RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-01
INTRODUCTORY RULES

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1140-01-.01 DEFINITIONS.

(1) "ACPE" means the Accreditation Council for Pharmacy 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) "Automated dispensing system" means a mechanical or electronic system outside the premises of an institutional or long-term care pharmacy that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.

(5) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(6) "Blood fraction/component" means that part of blood separated by physical or mechanical means.

(7) "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.

(8) "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.

(9) "Commercially available" means any marketed FDA-approved drug or biologic product not currently listed on any official shortage list recognized by the Board of Pharmacy.

(10) "Common carrier" means any person or entity who undertakes, whether directly or by any other arrangement, to transport property including prescription drugs and/or devices for

(Rule 1140-01-.01, continued)

compensation. A common carrier is only responsible for transportation. A common carrier has no responsibility to direct the sale or disposition of property.

(11) "Component" means any active ingredient, or any added substance, inactive ingredient, excipient or pharmaceutic ingredient, intended for use in the compounding of a drug product, including those that may not appear on the product label.

(12) "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.

(13) "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).

(14) "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.

(15) "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.

(16) "Electronic medical or prescription order" means a medical or prescription order which is transmitted by computer technology other than by electronic image transmission.

(17) "Facsimile (FAX) medical or prescription order" means a medical or prescription order which is transmitted by an electronic image transmission.

(18) "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.

(19) "Hazardous product" means any substance that may be cytotoxic, genotoxic, oncogenic, mutagenic, teratogenic, or otherwise pose a potential health hazard.

(20) "Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain acute or short-term health care services, including but not limited to a(n):

(a) Hospital and associated clinics;

(b) Developmental disability center;

(c) Inpatient psychiatric center;

(d) Sub-acute care facility; and

(e) University health center.

(Rule 1140-01-.01, continued)

(21) “Institutional pharmacy practice site” means a pharmacy practice site serving patients within an institutional facility.

(22) “Long term care pharmacy practice site” means a pharmacy practice site serving patients within a long term care facility.

(23) “Long term care facility” means any organization whose primary purpose is to provide a physical environment for patients to obtain healthcare services, and where patients spend a majority of their time within the facility, including, but not limited to a(n):

(a) Nursing home;

(b) Hospice or residential hospice; and

(c) Assisted living facility.

(24) “Medication assessment” means a consultation between a pharmacist and a patient undertaken for the specific purpose of managing or discussing a course of drug therapy or treatment. Counseling as required by Board Rule 1140-03-.01 shall not be considered a medication assessment for the purposes of this part.

(25) “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.

(26) “National Association of Boards of Pharmacy (NABP)” means the professional organization that represents the individual state boards of pharmacy.

(27) “Nuclear pharmacy practice site” means a pharmacy practice site providing radiopharmaceutical services.

(28) “Outsourcing facility” means a facility engaged in the compounding of sterile drugs which has elected to register as an outsourcing facility with the U.S. Food and Drug Administration and which complies with all relevant federal laws and regulations.

(29) “Oxygen supplier” means any person who sells, delivers, distributes or wholesales medical gases which require a prescription or medical order prior to administration, dispensing or delivery and which are considered legend drugs pursuant to the federal Food, Drug, and Cosmetic Act to any person residing in this state.

(30) “Patient counseling” means communication by the pharmacist of information to the patient or caregiver in order to improve therapeutic outcome.

(31) “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.

(32) “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.

(33) “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

(Rule 1140-01-.01, continued)

place outside of the state where prescription drugs or prescription devices are dispensed and pharmaceutical care is provided to persons residing in this state.

(34) "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.

(35) "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.

(36) "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.

(37) "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.

(38) "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.

(39) "Shall" means that compliance is mandatory.

(40) "Sterile product" means any dosage form, drug product, or biological product devoid from all living microorganisms, including but not limited to bacteria and fungus.

(41) "Sterile manufacturing" means the production, propagation, processing, pooling, or repackaging of sterile products for wholesale or any other form of distribution, not pursuant to a prescription or medical order.

(42) "Third-party logistics provider (3PL)" means a person who provides or coordinates warehousing or other logistics services of a drug or device on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device, but does not take ownership of the drug or device, nor has responsibility to direct the sale or disposition of the drug or device.

(43) "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.

(Rule 1140-01-.01, continued)

(44) "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.

(45) "Unit dose packaging" means that packaging which is designed to hold a quantity of a drug product intended for administration as a single dose.

(46) "USP" means the United States Pharmacopeia.

(47) "USP standards" means any applicable standard or standards published in the most current version of United States Pharmacopeia National Formulary guidelines, to the extent that such guidelines do not conflict with state law, rules, or Board Policy Statements and as those guidelines may, from time to time, be amended.

Authority: *T.C.A. §§ 63-10-101, 63-10-102, 63-10-204, 63-10-214, 63-10-216, 63-10-301, 63-10-304, 63-10-304(b)(1), 63-10-306, 63-10-404(5), (6), (14), (22), (26), (28), and (29), 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. Emergency rule filed January 31, 2014; effective through July 30, 2014. Emergency rule expired effective July 31, 2014, and the rule reverted to its previous status. Amendment filed July 11, 2014; effective October 9, 2014. Amendment filed March 24, 2015; effective June 22, 2015. Amendments filed November 22, 2016; effective February 20, 2017. Amendments filed September 12, 2018; effective December 11, 2018.*

1140-01-.02 VIOLATIONS CONSTITUTE UNPROFESSIONAL CONDUCT.

(1) 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. § 63-10-305(6).

Authority: *T.C.A. §§ 63-10-301, 63-10-304, and 63-10-305.* ***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. Emergency rule filed January 31, 2014; effective through July 30, 2014. Emergency rule expired effective July 31, 2014, and the rule reverted to its previous status. Repeal and new rule filed July 11, 2014; effective October 9, 2014.*

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

(Rule 1140-01-.03 continued)

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. § 63-10-306(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. § 63-10-305, 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.

(7) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 63-1-116, 63-10-101, 63-10-102(a), 63-10-202, 63-10-204, 63-10-304, 63-10-306, 63-10-308, 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. Amendments filed November 22, 2016; effective February 20, 2017.*

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 seven hundred (1,700) 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 seven hundred (1,700) hours must be acquired after enrollment in a recognized college or school of pharmacy; one thousand seven hundred (1,700) of these hours must 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) Foreign pharmacy graduates shall complete five hundred (500) hours of pharmacy internship in Tennessee within a period of six (6) consecutive months.

(Rule 1140-01-.04, continued)

(d) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 63-10-101, 63-10-102, 63-10-202, 63-10-204, 63-10-304, and 63-10-306.* ***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. Repeal and new rule filed March 24, 2015; effective June 22, 2015. Amendments filed November 22, 2016; effective February 20, 2017.*

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® by achieving (at least) the designated passing score on the exam.

(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.

(5) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

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. Amendments filed November 22, 2016; effective February 20, 2017.*

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.*

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;

(Rule 1140-01-.07, continued)

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) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 63-10-101, 63-10-102, 63-10-204, 63-10-210, 63-10-304, 63-10-306, 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. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-01-.08 APPLICATION FOR PHARMACY PRACTICE SITE, MANUFACTURER, OUTSOURCING FACILITY, OXYGEN SUPPLIER AND WHOLESALER/DISTRIBUTOR LICENSES.

(1) Application for a license to operate as a pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor 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, outsourcing facility, oxygen supplier or wholesaler/distributor 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, outsourcing facility, oxygen supplier or wholesaler/distributor physically located within the state of Tennessee must be filed when the pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor 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;

(Rule 1140-01-.08, continued)

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 outsourcing facility, oxygen supplier or wholesaler/distributor shall conduct business in the state of Tennessee until such pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor obtains the required license from the board. In order to obtain a license for a pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor 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.

(i) An out-of-state pharmacy practice site engaged in compounding must provide an inspection performed within the previous twelve (12) months.

(ii) An inspection completed by the United States Food and Drug Administration, or an inspection performed by the National Association of Boards of Pharmacy in lieu of an inspection by the regulatory or licensing

(Rule 1140-01-.08, continued)

agency of the state in which the pharmacy practice site is physically located is acceptable.

5. Maintain records of prescription orders dispensed to and/or of medication assessments provided 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.

10. The Board may require additional information before issuing or renewing a pharmacy license to ensure compliance with applicable laws of this state and rules of the Board.

(b) Manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor.

1. Submit an application for a license, which shall include the address of the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor, 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, outsourcing facility, oxygen supplier or wholesaler/distributor is physically located, or by the Food & Drug Administration. Thereafter, the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor 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, outsourcing facility, oxygen supplier or wholesaler/distributor is physically located, or by the FDA.

3. Comply with the requirements contained in Chapter 1140-09 of the rules of the Board of Pharmacy.

(4) Representatives of a manufacturer, outsourcing facility or wholesaler/distributor conducting business in the state of Tennessee and who possesses and distributes controlled substances shall obtain a controlled substance registration from the Board of Pharmacy.

(5) Any entity licensed as or applying for licensure as manufacturer or outsourcing facility conducting business in the state of Tennessee and who manufactures, prepares, propagates, repackages, or processes sterile drug products or biological products using aseptic

(Rule 1140-01-.08, continued)

processing must register and possess a modifier as a sterile manufacturer with the Board of Pharmacy in accordance with this chapter. This section shall not apply to wholesalers/distributors of sterile products.

(6) 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.

(7) 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.

(8) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 53-11-301, 53-11-302, 53-14-104, 53-14-107, 63-10-203, 63-10-204, 63-10-210, 63-10-216, 63-10-301, 63-10-308, 63-10-310, and 63-10-312.* ***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. Emergency rule filed January 31, 2014; effective through July 30, 2014. Emergency rule expired effective July 31, 2014, and the rule reverted to its previous status. Amendments filed July 11, 2014; effective October 9, 2014. Amendments filed March 24, 2015; effective June 22, 2015. Amendments filed November 22, 2016; effective February 20, 2017. Amendments filed December 15, 2023; effective March 14, 2024.*

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.

(3) Prior to renewal of its license in this state, an out-of-state pharmacy practice site engaged in compounding must provide to the Board the most recent inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located, an inspection performed by the United States Food and Drug Administration, or an inspection performed by the National Association of Boards of Pharmacy, that must have been within the previous twelve (12) months.

(4) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

(Rule 1140-01-.09, continued)

Authority: *T.C.A. §§ 53-11-301, 53-11-302, 63-10-204, 63-10-210, 63-10-216, 63-10-308, 63-10-310, and 63-10-312.* ***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. Amendments filed November 22, 2016; effective February 20, 2017. Amendments filed December 15, 2023; effective March 14, 2024.*

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 one-hundred twenty-five dollars ($125.00). 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 one-hundred twenty-five dollars ($125.00). Each person licensed as a 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 sixty-three dollars ($63.00).

(4) Each person becoming registered as a pharmacy technician shall pay a registration fee of fifty-five dollars ($55.00). 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 seventy-five dollars ($75.00).

(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 three-hundred dollars ($300.00) 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 of Pharmacy and shall pay a fee of three-hundred dollars ($300.00)

(6) All manufacturers, outsourcing facilities, oxygen suppliers, wholesalers/distributors, and 3PLs of prescription drugs and/or devices and related materials doing business in the state of Tennessee must be licensed by the Board of Pharmacy by paying a registration fee of five-hundred twenty-five dollars ($525.00), and thereafter a biennial renewal fee of five-hundred twenty-five dollars ($525.00).

(7) The fee for the Board of Pharmacy's publication of Pharmacy Drug Laws, Rules and Regulations shall be an amount which covers the cost of publication and shipping, as determined by the Board of Pharmacy. The Board may also publish Pharmacy Drug Laws, Rules and Regulations electronically, and may make an electronic publication freely available on the Board's website.

(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 the Department of Health.

(9) The fee for certification of license examination grades shall be twenty five dollars ($25.00).

(Rule 1140-01-.10, continued)

(10) The fee for any duplicate or revised license, registration, modifier or 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 one-hundred dollars ($100.00) biennially from the date of issuance.

(16) Any person, partnership, firm, corporation or agency owning or operating a pharmacy practice site or any other establishment licensed pursuant to this chapter, where sterile products are compounded, manufactured, prepared, propagated, repackaged, processed, stored, or distributed shall pay a registration fee of two-hundred and fifty dollars ($250.00), and thereafter a biennial renewal fee of two-hundred and fifty dollars ($250.00).

(17) Each automated dispensing system becoming registered with the Board shall pay a registration fee of three-hundred dollars ($300.00), and thereafter a biennial renewal fee of three-hundred dollars ($300.00).

(18) Each licensed practitioner, including pharmacy technicians, shall pay a fee of ten dollars ($10.00) in addition to any initial licensure or renewal fee. All fees collected pursuant to this paragraph shall be for the purpose of funding a peer assistance program.

(19) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

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Authority: *T.C.A. §§ 63-10-308, 63-10-310 and 63-10-312.* ***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 filed 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, 1988; 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,*

(Rule 1140-01-.10, continued)
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. Emergency rule filed January 31, 2014; effective through July 30, 2014. Emergency rule expired effective July 31, 2014, and the rule reverted to its previous status. Amendments filed July 11, 2014; effective October 9, 2014. Amendments filed March 24, 2015; effective June 22, 2015. Amendments filed November 22, 2016; effective February 20, 2017. Amendments filed September 12, 2018; effective December 11, 2018. Amendments filed December 15, 2023; effective March 14, 2024.

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/distributor 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, 63-10-102(a), 63-10-404, 63-10-404(6), 63-10-504, 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. Amendment filed July 11, 2014; effective October 9, 2014.*

1140-01-.12 STERILE PRODUCT REGISTRATION.

(1) No licensee may compound, manufacture, prepare, propagate, or process any sterile product to be dispensed, sold, traded, or otherwise distributed in or from this state without first obtaining a sterile compounding modifier registration from the Board of Pharmacy.

(2) A registration modifier to compound and dispense sterile products into or from this state may be suspended by the Board of Pharmacy, upon information that the registrant has:

(a) Knowingly furnished false or fraudulent material information in any application filed before the Board of Pharmacy; or

(b) Been convicted of a felony under any state or federal law relating to drugs or to the practice of pharmacy; or

(c) Had any of its licenses, permits, or registrations granted by the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), the Department of Health and Human Services (DHHS), or any other federal agency or subdivision thereof, suspended, revoked, or voluntarily surrendered; or

(d) Been enjoined from operation by the court of any state or a federal court; or

(e) Been identified by the Commissioner of Health or the Commissioner's designee, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), or an investigator of the Board of Pharmacy as a source of adulterated, misbranded, or otherwise unsafe sterile products which have been, or pose an imminent risk of being dispensed, sold, traded, or otherwise distributed.

(3) An order of suspension issued by the Board of Pharmacy may contain additional directives or requirements necessary to protect public health, safety and welfare, including but not limited to:

(Rule 1140-01-.12, continued)

(a) The quarantine or disposal of any sterile product compounded, manufactured, prepared, propagated or processed at the facility.

(b) The initiation of a recall of any sterile product compounded, manufactured, prepared, propagated or processed at the facility where such products or any label, container, packaging, or dosage form associated with such products may be adulterated, misbranded, contaminated, or otherwise unsafe.

(c) An order of suspension issued by the Board of Pharmacy may contain exceptions or allowances necessary to protect individual patients or the public health.

(4) Any order of suspension issued by the Board of Pharmacy pursuant to this chapter shall follow the procedures required by the Uniform Administrative Procedures Act, including those procedures required by T.C.A. § 4-5-320(d) where appropriate.

Authority: *T.C.A. §§ 63-10-301, 63-10-304, 63-10-305, and 63-10-306.* ***Administrative History:*** *Original rule filed July 11, 2014; effective October 9, 2014.*

1140-01-.13 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) If the practice site is a dispensing pharmacy, 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.

(Rule 1140-01-.13, continued)

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 device or vault in a secured place outside of the department, unless the pharmacy practice utilizes an electronic access device which is capable of restricting and preventing unauthorized access into the pharmacy. The key or access device may be used to allow emergency entrance to the department. A written or electronic record of persons accessing the pharmacy department using the key or other access device must be maintained on the premises of that pharmacy practice site for a period of 2 years.

(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. §§ 63-10-204, 63-10-304, 63-10-404(28), and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed May 11, 1998; effective July 25, 1998. Emergency rule filed January 31, 2014;*

(Rule 1140-01-.13, continued)
effective through July 30, 2014. Emergency rule expired effective July 31, 2014, and the rule reverted to its previous status. Rule was previously numbered 1140-01-.12 but was renumbered 1140-01-.13 with the introduction of new rule 1140-01-.12 filed July 11, 2014; effective October 9, 2014. Amendments filed November 22, 2016; effective February 20, 2017.

1140-01-.14 STANDARDS FOR MANUFACTURERS, OUTSOURCING FACILITIES, OXYGEN SUPPLIERS AND WHOLESALERS/DISTRIBUTORS.

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

Authority: *T.C.A. §§ 63-10-301, 63-10-304, and 63-10-306.* ***Administrative History:*** *Original rule filed May 11, 1998; effective July 25, 1998. Emergency rule filed January 31, 2014; effective through July 30, 2014. Emergency rule expired effective July 31, 2014, and the rule reverted to its previous status. Rule was previously numbered 1140-01-.13 but was renumbered 1140-01-.14 with the introduction of new rule 1140-01-.12 filed July 11, 2014; effective October 9, 2014. Amendments filed July 11, 2014; effective October 9, 2014. Repeal and new rule filed March 24, 2015; effective June 22, 2015.*

1140-01-.15 REPEALED.

Authority: *T.C.A. §§ 63-10-204, 63-10-205, 63-10-304, 63-10-304(b)(1), 63-10-404(14), 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. Emergency rule filed January 31, 2014; effective through July 30, 2014. Emergency rule expired effective July 31, 2014, and the rule reverted to reserved status. Rule was previously numbered 1140-01-.14 but was renumbered 1140-01-.15 with the introduction of new rule 1140-01-.12 filed July 11, 2014; effective October 9, 2014. Repeal filed November 22, 2016; effective February 20, 2017.*

1140-01-.16 PILOT PROGRAMS.

A licensee of the Board who wishes to undertake a temporary pilot program for the purpose of studying or investigating the impact of a public health initiative, or who wishes to address a recognized health emergency or crisis in the State shall submit a written application for such program to the executive director on a form approved by the Board, who may present such application to the Board for approval. The Board may authorize such a program to take place for a predetermined, temporary amount of time. A program authorized pursuant to this part may deviate from the board's rules if the Board determines such deviation is crucial to the proposed program and in the best interest of the public health, safety and welfare.

Authority: *T.C.A. §§ 63-10-301, 63-10-304, 63-10-305, and 63-10-308.* ***Administrative History:*** *New rule filed November 22, 2016; effective February 20, 2017.*