

Tennessee Board of Pharmacy
Board Meeting
July 7, 2014

TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive
Nashville, TN
July 7, 2014

BOARD MEMBERS PRESENT

Jason Kizer, D.Ph., President
Charles Stephens, D.Ph.
Kevin Eidson, D.Ph.
R. Michael Dickenson, D.Ph.
Joyce McDaniel, Consumer Member

STAFF PRESENT

Reginald Dilliard, Executive Director
Stephen Cange, Assistant General Counsel
Marc Guilford, Assistant General Counsel
Devin Wells, Deputy General Counsel
Tracy Bacchus, Administrator
Ashley Fine, Rules Coordinator

BOARD MEMBER PRESENT ELECTRONCIALLY

Will Bunch, D.Ph.

BOARD MEMBER ABSENT

Nina Smothers, D.Ph., Vice President

The Tennessee Board of Pharmacy convened on Monday, July 7, 2014 in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 9:06 a.m.

Rulemaking Hearing

Stefan Cange, Assistant General Counsel, served as moderator for the rulemaking hearing. This rulemaking hearing is based on the board's decision to amend board rules 1140-.01, 1140-07 and 1140-09.

**RULES
OF
THE TENNESSEE BOARD OF PHARMACY**

**CHAPTER 1140-01
INTRODUCTORY RULES**

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(Rule 1140-01-.01, continued)

Licenses
Manufacturer and Wholesaler/Distributor

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) "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.
- (9) "Component" means any active ingredient, or any added substance, inactive ingredient, excipient or pharmaceutical ingredient, intended for use in the compounding of a drug product, including those that may not appear on the product label.
- (10) "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.
- (11) "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).
- (12) "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.
- (13) "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.

(Rule 1140-01-.01, continued)

- (14) “ Electronic medical or prescription order” means a medical or prescription order which is transmitted by computer technology other than by electronic image transmission.
- (15) Facsimile (FAX) medical or prescription order” means a medical or prescription order which is transmitted by an electronic image transmission.
- (16) “ 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.
- (17) “ Hazardous product” means any substance that may be cytotoxic, genotoxic, oncogenic, mutagenic, teratogenic, or otherwise pose a potential health hazard.
- (18) “ 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.
- (19) “ Institutional pharmacy practice site” means a pharmacy practice site serving patients within an institutional facility.
- (20) “ 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.
- (21) “ National Association of Boards of Pharmacy (NABP)” means the professional organization that represents the individual state boards of pharmacy.
- (22) “ Nuclear pharmacy practice site” means a pharmacy practice site providing radiopharmaceutical services.
- (23) “ Patient counseling” means communication by the pharmacist of information to the patient or caregiver in order to improve therapeutic outcome.
- (24) “ Pharmaceutical care” is the responsible provision of drug therapy through, among other things, pharmacists identifying potential and actual drug-related problems and resolving and

(Rule 1140-01-.01, continued)

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.

- (25) "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.
- (26) "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.
- (27) "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.
- (28) "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.
- (29) "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.
- (30) "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.
- (31) "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.
- (32) "Shall" means that compliance is mandatory.
- (33) "Sterile product" means any dosage form, drug product, or biological product devoid from all living microorganisms, including but not limited to bacteria and fungus.
- (34) "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.

(Rule 1140-01-.01, continued)

- (35) “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.
- (36) “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.
- (37) “Unit dose packaging” means that packaging which is designed to hold a quantity of a drug product intended for administration as a single dose.
- (38)~~34~~ “USP” means the United States Pharmacopeia.
- (39) “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, 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.

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. § 63-10-505(6).~~
- (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. §§ 63-10-101, 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.

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

(Rule 1140-01-.03, continued)

- (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.*

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.

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.

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

(Rule 1140-01-.07, continued)

- (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;

(Rule 1140-01-.07, continued)

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.

1140-01-.08 APPLICATION FOR PHARMACY PRACTICE SITE, MANUFACTURER AND WHOLESALE/DISTRIBUTOR LICENSES.

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

(Rule 1140-01-.08, continued)

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

(Rule 1140-01-.08, continued)

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/distributor.
1. Submit an application for a license, which shall include the address of the manufacturer 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 or wholesaler/distributor is physically located. Thereafter, the manufacturer 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 or wholesaler/distributor is physically located.
 3. Comply with the requirements contained in Chapter 1140-09 of the rules of the Board of Pharmacy.
- (4) Representatives of a manufacturer 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) A manufacturer conducting business in the state of Tennessee and who manufactures, prepares, propagates, repackages, or processes sterile drug products or biological products using aseptic 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.

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.

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.

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 seventy-five dollars (\$75.00). 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 and wholesalers/distributors of prescription drugs and 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.

(Rule 1140-01-.10, continued)

- (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).
- (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 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).

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.

(Rule 1140-01-.10, continued)

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(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.

1140-01-.12 STERILE COMPOUNDING 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:
 - (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.

1140-01-.13 ~~1140-01-~~ 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.

~~1140-01-14~~ ~~1140-01-~~ **STANDARDS FOR MANUFACTURERS AND WHOLESALE/DISTRIBUTORS.**

No license to operate a new or remodeled manufacturer or wholesaler/distributor location within the state of Tennessee, or an existing manufacturer or wholesaler/distributor location which changes location or

ownership, will be issued unless the manufacturer or wholesaler/distributor meets the standards set forth in Chapter 1140-09 of the rules of the Board of Pharmacy.

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

1140-01-15 ~~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 jell)
- (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.

**RULES
OF
THE TENNESSEE BOARD OF PHARMACY**

**CHAPTER 1140-7
STERILE PRODUCT PREPARATION IN PHARMACY PRACTICE**

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1140-7-.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.

1140-07-.02 STANDARDS

Tennessee Board of Pharmacy
Board Meeting
July 7, 2014

- (1) All sterile products shall be prepared in compliance with applicable USP standards for pharmaceutical compounding.
- (2) The Board of Pharmacy, upon a showing of good cause and in the best interest of the public health, safety and welfare, may waive the requirements of any applicable portion of USP standards.
 - (a) All waiver requests submitted pursuant to this part shall be submitted in writing.
 - (b) The Board of Pharmacy may authorize the Executive Director to exercise some, or all, of its waiver authority under this part.
- (3) Noncompliance by a licensee with applicable standards and guidelines, or any other violation of the provisions of this rule shall be considered unprofessional conduct within the meaning of T.C.A. 63-10-305 and a violation of a duly promulgated rule of the Board of Pharmacy.
- (4) Any licensed pharmacy which compounds sterile products, except hospital pharmacies compounding for inpatients of a hospital, shall submit to the Board of Pharmacy, on a quarterly basis, a report listing the quantity of sterile products compounded and dispensed during the previous quarterly period and any other information as required by USP standards.
 - (a) Quarterly reports submitted pursuant to this paragraph shall be submitted by the 15th day of the month following the end of each calendar quarter.
 - (b) In any calendar year where any one of the above dates fall on a weekend or official state holiday, all quarterly reports due on that date shall be submitted on the following business day.
 - (c) The format for reports submitted pursuant to this paragraph shall be determined by the Board of Pharmacy through policy and made available to the public on the Board of Pharmacy's website.
- (5) Any licensed pharmacy which compounds and dispenses sterile products shall provide at a minimum upon request of the Board of Pharmacy the following information for any sterile drug product compounded, dispensed, traded, sold, or otherwise distributed:
 - (a) name, strength, and dosage form;
 - (b) quantity compounded, dispensed, traded, sold, or otherwise distributed during the preceding quarterly period;
 - (c) all components and an accurate statement of the weight or measure of each component;
 - (d) the beyond-use date;
 - (e) storage requirements;
 - (f) labels and labeling with appropriate beyond-use date and instructions for storage and use.
- (6) Any licensed pharmacy which compounds and dispenses sterile products must ensure that the following information is on file at the practice site and readily accessible for sterile products:
 - (a) documentation of the name and strength of all drug products compounded over the past two (2) years;

- (b) the sources and lot numbers of the components used in those drug products;
- (c) the total number of dosage units compounded over the past two (2) years;
- (d) the name of the person who prepared the drug product;
- (e) the name of the pharmacist who approved the drug product;
- (f) the name of the practitioner or the name of the patient or healthcare entity who received the compounded drug product;
- (g) the results of any sampling, testing or other quantitative evaluation conducted for the purposes of quality control for any sterile compounded products, as defined by chapter 1140-01, compounded over the past two (2) years.

1140-07-.03 ~~1140-7-~~ **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 products 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.

1140-07-.04 ~~1140-7-.03~~ PHYSICAL REQUIREMENTS.

- (1) Any facility that compounds sterile products shall comply with applicable USP standards.

1140-07-.05 ~~1140-7-.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 sterile compounding pursuant to USP standards, and shall, at a minimum, include:
 - (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, including the active notification of patients if they may be affected by a product found to have a defect or an out-of-specification result including any recall policy and procedures;
 - (o) attire; ~~and~~
 - (p) pharmacist, pharmacy intern, and pharmacy technician training.
 - (q) compliance with all applicable USP standards; and
 - (r) response to adverse events, outbreaks, and other public health threats associated with products compounded, dispensed, manufactured, propagated, distributed, or otherwise processed at the facility, including procedures for the rapid compilation and dissemination of records to appropriate authorities.
- (2) Any licensed facility which engages in sterile compounding shall conduct an annual review of its policy and procedure manual, and shall update its policy and procedure manual as necessary.
- (3) Failure by any licensee or registrant to comply with its policy and procedure manual, or any part of this rule shall be considered a violation of a duly promulgated rule of the Board of Pharmacy and may be considered dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-305(6).

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.

1140-07-.06 ~~1140-7-.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) or healthcare entity name;
 - (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, Beyond Use Dating (BUD);
 - (h) date of compounding;
 - (i) appropriate auxiliary label(s); and
 - (j) directions for use (if for outpatient), if applicable.
- (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.

1140-07-.07 ~~1140-7-.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.

1140-07-.08 ~~1140-7-.07~~ **ATTIRE.**

- (1) All pharmacists, pharmacy interns and pharmacy technicians shall wear applicable outer garments and shall use applicable respiratory precautions as set out in USP 797.

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.

1140-07-.09 ~~1140-7-.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.
- (3) All quality assurance programs shall follow applicable USP standards.
- (4) As part of its quality assurance program, any licensed facility which engages in sterile compounding shall perform a gap analysis pursuant to guidelines adopted by the Board of Pharmacy. Any exceptions or serious deficiencies noted in this analysis shall be reported to the Board of Pharmacy.
- (5) Failure by any licensee or registrant to comply with its quality assurance program shall be considered a violation of a duly promulgated rule of the Board of Pharmacy and may be considered dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-305(6).

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.

**RULES
OF
THE TENNESSEE BOARD OF PHARMACY**

**CHAPTER 1140-9
MANUFACTURERS AND WHOLESALERS/DISTRIBUTORS**

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1140-09-.01 MANUFACTURER AND WHOLESALER/DISTRIBUTOR LICENSING.

- (1) Every manufacturer or wholesaler/distributor, before engaging in the manufacture, 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 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.
 1. 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.

1140-09-.02 MINIMUM INFORMATION REQUIRED.

- (1) The board shall require the following minimum information from each manufacturer or wholesaler/[distributor](#) applying for a license or any renewal of such license:
 - (a) The name, full business address, and telephone number of the manufacturer or wholesaler/[distributor](#);
 - (b) All trade or business names used by the manufacturer or wholesaler/[distributor](#);
 - (c) Addresses, telephone numbers, and the names of contact persons for all facilities used by the manufacturer or wholesaler/[distributor](#) 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/[distributor](#), 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
 5. DEA registration number if applicable; and
 6. The results of a criminal background check for the owner or manager of the facility seeking licensure, submitted directly to the Board of Pharmacy by the vendor identified in the Board of Pharmacy's licensure application materials.
- (2) Applicants seeking to register as manufacturers shall provide the following materials to the Board of Pharmacy:
 - (a) Proof of registration with the Food and Drug Administration as a manufacturer and the most current inspection by that agency, or correspondence or other written proof from the Food and Drug Administration which states that registration with that agency is unnecessary;
 - (b) The name and contact information of the owner, the owner's agent, or another such individual employed at or contracted by the applicant that can be reached at any time by the Board of Pharmacy, the Department of Health or any agents thereof in the event of a potential or actual public health threat related to the sterility or potency of any drug or biologic product manufactured, wholesaled or distributed by the applicant.
- (3) Applicants seeking to register as sterile manufacturers shall provide the following materials to the Board of Pharmacy:
 - (a) Upon request by the Board of Pharmacy or the executive director, a list of sterile products currently being manufactured, wholesaled and distributed;

- (b) The name and contact information for any laboratory, corporation, or other organization that may perform sterility and potency testing, or similar procedures for the purposes of quality assurance on any drug or biologic product produced by the applicant;
- (4) Changes in any information in paragraphs (1), (2), or (3) of this rule shall be submitted in writing to the Board of Pharmacy 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.

1140-9-.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/[distributor](#):
 - (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.

1140-9-.04 PERSONNEL.

The board shall require that personnel employed by a manufacturer or wholesaler/[distributor](#) 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.

1140-09-.05 MINIMUM REQUIREMENTS FOR GENERAL 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/distributors:

- (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/[distributor](#) 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/[distributors](#) 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/[distributors](#) 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/[distributors](#) 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/[distributor](#) 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/[distributors](#) 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/[distributor](#) 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/[distributors](#) 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/[distributors](#) shall operate in compliance with applicable federal, state, and local laws and regulations.
 - (a) Manufacturers and wholesalers/[distributors](#) 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/[distributors](#) 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/[distributors](#) 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.

1140-09 -.06 MINIMUM REQUIREMENTS FOR STERILE PRODUCT OPERATION

- (1) Any manufacturer or wholesaler/distributor licensed pursuant to this chapter that also holds an active sterile compounding registration from the Board of Pharmacy and that holds a license or registration from the Federal Food and Drug Administration, shall comply with all applicable federal laws, regulations, and guidelines including, but not limited to:
 - (a) FDA Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs 21 CFR 210;
 - (b) FDA Current Good Manufacturing Practice for Finished Pharmaceuticals 21 CFR 211;
 - (c) DEA regulations relating to controlled substances 21 CFR 1300-99.
- (2) Any manufacturer or wholesaler/distributor licensed pursuant to this chapter who also holds an active sterile compounding registration from the Board of Pharmacy and who does not hold a license or registration from the federal Food and Drug Administration shall comply with all applicable USP standards.(3) Any manufacturer or wholesaler/distributor licensed pursuant to this chapter who also holds an active sterile compounding registration from the Board of Pharmacy shall comply with all other applicable Board of Pharmacy rules and all other applicable laws of this State.

- (4) [The Board of Pharmacy may waive any applicable USP standards upon a showing by the applicant that good cause exists and that a waiver would better promote public health, safety, and welfare.](#)

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.

After discussion, Mr. Cange reminded the board that any changes that the board recommends must be within the rules that were presented. The board cannot not add a new rule, definition or add a new word but they can delete. Mr. Wells stated that the while the board cannot make changes to these rules at this time they can allow these rules to continue the process and add the additions or corrections at another time. Dr. Dilliard stated that the board may want to make a statement or policy clarifying some of the issues. Mr. Wells stated that the board could issue a policy statement in the meantime. Dr. Kizer asked if a policy statement is needed for low and medium risk, outpatient and lot number issues. Mr. Cange stated that members of the board and attorney's Dr. Dickenson asked if board rule 1140-07-.01 could be amended to add the statement "regarding applying to all pharmacy practice site currently preparing high risk products and/or batch preparation can be made at the beginning of the document." Mr. Cange stated that it could be added to that section and that it is in the scope of the rule. Mr. Cange stated that the board could edit 1140-07-.05 and 1140-07-.06, which deal with the recordkeeping requirements, or the board could approve the rules as is and complete the policy statements at a later date. Dr. Dickenson made the motion to accept the changes to 1140-07-.01 concerning applicability for high risk and batch compounding products with the understanding that the board will address the issues of labeling and inpatient/outpatient at a later date. Dr. Stephens stated that this language does not include low and medium risk compounding and dispensing products. Mr. Cange stated that if you wanted the facilities to maintain the records of medium and low risk products then you can add the provision of this chapter shall apply to the facilities that compound and dispense high risk products. However, 1140-07-.05 and 1140-07-.06 shall apply to all practice sites that engage in sterile compounding. Dr. Dickenson amended his motion to add high risk and/or batch compounding to 1140-07-.02(4). Dr. Stephens seconded the motion. Mr. Cange stated that with the question concerning a patient name in an emergency room situation, the rule language allows for the name of the health care institution which is permissive and you don't have to put the patient name on the compounded product you can put the name of the institution on the product. He also stated that with respect to USP Standards and UPS 797, USP Standards is a defined term which states the most current version of USP Pharmacy standards that applies to sterile compounding as they may be amended. A roll call vote was taken with the motion carried. Dr. Bill Green from St. Jude asked about the intent of recording lot numbers referenced in board rule 1140-07-.02 (5) & (6) and objects to that requirement if it requires that the hospital specifically state which patient received a dose and what lot number was used in preparation of that dose. Dr. Stephens stated that at a retail pharmacy you are required to list that lot number for insurance purposes. Dr. Dilliard stated that the board only wants to know that hospitals have the ability to know what lot number was dispensed within a certain time period and have the ability to contact the patients if need be. Mr. Cange stated that the rules state lot numbers as components and that they are not saying that the lot number attached to the patient. Dr. Eidson made the motion to adopt the rules as amended. Dr. Dickenson seconded the motion. A roll call vote was taken and the motion carried.

**Summary Suspension
Corder's Community Pharmacy, Inc.**

Mr. Cange informed the board the summary suspension of Corder's Community Pharmacy, Inc. pharmacy license is pursuant to T. C. A. 4-5-320(c) and can take place when an agency finds that the public health, safety or welfare imperatively requires emergency action. Dr. Eidson recused himself. Mr. Cange explained to the board that this is a temporary measure and that Corder's Community Pharmacy, Inc. can request a hearing within seven (7) business days. Corder's Community Pharmacy, Inc. is charged with violating T. C. A. § 63-10-305 (6), T. C. A. § 63-10-305 (4), T.C.A. § 63-10-305 (8) and board rules 1140-03-.02, rule 1140-03-.02, 1140-03-.03 and 1140-01-.12. Dr. Kizer left the meeting and Dr. Stephens took over as chair. After discussion, Ms. McDaniel made the motion to adopt the draft order of suspension. Dr. Dickenson seconded the motion. The motion carried.

Ms. McDaniel left the meeting.

**Presentation
Affiliated Monitors, Inc.**

Wendy Anderson is a representative from Affiliated Monitors, Inc. Affiliated Monitors, Inc. has been in business for 10 years and they provide monitoring services and compliance programs for regulatory boards in 35 states. If the board decides to contract with Affiliated Monitors, Inc. the cost of the monitoring is to the licensee and not the board. They will provide progress reports to the board. Ms. Anderson stated that they are currently monitoring licensees for the Board of Medical Examiners, Board of Dentistry and Board of Osteopathic Examiners. Dr. Dilliard asked Ms. Anderson how they would go about monitoring a pharmacy that may have problems with controlled substances and the controlled substance monitoring database. Ms. Anderson stated that would put a program together that deal with education, recordkeeping and accountability. Dr. Stephens asked about monitoring for pharmacy technicians who may have substance abuse problems. Ms. Anderson stated that Affiliate Monitors, Inc. do monitoring for substance abuse. Dr. Bunch what the rate is for the monitoring. Ms. Anderson stated that the fee is per hour for the monitor. Mr. Guilford asked about what their experience is with monitoring a pharmacy, how often they go to the pharmacy and what records are being reviewed. Ms. Anderson stated that they adhere to what the board requests. At the beginning they may be in the pharmacy more frequently and as they see improvement the time spent in the pharmacy will decrease. Mr. Cange asked if they have seen a lasting effect on the person or facility that they have monitored. Ms. Anderson stated that they have seen lasting results with physicians and their practice.

Dr. Eidson made the motion to adjourn. Dr. Dickenson seconded the motion. The motion carried.

These minutes were approved and ratified as amended at the September 10-11, 2014 board meeting