1140-07-.07, TN ADC 1140-07-.07

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy[Chapter 1140-07.](#) Sterile Product Preparation in Pharmacy Practice ([Refs & Annos](#))**→→ 1140-07-.08. QUALITY ASSURANCE.**

- (1) There shall be a documented, ongoing quality assurance program that monitors process validation; pharmacist(s), pharmacy intern(s), and pharmacy technician(s) performance; equipment; and environment.
- (2) The program shall be designed to assure that the pharmacy practice site is capable of consistently compounding quality sterile products.

Authority: *T. C.A. § 63-10-404(26),(28),(29),(30), § 63-10-504(b)(1),(2).* **Administrative History:** *Original chapter filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-07-.08, TN ADC 1140-07-.08

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy**[Chapter 1140-08. Civil Penalties \(Refs & Annos\)](#)**→→ 1140-08-.01. CIVIL PENALTIES.**

- (1) The board may, in a lawful proceeding respecting licensing (as defined in the Uniform Administrative Procedures Act), in addition to or in lieu of any other lawful disciplinary action, assess civil penalties for violations of statutes, rules or orders enforceable by the board in accordance with the following schedule:

Violation	Penalty
T.C.A., Section 63-10-505(1)	\$0 - \$1000
T.C.A., Section 63-10-505(2)	\$0 - \$1000
T.C.A., Section 63-10-505(3)	\$0 - \$1000
T.C.A., Section 63-10-505(4)	\$0 - \$1000
T.C.A., Section 63-10-505(5)	\$0 - \$1000
T.C.A., Section 63-10-505(6)	\$0 - \$1000
T.C.A., Section 63-10-505(7)	\$0 - \$1000
T.C.A., Section 63-10-505(8)	\$0 - \$1000

In determining the amount of any civil penalty to be assessed pursuant to this rule the board may consider such factors as the following:

- (a) Willfulness of the violation.
 - (b) Repetitions of the violation.
 - (c) Magnitude of the risk of harm caused by the violation.
- (2) Each violation of any statute, rule or order enforceable by the board shall constitute a separate and distinct offense and render the person committing the offense subject to a separate fine for each violation.
- (3) Each day any person, partnership, firm, or corporation or agency causes or permits a pharmacy practice site to be conducted in violation of any statutes, rules or orders enforceable by the board constitutes a separate and distinct offense and renders such person, partnership, firm, or corporation or agency subject to a separate fine for each day.

Authority: *T.C.A. § 63-10-504(b)(1), and § 63-10-505. Administrative History:* Original rule filed November 15, 1989;

effective December 30, 1989. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

Tenn. Comp. R. & Regs. 1140-08-.01, TN ADC 1140-08-.01

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy**[Chapter 1140-09. Manufacturers and Wholesalers \(Refs & Annos\)](#)**→→ 1140-09-.01 MANUFACTURER AND WHOLESALE LICENSING.**

- (1) Every manufacturer or wholesaler, before engaging in the sale or distribution of prescription drugs and prescription devices in this state, must be licensed by the Board in accordance with this chapter.
- (2) An applicant with physical facilities in this state must obtain and display prominently a separate license for each principal place of business where the applicant manufactures or distributes prescription drugs and prescription devices.
- (3) The requirement of a license shall not apply to the following types of distributions:
 - (a) Intracompany sales;
 - (b) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;
 - (c) The sale, purchase or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in [section 501\(c\)\(3\) of the Internal Revenue Code of 1954](#) to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
 - (d) The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control; for purposes of this subparagraph, “common control” means the power to direct or cause the direction of the management and policies of a person or an organization whether by ownership of stock, voting rights, by contract or otherwise;
 - (e) The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons; for purpose of this subparagraph, “emergency medical reasons” includes transfers of prescription drugs by a retail pharmacy practice site to alleviate a temporary shortage;
 - (f) The sale, purchase, or trade of a prescription drug, an offer to sell, purchase or trade a prescription drug,

or the dispensing of a prescription drug pursuant to a medical or prescription order;

(g) The distribution of prescription drug samples by manufacturers' representatives; or

(h) The sale, purchase, or trade of blood and blood components intended for transfusion.

(i) The sale, purchase, or trade of a prescription drug, or an offer to sell, purchase or trade of a prescription drug by a pharmacy practice site to another pharmacy practice site or to authorized prescribing practitioners, except that the total gross dollar volume of such transfers shall not exceed five percent (5%) of the total medical and prescription orders sales revenue of either the transferor or transferee pharmacy during any twelve (12) consecutive month period.

Authority: *T.C.A. § 63-10-404(2),(8),(14),(18),(37), § 63-10-504(b)(1), § 63-10-506(f).* **Administrative History:** *Original rule filed January 7, 1992; effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-09-.01, TN ADC 1140-09-.01

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy[Chapter 1140-09.](#) Manufacturers and Wholesalers ([Refs & Annos](#))**→→ 1140-09-.02 MINIMUM INFORMATION REQUIRED.**

(1) The board shall require the following minimum information from each manufacturer or wholesaler applying for a license or any renewal of such license:

- (a) The name, full business address, and telephone number of the manufacturer or wholesaler;
- (b) All trade or business names used by the manufacturer or wholesaler;
- (c) Addresses, telephone numbers, and the names of contact persons for all facilities used by the manufacturer or wholesaler for storage, handling, and distribution;
- (d) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and
- (e) The name(s) of the owner and/or operator of the manufacturer or wholesaler, including:
 - 1. If a person, the name of the person;
 - 2. If a partnership, the name of each partner, and the name of the partnership;
 - 3. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation;
 - 4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity; and
 - 5. DEA registration number if applicable.

(2) Changes in any information in paragraph (1) of this rule shall be submitted to the board immediately.

Authority: *T.C.A. § 63-10-404(2),(18),(37), § 63-10-504(b)(1), § 63-10-506(f).* **Administrative History:** *Original rule filed January 7, 1992; effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July*

25, 1998.

Tenn. Comp. R. & Regs. 1140-09-.02, TN ADC 1140-09-.02

Current through rules effective December 2013

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy**[Chapter 1140-09. Manufacturers and Wholesalers \(Refs & Annos\)](#)**→→ 1140-09-.03 MINIMUM QUALIFICATIONS.**

- (1) The board shall consider, at a minimum, the following factors in reviewing an application for a license as a manufacturer or wholesaler:
- (a) Any convictions of the applicant under any federal, state, or local laws relating to drug samples or distribution of controlled substances;
 - (b) Any felony convictions of the applicant under federal, state, or local laws;
 - (c) The applicant's past experience in the manufacturing or distribution of prescription drugs and prescription devices, including controlled substances;
 - (d) The furnishing by the applicant of false or fraudulent material in any application made in connection with manufacturing or distribution;
 - (e) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances, prescription drugs and prescription devices;
 - (f) Compliance with licensing requirements under previously granted licenses, if any;
 - (g) Compliance with requirements to maintain and/or make available to the board or to federal, state, or local law enforcement officials those records required federal, state or local laws; and
 - (h) Any other factors or qualifications the board considers relevant to and consistent with the public health and safety.
- (2) The board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

Authority: *T.C.A. § 63-10-404(2),(6),(8),(14),(18),(37), § 63-10-504(b)(1).* **Administrative History:** *Original*

rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1999, effective July 25, 1998.

Tenn. Comp. R. & Regs. 1140-09-.03, TN ADC 1140-09-.03

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy [Chapter 1140-09.](#) Manufacturers and Wholesalers ([Refs & Annos](#))**→→ 1140-09-.04 PERSONNEL.**

The board shall require that personnel employed by a manufacturer or wholesaler have appropriate education and/or experience to assume positions of responsibility for compliance with board requirements.

Authority: *T.C.A. § 63-10-404(2),(18),(37), § 63-10-504(b)(1).* **Administrative History:** *Original rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

Tenn. Comp. R. & Regs. 1140-09-.04, TN ADC 1140-09-.04

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy [Chapter 1140-09.](#) Manufacturers and Wholesalers ([Refs & Annos](#))**→→ 1140-09-.05 MINIMUM REQUIREMENTS FOR OPERATION.**

The following shall be the minimum requirements for the storage and handling of prescription drugs and prescription devices and for the establishment and maintenance of prescription drug and prescription device distribution records by manufacturers and wholesalers:

- (1) Facilities. All facilities at which prescription drugs and prescription devices are stored, warehoused, handled, held, offered, marketed, or displayed shall:
 - (a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
 - (b) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
 - (c) Have a quarantine area for storage of prescription drugs and prescription devices that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
 - (d) Be maintained in a clean and orderly condition, and
 - (e) Be free from infestation by insects, rodents, birds, or vermin of any kind.
- (2) Security.
 - (a) All facilities shall be secure from unauthorized entry.
 1. Access from outside the premises shall be kept to a minimum and be well-controlled.
 2. The outside perimeter of the premises shall be well-lighted.
 3. Entry into areas where prescription drugs and prescription devices are held shall be limited to

authorized personnel.

(b) All facilities shall be equipped with an alarm system to detect entry after hours.

(c) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(3) Storage. All prescription drugs and prescription devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs and devices, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

(a) If no storage requirements are established for a prescription drug or prescription device it may be held at “controlled” room temperature, as defined in an official compendium, to help ensure that identity, strength, quality, and purity are not adversely affected.

(b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs and prescription devices.

(c) The record keeping requirements in paragraph (6) of this section shall be followed for all prescription drugs and prescription devices.

(4) Examination of materials.

(a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(b) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(c) The record keeping requirements in paragraph (6) of this section shall be followed for all incoming and outgoing prescription drugs.

(5) Returned, damaged, and outdated prescription drugs and prescription devices.

- (a) Prescription drugs and prescription devices that are outside, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs and prescription devices until destroyed or returned.
 - (b) Any prescription drugs and prescription devices whose immediate or sealed outer or sealed secondary containers have been opened or used shall be quarantined and physically separated from other prescription drugs and prescription devices until either destroyed or returned.
 - (c) If the conditions under which a prescription drug or prescription device has been returned cast doubt on safety, identity, strength, quality, or purity, then the prescription drug or prescription device shall be destroyed, or returned, unless examination, testing, or other investigation proves that the prescription drug or prescription device meets appropriate standards of safety, identity, strength, quality and purity. In determining whether the conditions under which a prescription drug or prescription device has been returned cast doubt on safety, identity, strength, quality, or purity, the manufacturer or wholesaler shall consider, among other things, the conditions under which the prescription drug or prescription device has been held, stored or shipped before or during return and the condition of the prescription drug or device or related material and its container, carton, or labeling, as a result of storage or shipping.
 - (d) The record keeping requirements in paragraph (6) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs and prescription devices.
- (6) Record keeping.
- (a) Manufacturers and wholesalers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and prescription devices. These records shall include the following information:
 - 1. The source of the prescription drugs and prescription devices including the name and principal address of the seller or transferor, and the address of the location from which the prescription drugs and prescription devices were shipped;
 - 2. The identity and quantity of the prescription drugs and prescription devices received and distributed or disposed of; and
 - 3. The dates of receipt and distribution or other disposition of the prescription drugs and prescription devices.
 - (b) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two (2) years following disposition of the prescription drugs and prescription devices.

- (c) Records described in this paragraph that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.
- (7) Written policies and procedures. Manufacturers and wholesalers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs and prescription devices; including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Manufacturers and wholesalers shall include in written policies and procedures the following:
- (a) A procedure whereby the older approved stock of a prescription drug or prescription device is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.
 - (b) A procedure to be followed for handling recalls and withdrawals of prescription drugs and prescription devices. Such procedures shall be adequate to respond to recalls and withdrawals due to:
 - 1. Any action initiated at the request of the United States Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the board;
 - 2. Any voluntary action by the manufacturer or wholesaler to remove defective or potentially defective prescription drugs and prescription devices from the market; or
 - 3. Any action undertaken to promote public health and safety by replacing of an existing product with an improved product or new package design.
 - (c) A procedure to ensure that manufacturers and wholesalers prepare for, protect against, and respond to any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.
 - (d) A procedure to ensure that any outdated prescription drugs and prescription devices shall be segregated from other prescription drugs and prescription devices and either returned to the manufacturer or wholesaler or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs and prescription devices. This documentation shall be maintained for two (2) years after disposition of the outdated prescription drugs and prescription devices.
- (8) Responsible persons. Manufacturers and wholesalers shall establish and maintain lists of officers, directors, managers, and other persons in charge of distribution, storage, and handling, including a

description of such persons' duties and a summary of such persons' qualifications.

(9) Compliance with federal, state, and local law. Manufacturers and wholesalers shall operate in compliance with applicable federal, state, and local laws and regulations.

(a) Manufacturers and wholesalers shall permit the board and authorized federal, state, and local law enforcement officials to enter and inspect premises and delivery vehicles, and to audit records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(b) Manufacturers and wholesalers that handle controlled substances shall register with the board and with the United States Drug Enforcement Administration (DEA) and shall comply with applicable state, local and DEA regulations.

(10) Salvaging and reprocessing. Manufacturers and wholesalers shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to salvaging or reprocessing of prescription drugs and prescription devices.

Authority: *T.C.A. § 63-10-404(8),(18),(33),(37), § 63-10-504(b)(1).* **Administrative History:** *Original rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*


Tenn. Comp. R. & Regs. 1140-09-.05, TN ADC 1140-09-.05

Current through rules effective December 2013

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Tennessee Rules and Regulations [Currentness](#)

1140. Board of Pharmacy

 [Chapter 1140-10.](#) Rules of Procedure for Hearing Contested Cases ([Refs & Annos](#))

→→ 1140-10. TRANSFERRED

For Rules of Procedure for Hearing Contested Cases see Rules of the Secretary of State.

Authority: [T.C.A. § 63-10-504\(b\) \(1\)](#), [§ 4-5-301](#). **Administrative History:**

Tenn. Comp. R. & Regs. Ch. 1140-10, TN ADC Ch. 1140-10

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-11. Controlled Substance Monitoring Database \(Refs & Annos\)](#)**→→ 1140-11-.01 DEFINITIONS.**

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

- (a) “Board” means the Board of Pharmacy created by T.C.A., Title 63, Chapter 10, part 3;
- (b) “Client” means the owner or custodian of any animal under the care of a licensed veterinarian.
- (c) “Commissioner” means the Commissioner of Health;
- (d) “Committee” means the Controlled Substance Database Committee created by T.C.A., Title 53, Chapter 10, part 3;
- (e) “Controlled substance(s)” means a drug, substance, or immediate precursor in Schedules I through VI as defined or listed in the Tennessee Drug Control Act, compiled in T.C.A., Title 39, Chapter 17, part 4;
- (f) “Controlled substance dispensed identifier” means the National Drug Code Number of the controlled substance;
- (g) “Database” means the controlled substance database created by T.C.A., Title 53, Chapter 10, part 3;
- (h) “Department” means the Department of Health;
- (i) “Dispense” means to physically deliver a controlled substance covered by this chapter to any person, institution or entity with the intent that it be consumed away from the premises in which it is dispensed. It does not include the act of writing a prescription by a practitioner to be filled at a pharmacy. For purposes of this part, physical delivery includes mailing controlled substances into this state;
- (j) “Dispenser” means any health care practitioner who is licensed and has current authority to dispense controlled substances;

- (k) “Dispenser identifier” means the Drug Enforcement Administration Registration Number of the dispenser as defined in [T.C.A. § 53-10-302\(8\)](#);
- (l) “Hardship” means a situation where a dispenser, including a veterinarian, does not have an automated recordkeeping system capable of producing an electronic report of the required data in the format established by the American Society for Automation in Pharmacy Telecommunications Format for Controlled Substances. “Hardship” may also include other situations as determined by the Committee in its sole discretion;
- (m) “Healthcare practitioner” means:
1. a physician, dentist, optometrist, veterinarian, or other person licensed, registered, or otherwise permitted to prescribe, distribute, dispense or administer a controlled substance in the course of professional practice; or
 2. a pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, or administer a controlled substance in the course of professional practice;
- (n) “Healthcare practitioner extender” means any registered or licensed healthcare professional, and up to two (2) unlicensed persons designated by the prescriber or dispenser, who act as agents of the prescriber or dispenser. The prescriber or dispenser shall be responsible for all actions taken by the agents, pursuant to this part;
- (o) “Law enforcement personnel” means agents of the Tennessee Bureau of Investigation, agents of a judicial district drug task force, federal law enforcement officers commissioned by a federal government entity, certified law enforcement officers certified pursuant to [T.C.A. § 38-8-107](#), and certified law enforcement officers in other states;
- (p) “Patient” means a person or an animal who is receiving medical treatment from a prescriber;
- (q) “Patient identifier” means the patient's full name; address including zip code; date of birth; and social security number or an alternative identification number as defined by this rule;
- (r) “Person” means any individual, partnership, association, corporation and the state of Tennessee, its departments, agencies and employees, and the political subdivisions of Tennessee and their departments, agencies and employees;
- (s) “Prescriber” means an individual licensed as a medical doctor, podiatrist, dentist, optometrist, veterinarian, osteopathic physician, a physician assistant who has authority to issue prescriptions for controlled substances, or an advanced practice nurse with a certificate of fitness to prescribe;

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

Authority: *T.C.A. §§ 53-10-302 and 53-10-303(f).* **Administrative History:** *Original rule filed December 22, 2005; effective March 7, 2006. Emergency rule filed January 4, 2013; effective through July 3, 2013. Repeal and new rule filed April 2, 2013; effective July 1, 2013.*

Tenn. Comp. R. & Regs. 1140-11-.01, TN ADC 1140-11-.01

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy**

⌕ [Chapter 1140-11. Controlled Substance Monitoring Database \(Refs & Annos\)](#)

➔➔ **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.

Authority: *T.C.A. §§ 53-10-303(f), 53-10-304(b), 53-10-305(e), 53-10-306, and 53-10-308.***Administrative History:** *Original rule filed December 22, 2005; effective March 7, 2006. Emergency rule filed January 4, 2013; effective through July 3, 2013. Repeal and new rule filed April 2, 2013; effective July 1, 2013.*

Tenn. Comp. R. & Regs. 1140-11-.02, TN ADC 1140-11-.02

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-11. Controlled Substance Monitoring Database \(Refs & Annos\)](#)**→→ 1140-11-.03 ALTERNATIVE IDENTIFICATION OF PATIENTS.**

- (1) If a patient does not have a social security number or refuses to provide his or her social security number to be used as a patient identifier, then the board shall use the patient's driver's license number or telephone number as the patient identifier in the database.
- (2) If a patient does not have a social security number, a driver's license number or a telephone number, then the board shall use the number "000-00-0000" as the patient identifier in the database.
- (3) If a patient or a patient's agent refuses to provide his or her social security number, driver's license number or telephone number to his or her prescriber or dispenser, then the board shall use the number "999-99-9999" as the patient identifier in the database.
- (4) If a patient's social security number is not available, then the board shall use the social security number, driver's license number or telephone number of the person obtaining the controlled substance on behalf of the patient as the patient identifier in the database or the numbers "000-00-0000" (does not have the data) or "999-99-9999" (refusal to provide data), as applicable.
- (5) If a patient is a child who does not have a social security number, then the board shall use the parent's or guardian's social security number, driver's license number, telephone number, or number "000-00-0000" (does not have data) or number "999-99-9999" (refusal to provide data) as the patient identifier in the database.
- (6) If a patient is an animal, then the board shall use the owner's social security, driver's license number, telephone number, or number "000-00-0000" (does not have data) or number "999-99-9999" (refusal to provide data) as the patient identifier in the database.

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

Tenn. Comp. R. & Regs. 1140-11-.03, TN ADC 1140-11-.03

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy [Chapter 1140-11.](#) Controlled Substance Monitoring Database ([Refs & Annos](#))**→→ 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 shall transmit the data that is required, pursuant to [T.C.A. § 53-10-305](#), in the 2009 version of the Telecommunications Format for Controlled Substances established by the American Society for Automation in Pharmacy (ASAP).
- (7) If the dispenser does not have an automated recordkeeping system capable of producing an electronic report of the required data in the format established by the ASAP, or for whom electronic reporting would cause an undue hardship as determined by the Committee, then that dispenser may request a waiver from the electronic reporting requirement from the Committee. The waiver may be valid for two (2) years from ratification by the Committee.
- (8) If the Committee grants the dispenser a waiver from the electronic reporting requirement, then the dispenser shall comply with an alternative method of reporting the data as determined by the Committee,


such as submitting the required data in writing on a form approved by the Committee.

Authority: *T.C.A. §§ 53-10-303(f), 53-10-304 and 53-10-305.* **Administrative History:** *Original rule filed December 22, 2005; effective March 7, 2006. Emergency rule filed January 4, 2013; effective through July 3, 2013. Repeal and new rule filed April 2, 2013; effective July 1, 2013.*

Tenn. Comp. R. & Regs. 1140-11-.04, TN ADC 1140-11-.04

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy [Chapter 1140-11.](#) Controlled Substance Monitoring Database ([Refs & Annos](#))**→→ 1140-11-.05 PRACTICE SITES - ELECTRONIC ACCESS.**

- (1) Each person or entity operating a practice site where a controlled substance is prescribed or dispensed to a human patient shall provide for electronic access to the database at all times when a prescriber or dispenser provides healthcare services to a human patient potentially receiving a controlled substance.
- (2) This rule shall not apply to dispensers who are not required to report, pursuant to [T.C.A. § 53-10-304\(d\)](#) or [§ 53-10-305\(g\)](#).
- (3) A violation of paragraph one (1) above is punishable by a civil penalty not to exceed one hundred dollars (\$100) per day assessed against the person or entity operating the practice site; provided, however, that the penalty shall only be imposed when there is a continued pattern or practice of not providing electronic access to the database

Authority: [T.C.A. §§ 53-10-303\(f\)](#) and [53-10-310](#). **Administrative History:** Emergency rule filed January 4, 2013; effective through July 3, 2013. Repeal and new rule filed April 2, 2013; effective July 1, 2013.

Tenn. Comp. R. & Regs. 1140-11-.05, TN ADC 1140-11-.05

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-11. Controlled Substance Monitoring Database \(Refs & Annos\)](#)**→→ 1140-11-.06 PRESCRIBER AND DISPENSER RESPONSIBILITIES (EFFECTIVE APRIL 1, 2013).**

- (1) All prescribers or their designated healthcare practitioner's extenders, unless otherwise exempted by T.C.A. Title 53, Chapter 10, part 3, shall check the database prior to prescribing one of the controlled substances identified below in paragraph (3) to a human patient at the beginning of a new episode of treatment and shall check the database for the human patient at least annually when that prescribed controlled substance remains part of treatment.
- (2) Before dispensing, a dispenser shall have the professional responsibility to check the database or have a healthcare practitioner extender check the database, if the dispenser is aware or reasonably certain, that a person is attempting to obtain a Schedule II-V controlled substance, identified by the Committee as demonstrating a potential for abuse for fraudulent, illegal, or medically inappropriate purposes, in violation of [T.C.A. § 53-11-402](#).
- (3) The controlled substances which trigger a check of the database pursuant to paragraph (1) above include, but are not limited to, all opioids and benzodiazepines.
- (4) Prescribers are not required to check the database before prescribing or dispensing one of the controlled substances identified in paragraph (3) above or added to that list by the Committee if one (1) or more of the following conditions is met:
 - (a) The controlled substance is prescribed or dispensed for a patient who is currently receiving hospice care;
 - (b) The Committee has determined that prescribers in a particular medical specialty shall not be required to check the database as a result of the low potential for abuse by patients receiving treatment in that medical specialty;
 - (c) The controlled substance is prescribed or dispensed to a patient as a non-refillable prescription as part of treatment for a surgical procedure that occurred in a licensed healthcare facility;
 - (d) The quantity of the controlled substance which is prescribed or dispensed does not exceed an amount which is adequate for a single, seven-day treatment period and does not allow a refill.

Authority: *T.C.A. §§ 53-10-303(f) and 53-10-310.* **Administrative History:** *Emergency rule filed January 4, 2013; effective through July 3, 2013. Repeal and new rule filed April 2, 2013; effective July 1, 2013.*

Tenn. Comp. R. & Regs. 1140-11-.06, TN ADC 1140-11-.06

Current through rules effective December 2013

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CTennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy [Chapter 1140-12.](#) Charitable Clinic Pharmacies ([Refs & Annos](#))**→→ 1140-12-.01. PURPOSE.**

The rules in this chapter implement the Nina Norman Prescription Drug Donation Act of 2006, [T.C.A. § 63-10-501, et seq.](#), which has been enacted into law to develop a prescription drug redispensing program that authorizes charitable clinic pharmacies to redispense medicines to indigent patients that would otherwise be destroyed.

Authority: Chapter 919 of the Public Acts of 2006, §1 and [T.C.A. §§63-10-501 through 63-10-505](#).

Administrative History: Public necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.

Tenn. Comp. R. & Regs. 1140-12-.01, TN ADC 1140-12-.01

Current through rules effective December 2013

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CTennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy**[Chapter 1140-12. Charitable Clinic Pharmacies \(Refs & Annos\)](#)**→→ 1140-12-.02. DEFINITIONS.**

In addition to the definitions contained in [T.C.A. § 63-10-503](#), the following definitions are applicable to this chapter:

- (1) “Board” means the Tennessee Board of Pharmacy;
- (2) “Dispense” shall have the same meaning as set forth in [T.C.A. § 63-10-204\(11\)](#);
- (3) “Distribute” shall have the same meaning as set forth in [T.C.A. § 63-10-204 \(12\)](#);
- (4) “Manifest” means a list of drugs being transferred or destroyed and shall include at a minimum, the drug name, strength, quantity, and expiration date;
- (5) “Person” means any individual, partnership, association, or corporation;
- (6) “Pharmacist” shall have the same meaning as set forth in [T.C.A. § 63-10-204\(26\)](#);
- (7) “Pharmacy” means a charitable clinic pharmacy as set forth in [T.C.A. § 63-10-503\(2\)](#);
- (8) “Pharmacy practice site” shall have the same meaning as set forth in Tenn. Comp. R. & Regs. Rule 1140-1-.01(23);
- (9) “Pharmacist in charge” shall have the same meaning as set forth in [T.C.A. § 63-10-204\(27\)](#);
- (10) “Program” means the drug donation program established by the Nina Norman Prescription Drug Donation Act of 2006 established in [T.C.A. § 63-10-501, et seq.](#);
- (11) “Single Unit Dose” means sealed, tamper-evident packaging of medication from a manufacturer, repackager licensed by the Food and Drug Administration, or from a pharmacy when packaged in individual dosage units in United States Pharmacopeia Class B packaging and labeled with the appropriate product

information including full product name, dosage form, strength, lot number, and expiration date.

Authority: Chapter 919 of the Public Acts of 2006, §1 and [T.C.A. §63-10-505\(g\)](#). **Administrative History:** Public Necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.

Tenn. Comp. R. & Regs. 1140-12-.02, TN ADC 1140-12-.02

Current through rules effective December 2013

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CTennessee Rules and Regulations **Currentness****1140.** Board of Pharmacy **Chapter 1140-12.** Charitable Clinic Pharmacies (Refs & Annos)**→→ 1140-12-.03. APPLICATION AND RENEWAL REQUIREMENTS.**

- (1) Any person who desires to obtain a charitable clinic pharmacy license shall submit an application to the board, along with the required license fee, and comply with the pharmacy practice site licensure requirements established in Rule 1140-1-.08(3)(a).
- (2) Applications for licensure are available upon request from the board.
- (3) All charitable clinic pharmacy licenses shall be renewed on a biennial basis from the date that the license was initially granted. All licenses shall be renewed on or before the last day of the two (2) year license cycle.
- (4) An applicant may renew the charitable clinic pharmacy license within six (6) months from the license expiration date with payment of the renewal fee and late renewal penalty fee.

Authority: Chapter 919 of the Public Acts of 2006, §1 and *T.C.A. §§63-10-502(2) and 63-10-505(g)(4)(A)*.

Administrative History: Public Necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.

Tenn. Comp. R. & Regs. 1140-12-.03, TN ADC 1140-12-.03

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CTennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy [Chapter 1140-12.](#) Charitable Clinic Pharmacies ([Refs & Annos](#))**→→ 1140-12-.04. FEES.**

- | | | |
|-----|---|----------|
| (1) | Initial license fee | \$168.00 |
| (2) | Renewal fee | \$168.00 |
| (3) | The late renewal penalty fee is ten dollars (\$10.00) per month for each month or fraction of a month that renewal is late. | |

Authority: Chapter 919 of the Public Acts of 2006, §1 [T.C.A. §§63-10-502\(2\)](#) and [63-10-505\(g\)\(4\)\(A\)](#). **Administrative History:** Public Necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.

Tenn. Comp. R. & Regs. 1140-12-.04, TN ADC 1140-12-.04

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-12. Charitable Clinic Pharmacies \(Refs & Annos\)](#)**→→ 1140-12-.05. PHARMACIST RESPONSIBILITIES.**

(1) Medication Transfers.

(a) Any pharmacist working at a charitable clinic pharmacy shall ensure that the following criteria are satisfied upon receiving medications from the institutional facility:

1. the only drugs that are accepted by the pharmacy to be dispensed are those drugs that are in their dispensed, sealed and tamper-evident packaging which includes, but is not limited to, single-unit doses or blister packs with the outside packaging opened if the single unit dose packaging remains intact;
2. the donor patient or donor patient's representative executed a drug donation form for the drugs transferred from the institutional facility to the pharmacy. In the event that the pharmacist does not receive a copy of the donor form with the transferred drugs, then the pharmacist shall not dispense the drugs;
3. the donor patient's name, prescription number, and any other identifying marks have been removed or redacted from the package by the institutional facility. In the event that the identifying patient information is not removed when received by the charitable clinic pharmacist from the institutional facility, then the pharmacist shall remove or redact this information;
4. the drug name, strength, lot number, and expiration date is on the drug package or label. In the event that the identifying drug information is not on the package or label when received from the institutional facility, the pharmacist shall not dispense these drugs and shall destroy them;
5. drug(s) that are being transferred are accompanied by a manifest from the institutional facility;
6. drugs that are expired, misbranded, recalled, deteriorated or not kept under the proper conditions shall not be dispensed from the pharmacy if they are transferred from the institutional facility. In the event that the pharmacist receives drugs that are expired, misbranded, recalled, deteriorated or not kept under the proper conditions from the institutional facility, the pharmacist shall not dispense these drugs and shall destroy them after creating the documentation required in Rule 1140-12-.05(3)(a);

7. controlled substances are not accepted or dispensed from the pharmacy if they are transferred. In the event that institutional facility transfers controlled substances, the pharmacist shall send the controlled substances back to the institutional facility;
8. the donated drugs may be transferred from one (1) pharmacy to another by an individual designated by the pharmacist in charge or through any other means by which the donated drugs may be tracked and delivery confirmed; and
9. the donated drugs are physically transferred from the institutional facility to the pharmacy by an individual designated by the pharmacist in charge of the pharmacy or through any other means by which the donated drugs may be tracked and delivery confirmed.

(2) Prohibited Activities.

- (a) Any pharmacist working at a charitable clinic pharmacy shall not purchase, possess, trade, distribute or dispense any controlled substances from the charitable clinic pharmacy.

(3) Recordkeeping.

- (a) Any pharmacist working at a charitable clinic pharmacy shall create and maintain a manifest of the prescription drugs transferred from the institutional facility to the pharmacy that were not dispensed because the drugs were expired, adulterated, misbranded, recalled, deteriorated, not kept under proper conditions, or did not have the identifying drug information on them as provided in Rule 1140-12-.05(4). Pharmacists shall maintain this manifest at the pharmacy for two (2) years from the date of destruction.
- (b) The pharmacists working at the charitable clinic pharmacy shall maintain a manifest of all prescription drugs transferred from the institutional facility to the pharmacy and dispensed from the pharmacy for two (2) years from the date of receipt.
- (c) The pharmacists working at the pharmacy shall maintain a manifest of all prescription drugs transferred from one (1) pharmacy to another for two (2) years from the date of transfer.

(4) Labeling.

- (a) Any pharmacist working at a charitable clinic pharmacy shall ensure that the donor patient's identifying information is redacted from the donated drugs prior to redispensing.
- (b) Any pharmacist working at a charitable clinic pharmacy shall redispense the donated drugs to an indigent patient and place a label on the drugs with the indigent patient's identifying information, dosage

instructions, auxiliary labels, and drug expiration date.

(5) All pharmacists working at a charitable clinic pharmacy shall comply with all other applicable Board rules.

Authority: Chapter 919 of the Public Acts of 2006, §1 and [T.C.A. §63-10-505 \(c\)\(1\) and \(g\)\(4\)\(A\)](#).

Administrative History: Public Necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.

Tenn. Comp. R. & Regs. 1140-12-.05, TN ADC 1140-12-.05

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy[Chapter 1140-12.](#) Charitable Clinic Pharmacies ([Refs & Annos](#))**→→ 1140-12-.06. PHARMACIST-IN-CHARGE RESPONSIBILITIES.**

(1) The pharmacist in charge at the charitable clinic pharmacy shall ensure that the following occurs at the pharmacy:

- (a) donated drugs dispensed from pharmacy are properly labeled;
- (b) donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, or not kept under proper conditions are not redispensed to indigent patients;
- (c) donated drugs are inspected prior to redispensing to determine that the donated drugs meet all federal and state requirements for product integrity;
- (d) donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, or not kept under proper conditions are destroyed;
- (e) manifests for donated drugs that are dispensed or destroyed are created or maintained at the pharmacy in accordance with Rule 1140-12-.05;
- (f) that the institutional facility transferring the drugs has a contract with the pharmacy about the transfer of drugs that is approved by the Board of Pharmacy in cooperation with the Department of Health in accordance with [T.C.A. § 63-10-505](#); and
- (g) that the contract between the institutional facility and the pharmacy will contain a description of the drugs that will be included in the contract. The pharmacist in charge is responsible for determining the description of the drugs.

Authority: Chapter 919 of the Public Acts of 2006, §1, [T.C.A. §§63-10-505\(g\)\(4\)\(A\)](#) and [63-10-505\(b\)\(3\)](#).

Administrative History: Public Necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.

Tenn. Comp. R. & Regs. 1140-12-.06, TN ADC 1140-12-.06

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CTennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy [Chapter 1140-12.](#) Charitable Clinic Pharmacies ([Refs & Annos](#))**→→ 1140-12-.07. DONOR PATIENT FORM.**

(1) The donor patient form shall include, at a minimum, the following:

- (a) name of the patient to whom the medication was originally dispensed;
- (b) name of the institutional facility authorized to deliver the unused prescription medication;
- (c) name of drug, quantity, prescription number, date of prescription and name of pharmacy where it was originally dispensed;
- (d) name of the charitable clinic pharmacy;
- (e) date the drug was donated;
- (f) authorization to donate the drug voluntarily for use in the program;
- (g) a signature line for the donor patient or for the donor patient's representative in the event that patient is deceased or not competent; and
- (h) a statement that the donor patient's participation in the pilot program shall not be used as an independent basis for a civil, criminal, or disciplinary action against the donor patient's, donor patient's estate, health care provider, charitable clinic, department of health, board, or the charitable clinic pharmacy, pharmacists and pharmacy technicians as long as they abide by board rules.

Authority: Chapter 919 of the Public Acts of 2006, §1 and [T.C.A. §§63-10-505\(g\)\(2\) and 63-10-505\(c\)\(5\)\(A\)](#).

Administrative History: Public Necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.

Tenn. Comp. R. & Regs. 1140-12-.07, TN ADC 1140-12-.07

Current through rules effective December 2013

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CTennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy[Chapter 1140-12.](#) Charitable Clinic Pharmacies ([Refs & Annos](#))**→→ 1140-12-.08. WAIVER FORM.**

(1) The waiver form shall include, at a minimum, the following:

- (a) name of indigent patient;
- (b) name of drug, quantity, prescription number, date of prescription, name of charitable clinic pharmacy dispensing the drug;
- (c) a signature line for the indigent patient; and
- (d) waiver releasing the institutional facility, donor patient, and donor patient' estate from liability.

Authority: Chapter 919 of the Public Acts of 2006, §1 and [T.C.A. §§63-10-505\(g\)\(3\) and 63-10-505\(f\)](#).

Administrative History: Public Necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.

Tenn. Comp. R. & Regs. 1140-12-.08, TN ADC 1140-12-.08

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy

▢ [Chapter 1140-12.](#) Charitable Clinic Pharmacies ([Refs & Annos](#))

→→ **1140-12-.09. CIVIL PENALTIES.**

(1) The board may, in a lawful proceeding respecting licensing (as defined in the Uniform Administrative Procedures Act), in addition to or in lieu of any other lawful disciplinary action, assess civil penalties for violations of statutes, rules or orders enforceable by the board in accordance with the following schedule:

Violation	Penalty
T.C.A. Section 63-10-505(b)(B)(3)	\$0-\$1,000
T.C.A. Section 63-10-505(c)(2)	\$0-\$1,000
T.C.A. Section 63-10-505(c)(3)	\$0-\$1,000
Rule 1140-12-.03	\$0-\$1,000
Rule 1140-12-.05	\$0-\$1,000
Rule 1140-12-.06	\$0-\$1,000

(2) Each day of continued violation may constitute a separate violation.

(3) In determining the amount of any penalty to be assessed pursuant to this rule, the board may consider such factors as the following:

(a) Willingness of the violation;

(b) Repetitions of the violation; and

(c) Magnitude of the risk of harm caused by the violation.

(4) Each violation of any statute, rule or order enforceable by the board shall constitute a separate and distinct offense and render the person committing the offense subject to a separate civil penalty for each violation.

Authority: Chapter 919 of the Public Acts of 2006, §1 and [T.C.A. §§56-1-308, 63-10-505\(g\)\(4\)\(A\)](#). **Administrative History:** Public Necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.

Tenn. Comp. R. & Regs. 1140-12-.09, TN ADC 1140-12-.09

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Tennessee Rules and Regulations [Currentness](#)

1140. Board of Pharmacy

⌕ [Chapter 1140-13.](#) Telepharmacy ([Refs & Annos](#))

➡➡ **1140-13-.01. PURPOSE.**

The rules in this chapter implement a pilot program for the dispensing of prescription medications from federally qualified health centers through the use of telepharmacy pursuant to [T.C.A. § 63-10-601, et seq.](#)

Authority: Chapter 1028 of the Public Acts of 2008, § 2 and [T.C.A. §§ 63-10-601 through 63-10-602](#). [effective July 1, 2008]. **Administrative History:** Public necessity rule filed November 25, 2008; effective through May 9, 2009. New rule filed February 24, 2009; effective May 10, 2009.

Tenn. Comp. R. & Regs. 1140-13-.01, TN ADC 1140-13-.01

Current through rules effective December 2013

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-13. Telepharmacy \(Refs & Annos\)](#)**→→ 1140-13-.02. DEFINITIONS.**

In addition to the definitions contained in [T.C.A. § 63-10-601](#), the following definitions are applicable to this chapter:

- (1) “Board” means the Tennessee Board of Pharmacy;
- (2) “Central pharmacy” means the central pharmacy practice site licensed by the Tennessee Board of Pharmacy located within a federally qualified health center that is connected through computer link, videolink, and audiolink to one (1) or more satellite clinics;
- (3) “Dispense” shall have the same meaning as set forth in [Tenn. Code Ann. § 63-10-204\(12\)](#);
- (4) “Issue” means the delivery of drugs from the pharmacy technician employed by the federally qualified health center participating in this program to the patient or patient's agent;
- (5) “Person” means any individual, partnership, association, corporation, or entity;
- (6) “Pharmacist” shall have the same meaning as set forth in [Tenn. Code Ann. § 63-10-204\(30\)](#) and who is an employee of a federally qualified health center participating in this program;
- (7) “Pharmacist-in-charge” shall have the same meaning as set forth in [Tenn. Code Ann. § 63-10-204\(31\)](#) and who is an employee of a federally qualified health center participating in this program;
- (8) “Pharmacy practice site” shall have the same meaning as set forth in [Tenn. Comp. R. & Regs. Rule 1140-01-.01\(23\)](#);
- (9) “Pharmacy technician” means an individual registered by the Board as a pharmacy technician who is an employee of a federally qualified health center participating in this program and is being supervised by a pharmacist at the central pharmacy;
- (10) “Program” means the pilot program established in [T.C.A. § 63-10-601](#) for the dispensing of medications (with the exception of controlled substances schedules I, II, III, and IV) from federally qualified health

centers through the use of telepharmacy;

(11) “Satellite clinic” means a clinic location located within federally qualified health center where any prescription dispensed at the central pharmacy shall be issued to the patient or patient's agent through telepharmacy;

(12) “Telepharmacy” means the method of providing pharmaceutical services through a remote site connection between a central pharmacy and a satellite clinic.

Authority: Chapter 1028 of the Public Acts of 2008, § 2 and [T.C.A. §§ 63-10-601 through 63-10-602](#). [effective July 1, 2008]. **Administrative History:** Public necessity rule filed November 25, 2008; effective through May 9, 2009. New rule 1140 filed February 24, 2009; effective May 10, 2009.

Tenn. Comp. R. & Regs. 1140-13-.02, TN ADC 1140-13-.02

Current through rules effective December 2013

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-13. Telepharmacy \(Refs & Annos\)](#)**→→ 1140-13-.03. LICENSING AND RENEWAL.**

(1) Licensing.

(a) Beginning July 1, 2008, the central pharmacy that desires to participate in this pilot program shall obtain a pharmacy license for the central pharmacy to be issued by the Board by submitting an application to the Board, along with the required license fee, and shall comply with the pharmacy practice site licensure requirements established in [Tenn. Comp. R. & Regs. Rule 1140-01-.08\(1\)](#) and [Rule 1140-01-.12](#).

(b) As a condition for licensure, the central pharmacy participating in this program shall meet all of the standards established in [Tenn. Comp. R. & Regs. Rule 1140-01-.12\(1\), \(2\), and \(3\)](#) and shall also meet the following minimal operating requirements:

1. shall be connected to the satellite clinic through computer link, videolink, and audiolink;
2. shall have a computer system that is connected to the satellite clinic's computer system that shares common electronic files;
3. shall have its own computer(s) that is/are not accessed by others employed by the federally qualified health center, scanner(s), printer(s), and fax machine(s); and
4. shall have a licensed pharmacist at the central pharmacy location.

(2) The central pharmacy license shall expire two (2) years from the date of issuance. All licenses shall be renewed on or before the last day of the two (2)-year license cycle.

(3) The central pharmacy may renew its license within six (6) months after the license expiration date with payment of the renewal fee and late renewal penalty fee. After the six (6) month grace period, the licensee may reapply for licensure.

Authority: Chapter 1028 of the Public Acts of 2008, § 2 and [T.C.A. §§ 63-10-601 through 63-10-602](#). [effective July 1, 2008]. **Administrative History:** Public necessity rule filed November 25, 2008; effective through May 9, 2009. New rule filed February 24, 2009; effective May 10, 2009.

Tenn. Comp. R. & Regs. 1140-13-.03, TN ADC 1140-13-.03

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Tennessee Rules and Regulations [Currenttness](#)**1140. Board of Pharmacy**[Chapter 1140-13. Telepharmacy \(Refs & Annos\)](#)**→→ 1140-13-.04. FEES.**

(1) Initial license fee	\$168.00
(2) Renewal fee	\$168.00
(3) Regulatory fee	\$ 10.00
(4) The late renewal penalty fee is ten dollars (\$10.00) per month for each month or fraction of a month that renewal is late.	

Authority: Chapter 1028 of the Public Acts of 2008, § 2 and [T.C.A. §§ 63-10-601 through 63-10-602](#). [effective July 1, 2008]. **Administrative History:** Public necessity rule filed November 25, 2008; effective through May 9, 2009. New rule filed February 24, 2009; effective May 10, 2009.

Tenn. Comp. R. & Regs. 1140-13-.04, TN ADC 1140-13-.04

Current through rules effective December 2013

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy**[⌕ Chapter 1140-13. Telepharmacy \(Refs & Annos\)](#)**→→ 1140-13-.05. CIVIL PENALTIES.**

- (1) With respect to any licensed central pharmacy, the Board may, in addition to or in lieu of any other lawful disciplinary action, assess a civil penalty for each separate violation of a statute, rule, or Board's order pertaining to drugs or the practice of pharmacy, including, but not limited to telepharmacy, in accordance with the following schedule:

Violation	Penalty
T.C.A. §63-10-305	\$0-\$1,000
T.C.A. §63-10-601	\$0-\$1,000
Rule 1140-02-.01	\$0-\$1,000
Rule 1140-02-.02	\$0-\$1,000
Rule 1140-13-.06	\$0-\$1,000
Rule 1140-13-.07	\$0-\$1,000
Rule 1140-13-.08	\$0-\$1,000

- (2) Each day of continued violation may constitute a separate violation.
- (3) In determining the amount of any penalty to be assessed pursuant to this rule, the board may consider such factors as the following:
- (a) Whether the amount imposed will be a substantial economic deterrent to the violator;
 - (b) The circumstances leading to the violation;
 - (c) The severity of the violation and the risk of harm to the public;
 - (d) The economic benefits gained by the violator as a result of noncompliance;
 - (e) The interest of the public; and
 - (f) The willfulness of the violation.

Authority: Chapter 1028 of the Public Acts of 2008, § 2 and [T.C.A. §§ 63-10-601 through 63-10-602](#). [effective July 1, 2008]. **Administrative History:** Public necessity rule filed November 25, 2008; effective through May 9, 2009. New rule filed February 24, 2009; effective May 10, 2009.

Tenn. Comp. R. & Regs. 1140-13-.05, TN ADC 1140-13-.05

Current through rules effective December 2013

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-13. Telepharmacy \(Refs & Annos\)](#)**→→ 1140-13-.06. PHARMACIST RESPONSIBILITIES.****(1) Pharmacy Operations and Security.**

- (a) The pharmacist-in-charge shall ensure that the central pharmacy's connection with the satellite clinic through computer, videolink, and audiolink is operational at all times that the satellite clinic is open.
- (b) In the event that the computer, videolink, or audiolink connection is not operational, the pharmacist-in-charge shall ensure that the satellite clinic shall cease to operate relative to the issuance of prescriptions supplied by the central pharmacy until the links are reconnected. Whenever an interruption of data, video, or audiolink occurs between the central pharmacy and the satellite clinic, no prescription shall be dispensed, and a sign shall be posted noting the closure with an estimated time until a resumption of services can be expected.
- (c) The pharmacist-in-charge shall ensure that prescriptions for controlled substances schedules I, II, III, or IV are not issued from the satellite clinic.
- (d) The pharmacist-in-charge shall ensure that only the pharmacists and pharmacy technicians employed by the federally qualified health center and working in the satellite clinic shall have keys to the satellite clinic.
- (e) The pharmacist-in-charge shall ensure that the security at the central pharmacy shall be performed in accordance with [Tenn. Comp. R. & Regs. Rule 1140-01-.12](#).
- (f) The pharmacist-in-charge shall ensure the security of the storage of drugs at the central pharmacy and the satellite clinic.
- (g) The pharmacist-in-charge shall ensure that the prescriptions filled at the central pharmacy and stored in the satellite clinic to be issued to patients and caregivers by means of telepharmacy shall be segregated in a secure area in the pharmacy room from other medications stored in the pharmacy room that have not been filled and will not be issued through the telepharmacy program.
- (h) The pharmacist-in-charge shall ensure that pharmacy technicians working at the central pharmacy are supervised by a pharmacist in accordance with Rule 1140-02-.02(8).

- (i) The pharmacist-in-charge shall ensure that pharmacy technicians working at the satellite clinic shall be supervised by a pharmacist without a pharmacist being physically present.
- (j) The pharmacist-in-charge may request a waiver of [Tenn. Comp. R. & Regs. Rule 1140-03-.14\(12\)](#) upon a showing of good cause.

(2) Verification.

- (a) The pharmacist shall perform all in-process and end-process verification of the pharmacy technician's activities, including, but not limited to: checking the contents of the prescription bottle; checking the bottle label; checking the prescription; performing a drug utilization review in accordance with [Tenn. Comp. R. & Regs. Rule 1140-03-.01\(3\)](#); and performing patient counseling.

(3) Patient Counseling.

- (a) If a pharmacist is not physically present at the satellite clinic and the patient or patient's agent is being issued a new prescription, then the pharmacist shall counsel the patient or patient's caregiver by means of telepharmacy before the prescription is issued.
- (b) If a pharmacist is not physically present at the satellite clinic and the patient or patient's agent is being issued a refilled prescription, then the pharmacy technician shall offer counseling to the patient or patient's caregiver by means of telepharmacy before the prescription is issued.
- (c) Pharmacists shall counsel patients in accordance with Board of Pharmacy rules whether the medication is issued from the central pharmacy or the satellite clinic.

(4) Supervision.

- (a) The pharmacist-in-charge shall ensure that each individual operating as a pharmacy technician while employed by a federally qualified health center at a central pharmacy or satellite clinic is properly registered with the Board at all times.
- (b) The pharmacist-in-charge or a designee of the pharmacist-in-charge shall complete an in-person inspection twice a month of the satellite clinics to ensure compliance with all applicable laws and rules relative to drugs and the practice of pharmacy outlined in the central pharmacy's policies and procedures.
- (c) The pharmacists working at the federally qualified health center are not required to be physically present to verify the accuracy of all pharmacy technician functions performed at the satellite clinic while participating in this program; verification may be conducted by means of the computer link, videolink,

and audiolink.

(5) Policies and Procedures.

(a) The pharmacist-in-charge shall ensure that the central pharmacy and satellite clinic have policies and procedures including, but not limited to the following:

1. when and how a pharmacy technician should contact a pharmacist to perform the issuing process;
2. how the pharmacy technician is to use the computer, videolink, and audiolink technology to communicate with the pharmacist;
3. delivery of the filled prescriptions to the satellite clinic to be issued to the patient or the patient's caregiver;
4. recordkeeping process to track the prescriptions dispensed from the central pharmacy and issued from the satellite clinic;
5. recordkeeping process to track the filled prescriptions received by the satellite clinic from the central pharmacy;
6. how to securely transport the filled prescriptions from the central pharmacy to the satellite clinic;
7. how to order prescriptions and refills for the central pharmacy;
8. how to ensure that patient counseling is performed in accordance with this chapter;
9. when and how unissued medications will be disposed of or sent back to the central pharmacy.

Authority: Chapter 1028 of the Public Acts of 2008, § 2 and [T.C.A. §§ 63-10-601 through 63-10-602](#). [effective July 1, 2008]. **Administrative History:** Public necessity rule filed November 25, 2008; effective through May 9, 2009. New rule 1140 filed February 24, 2009; effective May 10, 2009.

Tenn. Comp. R. & Regs. 1140-13-.06, TN ADC 1140-13-.06

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Tennessee Rules and Regulations [Currentness](#)**1140. Board of Pharmacy** [Chapter 1140-13. Telepharmacy \(Refs & Annos\)](#)**→→ 1140-13-.07. PHARMACY TECHNICIAN RESPONSIBILITIES.**

- (1) The pharmacy technician shall ensure that the central pharmacy's connection with the satellite clinic through computer, videolink, and audiolink is operational at all times that the satellite clinic is open.
- (2) In the event that the computer, videolink, and audiolink connection is not operational, the pharmacist-in-charge shall ensure that the satellite clinic shall cease to operate relative to the issuance of medications supplied by the central pharmacy until the links are reconnected. Whenever an interruption of data, video, or audio link occurs between the central pharmacy and the satellite clinic, no prescription shall be issued, and a sign shall be posted noting the closure of the clinic with an estimated time that a resumption of services can be expected.
- (3) While working at a satellite clinic, the pharmacy technician shall notify the pharmacist at the central pharmacy prior to any medication being issued in order to ensure that patient counseling is performed or offered.
- (4) The pharmacy technician shall only issue prescriptions dispensed by the central pharmacy.

Authority: Chapter 1028 of the Public Acts of 2008, § 2 and [T.C.A. §§ 63-10-601 through 63-10-602](#). [effective July 1, 2008]. **Administrative History:** Public necessity rule filed November 25, 2008; effective through May 9, 2009. New rule filed February 24, 2009; effective May 10, 2009.

Tenn. Comp. R. & Regs. 1140-13-.07, TN ADC 1140-13-.07

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Tennessee Rules and Regulations [Currentness](#)**1140.** Board of Pharmacy [Chapter 1140-13.](#) Telepharmacy ([Refs & Annos](#))**→→ 1140-13-.08. RECORDKEEPING AND INSPECTIONS.**

- (1) The pharmacist-in-charge, pharmacists, and pharmacy technicians employed by the federally qualified health center working at a central pharmacy or satellite clinic shall ensure that a record is maintained at each central pharmacy and satellite clinic containing the prescriptions dispensed or issued from each location, including but not limited to the date dispensed/issued; date dispensed from the central pharmacy; date received by the satellite clinic; the drug name; quantity, dosage; strength; and patient name.
- (2) All records of prescriptions dispensed from the central pharmacy and issued from the satellite clinic shall be retained for at least two (2) years from the date dispensed.
- (3) Board of Pharmacy investigators shall be able to inspect the central pharmacies and the satellite clinics to ensure compliance with the applicable laws and rules related to drugs and the practice of pharmacy.

Authority: Chapter 1028 of the Public Acts of 2008, § 2 and [T.C.A. §§ 63-10-601 through 63-10-602](#). [effective July 1, 2008] and [T.C.A. §63-10-307](#). **Administrative History:** Public necessity rule filed November 25, 2008; effective through May 9, 2009. New rule filed February 24, 2009; effective May 10, 2009.

Tenn. Comp. R. & Regs. 1140-13-.08, TN ADC 1140-13-.08

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