

**DRAFT OF PROPOSED REVISIONS TO THE
RULES & REGULATIONS OF THE
TENNESSEE BOARD OF PHARMACY**

June 30, 2014

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CHAPTER 1140-01 - INTRODUCTORY RULES

(Current Rules: <http://www.state.tn.us/sos/rules/1140/1140-01.20140131.pdf>)

1140-01-.01 DEFINITIONS.

- (1) "ACPE" means the Accreditation Council for **Pharmacy** Education.
- (2) "Alternate or alternative infusion pharmacy practice site" means a pharmacy practice site, **other than institutional or long-term care**, where parenteral, enteral or respiratory therapies, and ancillary supplies, medications and equipment are provided to patients in a non-institutional setting.
- (3) "Accreditation Council for Pharmacy Education (ACPE)" means the national organization for accreditation of professional degree programs in pharmacy and for accreditation of providers of continuing pharmacy education.
- (4) **"Automated Dispensing System" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.**
- (5) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.
- (6) "Blood fraction/component" means that part of blood separated by physical or mechanical means.
- (7) "Centralized Prescription Processing" is the filling or refilling of a lawful prescription order written by the patient's authorized prescriber by one (1) pharmacy licensed by the State of Tennessee at the request of another pharmacy licensed by the State of Tennessee for the delivery of the prescription drugs to the patient or patient's agent.
- (8) "Certified pharmacy technician" means an individual who is certified by a national or state agency that offers a certification program that is recognized by the board.
- (9) "Consultant pharmacist" means a pharmacist retained on a routine basis to consult with organizations, institutional **or long-term care** facilities or patients in areas that pertain to the practice of pharmacy.
- (10) "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).

(11) "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.

(12) "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.

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

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

(15) "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.

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

(17) "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. An Institutional facility may include but is not limited to a(n):

- (a) hospital and associated clinics;
- (b) developmental disability center;
- (c) inpatient psychiatric center;
- (d) sub-acute care facility; and
- (e) university health center.

(18) "Long-term care facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services including but not limited to a(n):

- (a) adult care home;
- (b) intermediate care facility;
- (c) intermediate care facility for the developmentally disabled;
- (d) mental health facility;
- (e) assisted living facility;
- (f) correctional facility;
- (g) mental health facility;

- (h) nursing facility;
- (i) skilled nursing facility;
- (j) rehabilitation nursing facility;
- (k) personal care home;
- (l) residential drug or alcohol treatment center;
- (m) hospice;
- (n) rest home; and
- (o) retirement center.

(19) "Long-term care pharmacy practice site" means a pharmacy practice site serving patients within a long-term care 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 or long-term care facility or institutional or long-term care 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 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/or where pharmaceutical care is provided, and any place outside of the state where prescription drugs and/or prescription devices are dispensed and/or 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) "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.

(34) "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.

(35) "Unit dose cart" means a mobile cart, secure and under the specific control of pharmacy personnel, in which medications are provided in unit-of-use for patients in a specific location.

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

1140-01-.02 VIOLATIONS CONSTITUTE UNPROFESSIONAL CONDUCT

(1) Any person who violates any rule of the board may be deemed guilty of dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A.63-10-305(6)

1140-01-.03 APPLICATION FOR A PHARMACIST LICENSE

Add "Upon request, the Board shall consider waiver of selected portions of these requirements" to this section.

1140-01-.04 PHARMACY INTERNSHIP

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; **at least 1100 of these hours must be obtained 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.

(e) Upon request, the Board shall consider waiver of selected portions of these requirements.

1140-01-.05 LICENSING EXAMINATIONS

(1) An applicant for an initial license to engage in the practice of pharmacy in the State of Tennessee shall take the National Association of Boards of Pharmacy (NABP) Multistate Pharmacy Jurisprudence Examination (MPJE®) and the NABP North American Pharmacy Licensing Examination (NAPLEX®), which shall be administered on the dates scheduled by the NABP. An applicant shall also meet the minimum acceptable passing scores on the NAPLEX® and MPJE® as established and nationally accepted.

(2) An applicant to obtain a pharmacy license by reciprocity shall successfully complete the MPJE® **by achieving (at least) the designated passing score on the exam.**

(3) In addition to completing the requirements in paragraph (1) of this rule, a pharmacy foreign graduate shall successfully complete the foreign pharmacy equivalency examination, the Test of Spoken English (TSE®) examination and any other requirements established by the NABP.

(4) Any applicant who fails either the NAPLEX® or MPJE® may retake the examinations at any of the next examination dates scheduled by the NABP. If an applicant fails the NAPLEX® or MPJE® three (3) consecutive times, then the Board may require that applicant to take review courses prior to any following reexamination.

(5) Upon request, the Board shall consider waiver of selected portions of these requirements.

1140-01-.06 No changes

1140-01-.07 No changes

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

(1) Application for a license to operate as a pharmacy practice site, manufacturer or wholesaler within the state of Tennessee shall be submitted to the office of the board at least thirty (30) days prior to the scheduled opening date. No pharmacy practice site, manufacturer or wholesaler may open within the state of Tennessee until a license has been obtained; and such license will not be issued until an inspection by an authorized representative of the board has been made.

(2) An application for an existing pharmacy practice site, manufacturer or wholesaler physically located within the state of Tennessee must be filed when the pharmacy practice site, manufacturer or wholesaler changes name, location or ownership.

(a) Transactions constituting a change of ownership include, but are not limited to, the following:

1. A sole proprietor becomes a member of a partnership or corporation, which succeeds him as the new operator;
2. A partnership dissolves;
3. One partnership is replaced by another through the removal, addition or substitution of a partner;

4. Two (2) or more corporations merge and the originally-licensed corporation does not survive; and

5. Transfers between levels of government.

(b) Transactions which do not constitute a change of ownership include, but are not limited to, the following:

1. Changes in the membership of a corporate board of directors or board of trustees;

2. Two (2) or more corporations merge and the originally-licensed corporation survives; and

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

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

(a) Pharmacy practice site.

1. Submit an application for a license, which shall include the address of the pharmacy practice site, name of owner if a sole proprietorship, names of partners if a partnership or names and titles of all officers if a corporation and names of all pharmacists who practice at the site, together with the appropriate application fee. The director shall be notified in writing within thirty (30) days of any change in the information contained on the original application for a license, including names of pharmacists practicing at the site.

2. Comply with all statutorily authorized directions and requests for information from the board.

3. Maintain at all times a current permit, license or registration to conduct the pharmacy practice site in compliance with the laws of the state in which the site is physically located.

4. Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located. Thereafter, the pharmacy practice site shall submit to the director a copy of any subsequent inspection report conducted by the regulatory or licensing agency of the state in which the site is physically located.

5. Maintain records of prescription orders dispensed to **and/or of medication assessments/consultations provided to** persons residing in Tennessee.

6. All records of prescription orders prepared and dispensed to persons residing in Tennessee shall be readily retrievable from other records.

7. During regular hours of operation, but not less than six (6) days per week nor for a minimum of forty (40) hours per week provide access to a pharmacist by a toll-free telephone service. A toll-free number shall be placed on the label affixed to the dispensing container for each prescription dispensed to a person residing in Tennessee.

8. Designate a pharmacist in charge who shall be responsible for compliance with the provisions in this section, and who shall hold a current Tennessee pharmacist license.

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

(b) Manufacturer or wholesaler.

1. Submit an application for a license, which shall include the address of the manufacturer or wholesaler, name of owner if a sole proprietorship, names of partners if a partnership or names and titles of all officers if a corporation, together with the appropriate application fee. The director shall be notified in writing within thirty (30) days of any change in the information contained on the original application for a license.

2. Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the manufacturer or wholesaler is physically located, **or by the Food & Drug Administration**. Thereafter, the manufacturer or wholesaler shall submit to the director a copy of any subsequent inspection report conducted by the regulatory or licensing agency of the state in which the manufacturer or wholesaler is physically located.

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

(4) Representatives of a manufacturer or wholesaler conducting business in the state of Tennessee and who possess and distribute controlled substances shall obtain a controlled substance registration from the board.

(5) It shall be unlawful for any person to procure or attempt to procure a license or certificate of registration for such person or for any other person by making any false representations.

(6) In determining whether to grant a license under this rule, the board shall require from the applicant proof satisfactory to the board that the:

(a) Applicant is of good moral character, or, if the applicant is a partnership or corporation, that the managing officers are of good moral character; and

(b) That the applicant is equipped as to land, buildings and equipment necessary to conduct the business for which the application has been submitted.

(7) Upon request, the Board shall consider waiver of selected portions of these requirements.

1140-01-.09 RENEWAL OF LICENSES

Add "Upon request, the Board shall consider waiver of selected portions of these requirements" to this section.

1140-01-.10 FEES

Add "Upon request, the Board shall consider waiver of selected portions of these requirements" to this section.

1140-01-.11 CONTROLLED SUBSTANCE REGISTRATION.

Add "Upon request, the Board shall consider waiver of selected portions of these requirements" to this section.

1140-01-.12 STERILE COMPOUNDING REGISTRATION.

A task force of the Tennessee Board of Pharmacy is actively examining this chapter at this time and is to recommend appropriate changes to this section.

1140-01-.13 STANDARDS FOR PHARMACIES AND PRESCRIPTION DEPARTMENT SECURITY.

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

(1) The pharmacy practice site and equipment therein shall be maintained in a clean, sanitary, orderly and well-lighted condition, and all persons working in the pharmacy practice site shall be required to keep themselves and their apparel in a clean and sanitary condition.

(2) All new or relocated pharmacies opening after July 1, 1998 shall provide a consultation area which offers sufficient privacy to the patient before a license will be

issued. All existing pharmacies shall be in compliance with this requirement on or before January 1, 2000.

(3) **If the practice site is a dispensing pharmacy**, the prescription department at the pharmacy practice site shall meet the following standards.

- (a) The department shall have necessary counters and storage space.
- (b) The department shall have a representative stock of prescription drugs and devices and related materials sufficient to compound and dispense medical and prescription orders as indicated by experience.
- (c) The department shall have the apparatus and equipment needed to compound and dispense medical and prescription orders properly.
- (d) The department shall occupy a space of not less than one hundred eighty (180) square feet.
- (e) The department shall have hot and cold running water and immediate area refrigeration.
- (f) The department shall have a physical barrier sufficient to protect against unauthorized entry and pilferage of prescription drugs and devices and related materials.
- (g) Keys or other access devices to the physical barriers shall be subject to the following standards.
 - 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

1140-01-.14 No Changes

1140-01-.15 Prescription Drugs Dispensed by Health Departments

Add "Upon request, the Board shall consider waiver of selected portions of these requirements" to this section.

CHAPTER 1140-02
PROFESSIONAL CONDUCT AND RESPONSIBILITIES

(Current Rules: <http://www.state.tn.us/sos/rules/1140/1140-02.20120403.pdf>)

1140-02-.01 No changes

1140-02-.02 Pharmacy Technicians

(1) Any person acting as a pharmacy technician shall register with the Board by submitting a complete application on a form prescribed by the Board accompanied by the following:

(a) An affidavit signed by both the applicant and employer attesting that the applicant has read and understands the laws and rules relative to pharmacy technicians and the practice of pharmacy in Tennessee. (A copy of this affidavit shall be retained at the applicant's place of employment);

(b) Registration fee established in rule 1140-01-.10; and

(c) The result of a criminal background check, which the applicant shall pay for and cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's registration application materials.

(d) Any application submitted which lacks required information or reflects a failure to meet any of the requirements for registration will be returned to the applicant with written notification of the information that is lacking or the reason(s) the application does not meet the requirements for registration and will be held in "pending" status until satisfactorily completed within a reasonable period of time, not to exceed sixty (60) days from date of written notification.

(2) The following individuals are exempt from registration as a pharmacy technician:

(a) Any individual performing tasks that may be performed by a pharmacy technician who is classified by the employer as a probationary employee. The exemption shall not exceed ninety (90) days from the date of employment.

(b) A student enrolled in a formal pharmacy technician training program while performing experiential rotations as a part of the academic curriculum. The student shall wear a school-issued identification badge.

(3) The pharmacist in charge at each pharmacy practice site is responsible for compliance with the provisions of this chapter by pharmacy technicians at that pharmacy practice site.

(4) A registered pharmacy technician may, **under the supervision of a pharmacist**, perform those tasks associated with the preparation and dispensing process except those tasks identified in Rule 1140-02-.01(13) that must be personally performed by a

pharmacist or pharmacy intern under the personal supervision and in the presence of a pharmacist.

(5) Certified pharmacy technicians may also:

(a) Receive new or transferred oral medical and prescription orders;

(b) Receive and transfer copies of oral medical and prescription orders between pharmacy practice sites; and

(c) Verify the contents of unit dose carts/**automated dispensing systems** prepared by other registered technicians when an additional verification by use of bar code technology or a licensed health care professional is performed prior to administration to the patient.

(6) No prescription drugs and devices and related materials may be released to a patient without verification by a pharmacist of the functions performed by a pharmacy technician.

(7) Pharmacy Technician to Pharmacist Ratio

(a) The pharmacy technician to pharmacist ratio shall not exceed 2:1; however the ratio may be increased up to a maximum of 4:1 by the pharmacist in charge based upon public safety considerations but only if the additional pharmacy technicians are certified pharmacy technicians. However, the pharmacist in charge may request a modification of the ratio from the Board in writing which addresses:

1. the pharmacy technician's experience, skill, knowledge and training; and

2. the workload at the practice site; and

3. detailed information regarding the numbers of pharmacy technicians and the specific duties and responsibilities of each of the pharmacy technicians; and

4. justification that patient safety and quality of pharmacy services and care can be maintained at the pharmacy.

(b) Requested modifications of the established ratios may not be implemented until the written request is considered and approved by the Board.

(8) Pharmacy technicians must wear appropriate identification showing name and appropriate title (e.g. pharmacy technician, certified pharmacy technician).

(9) All pharmacy technician functions shall be performed under the supervision of a pharmacist, who shall direct and verify the accuracy of all pharmacy technician functions.

(10) A registered technician shall maintain his or her registration certificate at the pharmacy practice site; additionally, all certified technicians shall display in like manner evidence of certification. Pharmacy technicians shall possess at all times, while on duty, proof of registration and proof of certification, if applicable.

(11) All registered technicians shall immediately notify the board in writing of any change of address or employer.

(12) For purposes of this rule, a pharmacy intern is not considered to be a pharmacy.

(13) Upon request, the Board shall consider waiver of selected portions of these requirements.

DRAFT

**CHAPTER 1140-03
STANDARDS OF PRACTICE**

(Current Rules: <http://www.state.tn.us/sos/rules/1140/1140-03.20090207.pdf>)

1140-03-.01 RESPONSIBILITIES FOR PHARMACEUTICAL CARE.

(1) Patient counseling

(a) Upon the receipt of a medical or prescription order and following a review of the patient's record, a pharmacist shall personally counsel the patient or caregiver "face-to-face" if the patient or caregiver is present. If the patient or caregiver is not present, a pharmacist shall make a reasonable effort to counsel through alternative means.

(b) Alternative forms of patient information may be used to supplement, but not replace, face-to-face patient counseling.

(c) Patient counseling, as described herein, shall also be required for outpatients of hospitals or other institutional facilities dispensing medical and prescription orders and for patients when medications are dispensed on discharge from the hospital or other institutional facility.

(d) Patient counseling as described in this rule shall not be required for inpatients of an institutional **or long term care** facility.

(e) Patient counseling shall cover matters, which in the exercise of the pharmacist's professional judgment, the pharmacist deems significant including:

1. the name and description of the medication;
2. the dosage form, dose, route of administration, and duration of drug therapy;
3. special directions and precautions for preparation, administration, and use by the patient;
4. common side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
5. techniques for self-monitoring drug therapy;
6. proper storage;
7. prescription refill information; and

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

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

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

(2) Patient Profiling.

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

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

1. Name, address, telephone number.
2. Date of birth (age), gender.
3. An individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.
4. Pharmacist's comments as deemed relevant. This may be done manually or by computer.

(3) Drug Regimen Review.

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

1. over-utilization or under-utilization;
2. therapeutic duplication;
3. drug-disease contraindication;

4. drug-drug interactions;
5. incorrect drug dosage or duration of drug treatment;
6. drug-allergy interactions;
7. clinical abuse/misuse;
8. in-depth assessment of drug benefit-to-risk ratio
9. appropriate generic drug usage

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

(4) Implementation of Pharmaceutical Care.

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

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

1140-03-.02 LOCATION OF PRACTICE.

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

1140-03-.03 MEDICAL AND PRESCRIPTION ORDERS.

(1) To the extent that a medical order contains an order for the compounding, dispensing or administration of a prescription drug or device or related material, the medical order shall be treated as a prescription order. Written medical and prescription orders must be signed by the prescriber. Verbal medical and prescription orders must be immediately reduced to writing (by hand or other means), dated, and initialed by the authorized individual accepting the medical and prescription orders. **If received by a pharmacist using an electronic system, the order shall be entered and recorded as a verbal order.**

(2) Each medical and prescription order when dispensed shall be serially numbered, filed numerically and maintained so as to be readily retrievable at the pharmacy practice site for at least two (2) years from the date the medical and prescription order was last dispensed. Institutional pharmacies shall not be required to serially number medical and prescription orders dispensed for administration to inpatients of that institution.

(3) A pharmacist upon initial dispensing of a medical or prescription order shall record on that medical or prescription order: the date such medical or prescription order was dispensed, the pharmacist's initials, and the amount of any product dispensed. If the pharmacist merely initials and dates a medical or prescription order the pharmacist shall be deemed to have dispensed the full face amount of the medical or prescription order. **In electronic systems, the login code (or similar) for the pharmacist shall suffice as the pharmacist's initials; other electronic notes shall be appended/annotated to the order as needed to provide clarity. Orders may be verified electronically.**

(4) A pharmacist upon refilling a medical or prescription order shall enter on the back of that medical or prescription order: the date such medical or prescription order was refilled, the pharmacist's initials, and the amount of any product dispensed on such refill. If the pharmacist merely initials and dates the back of the medical or prescription order the pharmacist shall be deemed to have dispensed a refill for the full face amount of the medical or prescription order. As an alternative to recording refill information on the back of medical and prescription orders, an automated data processing system may be used for the storage and retrieval of refill information for medical and prescription orders, subject to the following conditions:

(a) Any such computerized system must provide on-line retrieval (via CRT display or hard-copy printout) of the original medical or prescription order information and the complete refill history of all medical and prescription orders which are currently authorized for refilling. This shall include all the information contained in and required to be entered on each such medical or prescription order. This data must include at least the medical or prescription order serial number; date of issuance of the medical or prescription order; patient's name (and address on controlled substance medical and prescription orders); prescriber's name (and address and DEA registration number on controlled substance medical and prescription orders); product name, strength, dosage form, and quantity prescribed; directions for use,

and labeling instructions; refill instructions; and the date of dispensing, quantity dispensed, and identity (name, initials, or identification code) of the dispensing pharmacist for the original dispensing and each refill.

(b) Any such computerized system shall have the capability of producing a hard-copy printout of any medical or prescription order refill data which the pharmacy practice site is responsible for maintaining under the laws and/or regulations of this state and/or the federal government. Such a printout must include: the medical or prescription order serial number; patient's name (and address on controlled substance medical and prescription orders); name of prescriber; name, strength, and dosage form of the product; and the date of each refill, quantity dispensed on each refill, and the name or identification code of the dispensing pharmacist. Controlled substance data contained on such a printout must be separated, asterisked, or in some other manner visually identifiable apart from other items appearing on the printout. Any computerized system employed by a pharmacy practice site must, upon the request of an authorized representative of the board, send or provide such a printout to the pharmacy practice site within forty eight (48) hours excluding weekends (Saturdays and Sundays) and legal holidays.

(c) In the event that a pharmacy practice site which utilizes such a computerized system experiences system down-time, the pharmacy practice site must have a written or readily retrievable auxiliary policy and procedure which will be used for documentation of refills of all medical and prescription orders. This auxiliary procedure must ensure that each refill is authorized, and that all appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

(5) A pharmacist may dispense an appropriately authorized refill of a medical or prescription order by referral to a patient profile (medication record) instead of the original medical or prescription order on file at that pharmacy practice site, subject to the following conditions:

(a) The patient profile must contain all the information contained in and required to be entered on the original medical or prescription order, including the complete refill history of that medical or prescription order. This data includes the medical or prescription order serial number; date of issuance of the medical or prescription order; name of patient; name of the prescriber; product name; strength; dosage form, and quantity prescribed; directions for use, and labeling instructions; refill instructions; and the date of dispensing, quantity dispensed, and initials of the dispensing pharmacist for the original dispensing and each refill. Dispensing data must be identified as to whether it pertains to the original dispensing or to a refill.

(b) The patient profile system must contain a complete and accurate record of the refill history of all medical and prescription orders dispensed at the pharmacy practice site. (This record will constitute compliance with the provisions of paragraph four (4) of this rule.)

(d) Each such profile must be maintained so as to be readily retrievable at the pharmacy practice site for at least two (2) years from the date of the last dispensing recorded on the profile.

(e) A pharmacist dispensing a medical or prescription order by referral to a patient profile in so doing certifies as to the accuracy and validity of the information contained on the patient profile.

(6) No pharmacist, or pharmacy intern or pharmacy technician under the supervision of a pharmacist, shall compound or dispense any medical or prescription order except upon the following conditions:

(a) All medical and prescription orders shall be compounded and dispensed in conformity with any directions of the prescriber. Nothing in this rule shall prohibit a pharmacist from substituting a therapeutically equivalent prescription drug or device or related material containing the same active ingredient or ingredients, dosage form and strength;

(b) No medical or prescription order shall be refilled if it contains a statement over the signature of the prescriber that it is not to be refilled, and a medical or prescription order shall not be refilled unless so authorized by the prescriber;

(c) If any medical or prescription order contains a statement that it may be refilled a specified number of times within or during any particular period, such order shall be refilled in conformity with such statement; and

(d) If a prescription contains a statement that during any particular time it may be refilled at will, the order shall be refilled in conformity to dosage directions, with the exception that it may not be refilled after the expiration of the time specified or one (1) year from the date the order was originally issued or dispensed, whichever comes first. **The first filling of a given prescription must occur within 6 months, after which the prescription should be considered invalid.**

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

(7) Copies of Medical and Prescription Orders.

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

pharmacist of such copy or label shall contact the prescriber or transferor pharmacy practice site and obtain all information required by this rule, which is the same as obtaining an original medical or prescription order;

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

1. The name, address and original medical or prescription order serial number at the pharmacy practice site from which the order was transferred;
2. The name of the transferor; and
3. All information constituting a medical or prescription order including the following:
 - (i) Date **the order was originally issued or dispensed;**
 - (ii) Original number of refills authorized on the original order;
 - (iii) Date of last dispensing; and
 - (iv) Number of valid refills remaining.

(c) The transferee informs the patient that the original medical or prescription order has been canceled at the pharmacy practice site from which it was obtained.

(d) Computerized systems must satisfy all information requirements.

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

(8) It is unlawful for any pharmacy practice site, pharmacist, or pharmacy intern or pharmacy technician under the supervision of a pharmacist, or any other place of business engaged in compounding and dispensing prescription drugs and devices and related materials for human consumption to receive from any patient or other person the return of any portion of an order that has been taken from the premises of the pharmacy practice site or other place of business, except pursuant to **1140-03-.10 or 1140-4-.10, or in strict compliance with applicable rules and regulations issued by the Drug Enforcement Agency or other regulatory agency authorizing the collection or disposal of controlled substances by authorized pharmacists or pharmacies.**

(9) Medical and prescription orders **should generally be** accepted, solicited, collected or advertised at **the** pharmacy practice site for which a license has been issued by the board; **it is acceptable for a pharmacist to accept a prescription in an alternative environment as long as this practice is not routine.**

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

1140-03-.04 FACSIMILE AND ELECTRONIC MEDICAL AND PRESCRIPTION ORDERS.

(1) Facsimile Orders

(a) The transmission of a facsimile medical or prescription order shall be to a pharmacy practice site of the patient's choice and shall occur only at the option of the patient.

(b) Medical and prescription orders may be transmitted to a pharmacy practice site by a facsimile device. Medical and prescription orders for controlled substances may be transmitted by facsimile devices in compliance with 21 C.F.R. 21306.11, 1306.21 and 1306.31.

(c) A pharmacist may dispense medical and prescription orders transmitted by facsimile devices only when transmitted by an authorized prescriber or the prescriber's designated agent.

(d) A facsimile medical or prescription order which meets the requirements of this rule shall be deemed the original medical or prescription order for purposes of filing. The facsimile medical or prescription order must either be photocopied or the original medical or prescription order should be of such quality to not fade within the legal requirements of medical or prescription order record keeping.

(e) Wholesalers, manufacturers, pharmacists and pharmacy practice sites are prohibited from supplying facsimile devices or supplies to any authorized prescriber under any conditions.

(f) An original medical or prescription order that indicates that it has been faxed to a pharmacy practice site, consistent with the provisions of this rule, may only be dispensed as an original medical or prescription order by the pharmacy practice site to which it was faxed, consistent with the notation on the medical or prescription order to be made in accordance with the requirements contained in this rule.

(2) Electronic Orders

(a) Prescription or medical orders transmitted electronically shall meet the following criteria:

1. All prescription or medical orders shall be transmitted directly from an authorized prescriber or prescriber's agent to a licensed pharmacist or to an area in a licensed pharmacy of the patient's choice that is under the direct

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

2. The transmission shall include:

- (i) The telephone number of the authorized prescriber to allow verbal confirmation of the validity and accuracy of the order;
- (ii) The correct time and date of the transmission;
- (iii) The name of the pharmacy to which the order is being transmitted; and
- (iv) The prescribing practitioner's electronic signature or other secure method of validation. "Electronic Signature" is defined as the process that secures the user authentication (proof of claimed identify, such as by biometrics, fingerprints, retinal scans, hand written signature verification, etc.) at the time the signature is generated and creates the logical manifestation of a signature.
- (v) If the transmission is delegated by the prescriber to an agent of the prescriber, the identity of the agent shall be included in the transmission.

(b) Electronic data related to the transmitted order shall be maintained in the pharmacy and shall be deemed the original prescription or medical order meeting all requirements of rule 1140-03-.03 of the rules of the board.

(c) The Pharmacist receiving any transmitted order shall not knowingly participate in any system that restricts the patient's choice of pharmacy.

(d) The pharmacist may not provide financial or other remuneration to the prescriber for any prescription transmitted to the dispensing pharmacy. No person or entity, including but not limited to wholesalers, distributors, manufacturers, pharmacists, and pharmacies, shall supply electronic equipment, software, devices, or modems to any prescriber in exchange for transmitting orders.

(e) The pharmacist shall not use the electronic transmission of orders to circumvent or violate any provision of state or federal drug laws, or the Tennessee Pharmacy Practice Act, or the regulations of the board.

(f) Upon request, the Board shall consider waiver of selected portions of these requirements

1140-03-.05 No Changes

1140-03-.06 LABELING REQUIREMENTS.

Add "Upon request, the Board shall consider waiver of selected portions of these requirements" to this section.

1140-03-.07 TEMPORARY ABSENCE OF PHARMACIST.

Add: "Upon request, the Board shall consider waiver of selected portions of these requirements" to this section.

1140-03-.08 REPACKAGING

(1) Any repackaging of prescription drugs and devices and related materials must be supervised and controlled by a pharmacist with in-process and end-process verification and documentation.

(2) If a Wholesaler is engaged in repackaging drug products, this repackaging must be under the supervision of a pharmacist.

(3) Prescription drugs and devices and related materials which are repackaged by an institutional pharmacy practice site for subsequent dispensing and use within the institution shall be labeled to include:

(a) the name, strength, and quantity of prescription drug or device or related material, if larger than one (1), in the container;

(b) the manufacturer's name, and lot or control number;

(c) the expiration date of the prescription drug or device or related material being repackaged; and

(d) cautionary notations (e.g., refrigerate, shake well, not for injection), if applicable.

(4) A batch number assigned by the pharmacy practice site may be placed on the label in lieu of the manufacturer's name and lot number, provided that the pharmacy practice site maintains a readily retrievable record which identifies, by batch number, the manufacturer and lot number of the prescription drug or device or related material.

(5) The pharmacy practice site shall have proper facilities, qualified personnel, effectual operational practices, suitable packaging material, and adequate control procedures to assure that the purity, integrity, safety, and effectiveness of the prescription drug or device or related material are not affected by such repackaging. All repackaging must be performed by a pharmacist or by a pharmacy intern or pharmacy technician under the supervision of a pharmacist.

(6) "Upon request, the Board shall consider waiver of selected portions of these requirements"

1140-03-.09 No changes

1140-03.10 CONDITIONS FOR DELIVERY OR SALE

(1) No package containing any prescription drug or device or related material damaged by fire, heat, smoke, water, or other causes shall be placed in stock, offered for sale or dispensed or otherwise sold. Any repossession proceedings must be performed with the approval of the board.

(2) Under no circumstances shall any prescription drug or device or related material damaged by fire, heat, smoke, water, or other causes be delivered or handed over to any insurance company, adjustor, salvage company, or other person unless approved by the board prior to delivery.

(3) Medications may be returned to, and received by, the pharmacy/pharmacist if received expressly for the purpose of destruction of the returned medication, provided the pharmacy is equipped for doing so with a policy for complete and timely destruction of medications.

(4) Upon request, the Board shall consider waiver of selected portions of these requirements.

1140-03-.11 OUTDATED OR DETERIORATED DRUGS

Add: "Upon request, the Board shall consider waiver of selected portions of these requirements."

1140-03-.12 No Changes

1140-03-.13 AUTOMATED DISPENSING DEVICES FOR AMBULATORY PHARMACY PRACTICE

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

1. The lot number of each drug contained therein must be listed or posted on the device.
2. The portion of the device where the drug was contained must be thoroughly cleaned to remove all residue before refilling.
3. Lot numbers used shall be tracked/stored by the automated device.
4. The device may be loaded by a pharmacist; or a pharmacy intern or a pharmacy technician under the supervision of a pharmacist.

1140-03-.14 PHARMACIST-IN-CHARGE

Add: "Upon request, the Board shall consider waiver of selected portions of these requirements."

1140-03-.15 REFERENCE BOOKS

Add: "Upon request, the Board shall consider waiver of selected portions of these requirements."

1140-03-.16 AUTOMATED DISPENSING DEVICES FOR PHARMACY PRACTICE

(1) A pharmacy may perform or outsource centralized prescription processing services to another pharmacy, provided that the following criteria are satisfied:

- (a) both pharmacies shall be licensed by the State of Tennessee;
- (b) both pharmacies shall share a common electronic file or both shall have the appropriate technology to allow each other access to information that is necessary to fill or refill a prescription order; and
- (c) both pharmacies shall have the same owner or in the event that the pharmacies do not have the same owner, then the pharmacies shall enter a written contract stating the services that will be provided by each pharmacy as well as the responsibilities of each pharmacy in fulfilling the terms of the contract and in complying with federal and state laws and rules.

(2) The pharmacy performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual stating how prescription orders will be filled or refilled through centralized prescription processing. The pharmacies shall provide the Board with a copy of the manual and appropriate documentation of the processes for the Board's review, upon the Board's request. The pharmacies shall ensure that the manual includes, but is not limited to the following:

- (a) a description of how the pharmacies will comply with federal and state law and rules;
- (b) the maintenance of records to identify the responsible pharmacist(s) in the dispensing process;
- (c) the maintenance of a mechanism for tracking the prescription order during each step of the dispensing process:
 - 1. the maintenance of a mechanism to identify all of the pharmacies involved in dispensing the prescription order on the prescription label;
 - 2. adequate security measures to protect the confidentiality and integrity of the patient information; and
 - 3. the maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality of

patient care, the identification of problems with patient care and the resolution of any identified problems with patient care.

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

1140-03-.17 COLLABORATIVE PHARMACY PRACTICE AGREEMENTS

DRAFT

CHAPTER 1140-04: INSTITUTIONAL AND ALTERNATE OR ALTERNATIVE INFUSION PHARMACY PRACTICE SITES

(Current Rules: <http://www.state.tn.us/sos/rules/1140/1140-04.pdf>)

1140-04-.01 No changes

1140-04-.02 PERSONNEL.

(1) Pharmacist in charge. The practice of pharmacy and the performance of pharmacists and supportive pharmacy personnel associated with any institutional facility shall be under the direction, supervision and responsibility of the pharmacist in charge. The pharmacist in charge shall also be responsible for the dispensing, distribution, compounding, storage and the procurement of prescription and nonprescription drugs used throughout the institutional facility. Policies and procedures defining the scope of pharmacy practice, **collaborative working relationships**, and the responsibilities of the pharmacists and supportive personnel, and the safe use and management of drugs, devices and related materials shall be established by the pharmacist in charge. The pharmacist in charge or designee shall participate in the institution's drug policy committees which serve to ensure rational drug use, patient care evaluation processes relating to drug utilization and effectiveness, drug delivery device selection and evaluation systems, and educational activities for the safe and appropriate use of drugs which will assess the quality of services and products provided and document actions taken. Policies and procedures as indicated in this chapter shall be written and shall be made available to the board.

(2) Pharmacists. The pharmacist in charge shall be supported by a sufficient number of pharmacists to provide appropriate practice of pharmacy for the patients served by the institutional facility. Employment of pharmacists by the institutional facility shall be determined by the pharmacist in charge.

(3) Institutional consultant pharmacist. An institutional facility may utilize a consultant pharmacist who may or may not be independent of the pharmacy practice site, who shall provide patient care service which includes, but is not limited to:

- (a) development, interpretation, and communication of drug, device and related materials orders and health information;
- (b) providing consultation on matters pertaining to efficient drug distribution systems, proper drug selection, rational and safe drug use, and drug therapy assessment;
- (c) evaluation of a patient's drug therapy to maximize outcome(s), including effective communication with prescribing practitioners and other healthcare professionals;
- (d) effective counseling of a patient or a patient's attorney for healthcare or other caregiver;

(e) service on committees or governing bodies; and

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

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

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

SECTIONS 1140-04-.03 THROUGH 1140-04-.12

Add "Upon request, the Board shall consider waiver of selected portions of these requirements" to each section.

1140-04-.13 No changes

1140-04-.14 No changes

1140-04-.15 AUTOMATED DISPENSING SYSTEMS.

(1)–(6) – No changes

(7) The facility may provide off-campus automated dispensing systems for care provided by the institution when the following conditions are met:

(a) Each pharmacy holding an active license with the Tennessee Board of Pharmacy and using automated dispensing systems shall register each automated dispensing device, and its physical location, with the Tennessee Board of Pharmacy. Each pharmacy shall be responsible to pay a registration fee, as defined in 1140-01-.10, for each automated dispensing device, which the licensed pharmacy is responsible for and which is located in an institutional facility.

(b) The pharmacist in charge of the institutional pharmacy practice site shall be designated to be accountable for this automated dispensing system.

(i) The filling/stocking of all medications in the automated dispensing system shall be completed by a pharmacist or pharmacy technician under the direct supervision of a pharmacist, except as provided below:

(A) If the automated dispensing system uses removable cartridges or containers to hold drugs, the prepackaging of the cartridges or containers

shall occur at the provider pharmacy unless provided by an FDA approved repackager.

(B) The prepackaged cartridges or containers may be sent to the off-campus site to be loaded into the machine by personnel designated by the pharmacist-in-charge provided:

(1) a pharmacist verifies the cartridge or container has been properly filled and labeled;

(2) the individual cartridges or containers are transported to the off-campus site in a secure, tamper-evident container;

(3) the automated dispensing system uses bar-coding, microchip, or other technologies to ensure that the containers are accurately loaded in the automated dispensing system;

(4) all drugs to be stocked in the automated dispensing system shall be delivered to the off-campus site by the institutional pharmacy.

(ii) A record of medications filled/stocked into an automated dispensing system shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.

(iii) All containers of medications stored in the automated dispensing system shall be packaged and labeled in accordance with federal and state laws and regulations.

(iv) All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.

(v) The automated dispensing system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated dispensing system, all in accordance with existing state and federal law.

(vi) The automated dispensing system shall provide a mechanism for securing and accounting for wasted medications or discarded medications in accordance with existing state and federal law.

(c) Nothing in this section shall be interpreted to authorize the stocking of controlled substances in automated dispensing systems, except when done in a manner consistent with federal controlled substance rules and regulations.

(d) The registration fee for each automated dispensing device shall be determined by the Tennessee Board of Pharmacy and listed in 1140-01-.10. The Board shall

maintain a list of registered automated dispensing devices, including physical address and number of devices located at each physical address. Registrations for automated dispensing devices must be renewed every two (2) years.

SECTIONS 1140-04-.16 THROUGH 1140-04-.18

Add "Upon request, the Board shall consider waiver of selected portions of these requirements" to each section.

DRAFT

Chapter 1140-05, CONTINUING EDUCATION

(Current Rules: <http://www.state.tn.us/sos/rules/1140/1140-05.20090207.pdf>)

SECTION 1140-05-.02

Add “Upon request, the Board shall consider waiver of selected portions of these requirements” to this section.

DRAFT

Chapter 1140-06, NUCLEAR PHARMACY PRACTICE SITES
(Current Rules: <http://www.state.tn.us/sos/rules/1140/1140-06.20090207.pdf>)
No changes recommended

DRAFT

**CHAPTER 1140-07, STERILE PRODUCT PREPARATION IN PHARMACY
PRACTICE**

(Current Rules: <http://www.state.tn.us/sos/rules/1140/1140-07.20140131.pdf>)

SECTIONS 1140-07-.02 THROUGH 1140-07-.08

Add “Upon request, the Board shall consider waiver of selected portions of these requirements” to each section.

DRAFT

CHAPTER 1140-08, CIVIL PENALTIES

(Current Rules: <http://www.state.tn.us/sos/rules/1140/1140-08.pdf>)

No changes recommended

DRAFT

CHAPTER 1140-09, MANUFACTURERS AND WHOLESALERS/DISTRIBUTORS
(Current Rules: <http://www.state.tn.us/sos/rules/1140/1140-09.20140131.pdf>)

Refer to Emergency rules filed January 31, 2014

ALL SECTIONS

Add “Upon request, the Board shall consider waiver of selected portions of these requirements” to all sections.

DRAFT

CHAPTER 1140-10, RULES OF PROCEDURE FOR HEARING CONTESTED CASES
(Current Rules: <http://www.state.tn.us/sos/rules/1140/1140-10.pdf>)
No changes recommended

DRAFT

CHAPTER 1140-11, CONTROLLED SUBSTANCE MONITORING DATABASE
(Current Rules: <http://www.state.tn.us/sos/rules/1140/1140-11.20130701.pdf>)

No changes recommended

DRAFT

CHAPTER 1140-12, CHARITABLE CLINIC PHARMACIES
(Current Rules: <http://www.state.tn.us/sos/rules/1140/1140-12.pdf>)
No changes recommended

DRAFT

CHAPTER 1140-13, TELEPHARMACY

(Current Rules: <http://www.state.tn.us/sos/rules/1140/1140-13.20090510.pdf>)

SECTION 1140-13-.03

Add “Upon request, the Board shall consider waiver of selected portions of these requirements” to this section.

DRAFT

CHAPTER 1140-14
LONG-TERM CARE PHARMACY PRACTICE SITES
(new section)

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1140-14-.01 APPLICABILITY.

A **long-term care** pharmacy **practice site** providing products and services to any **long-term care** facility shall be subject to all rules of the board dependent upon services provided.

1140-14-.02 PERSONNEL.

(1) Pharmacist in charge. The practice of pharmacy and the performance of pharmacists and supportive pharmacy personnel associated with any **long-term care** facility shall be under the direction, supervision and responsibility of the pharmacist in charge. The pharmacist in charge shall also be responsible for the **dispensing and storage** of prescription and nonprescription drugs used throughout the **long-term care** facility. Policies and procedures defining the scope of pharmacy practice and the responsibilities of the pharmacists and supportive personnel, and the safe use and management of drugs, devices and related materials shall be established by the pharmacist in charge. The pharmacist in charge or designee shall participate in the **long-term care facility's** drug policy committees which serve to ensure rational drug use, patient care evaluation processes relating to drug utilization and effectiveness, drug delivery device selection and evaluation systems, and educational activities for the safe and appropriate use of drugs which will assess the quality of services and products provided and document actions taken. Policies and procedures as indicated in this chapter shall be written and shall be made available to the board.

(2) Pharmacists. The pharmacist in charge shall be supported by a sufficient number of pharmacists to provide appropriate practice of pharmacy for the patients served by the **long-term care** facility.

(3) **Long-term care** consultant pharmacist. A **long-term care** facility may utilize a consultant pharmacist who may or may not be independent of the pharmacy practice site, who shall provide patient care service which includes, but is not limited to:

- (a) providing consultation on matters pertaining to efficient drug distribution systems, proper drug selection, rational and safe drug use, and drug therapy assessment;
- (b) evaluation of a patient's drug therapy to maximize outcome(s), including effective communication with prescribing practitioners and other healthcare professionals;
- (c) service on committees or governing bodies; and
- (d) providing in service educational programs for members of the healthcare team.

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

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

1140-14-.03 PHYSICAL REQUIREMENTS.

(1) Area. A **long-term care** pharmacy practice site shall have sufficient floor space allocated to it to ensure that medical and prescription orders are prepared and dispensed in sanitary, well lighted, and enclosed spaces. The **long-term care** pharmacy shall also have sufficient counter space or other suitable work module to ensure that medical and prescription orders are prepared and dispensed in an orderly manner.

(2) Equipment and Materials. The pharmacy practice site shall have sufficient equipment and physical facilities for the practice of pharmacy. This shall include but not be limited to:

- (a) hot and cold running water;
- (b) refrigerated storage space;

(c) frozen storage space as appropriate; and

(d) adequate information systems.

(3) Storage. All prescription drugs and devices and related materials shall be stored in designated areas within the pharmacy practice site which are sufficient to ensure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security.

(4) Alcohol and Flammables. Alcohol and flammables shall be stored in an area that shall, at a minimum, meet basic local building code requirements for the storage of volatiles, and such other laws, ordinances, or regulations that may apply.

(5) Security. A pharmacy practice site shall be capable of being locked to prevent access by unauthorized personnel. **If a long-term care pharmacy practice site is located within a long-term care facility, a pharmacist must be accessible within that long-term care facility;** and when no pharmacist is present at the **long-term care facility**, the pharmacy practice site must be kept closed and securely locked except as provided in **1140-14-.11**.

1140-14-.04 PRESCRIPTION ORDERS.

A pharmacist shall review all prescription orders before the drug is first dispensed. In the event that medications available in the **long-term care facility** are ordered and administered before the pharmacist's review, the order shall be reviewed by a pharmacist in a timely manner. The pharmacist shall have access to the patient's medical record. The **prescription** order must be maintained in a readily retrievable manner according to the pharmacy practice site policy.

1140-14-.05 DISTRIBUTION AND CONTROL OF DRUGS.

The pharmacist in charge shall be responsible for approving policies for the distribution and control of drugs within the **long-term care facility**. The process shall be established to provide for the safe and efficient distribution of drugs and for the provision of pharmaceutical care, and shall include but not be limited to:

(1) A drug dispensed from the pharmacy for subsequent administration to a patient shall be appropriately identified with the name and location of the patient and the name and strength of the drug.

(2) The pharmacist in charge is responsible for the development and maintenance of an audit trail on drugs **dispensed and delivered**.

(3) The prescription order shall be recorded on a patient medication profile that will be maintained during the patient's treatment. This profile shall include the

date of the prescription order, the name and dosage form of the drug and the dose and administration frequency.

(4) The **long-term care facility** distribution system may be based on a combination of processes that will ensure compliance with federal and state guidelines such as, **but not limited to**, emergency kits/crash carts, automated dispensing devices, and/or after-hours procedures for pharmacy site access.

1140-14-.06 CONTROLLED DRUGS.

(1) **As permitted by state and federal rules and regulations**, controlled substances (and those drugs deemed by the pharmacist in charge to have a potential for abuse) which are issued as floorstock shall be accounted for by providing documentation of:

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

(2) **As permitted by state and federal rules and regulations**, record of the destruction of controlled substances previously dispensed to or for patients **and returned to the dispensing pharmacy for destruction** shall be maintained so as to be readily retrievable, and such records shall include:

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

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

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

1140-14-.07 EMERGENCY AND HOME CARE KITS.

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

(1) Emergency Kits.

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

1. Emergency kit drugs are those drugs which may be required to meet the therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients.
2. The policies and procedures to implement the requirements of this subsection and to approve the contents of the emergency kit will be determined by the pharmacist in charge or his/her designee.
3. The emergency kit shall be sealed or electronically secured by authorized personnel in accordance with established policies. The expiration date of the kit shall be clearly marked on the exterior of the kit to represent the earliest expiration date of any drug, device, or related materials contained in the kits.
4. Emergency kits shall be stored in a secured area at the **long-term care** facility or patient care site to prevent unauthorized access. To ensure a proper environment for preservation of the drugs contained therein, appropriate policies and procedures shall be written to include storage at the site of patient care.
5. Only authorized individuals may obtain drugs, devices or related materials from the emergency kit in accordance with established policies and state and federal laws and regulations.
6. A list of the emergency kit contents shall be readily accessible and it shall include the drugs, devices, and related materials contained therein and include the name (trade and/or generic), strength, and quantity of the products contained therein.
7. Drugs contained within the emergency kit shall be properly labeled according to the United States Food and Drug Administration (FDA) labeling requirements for the drug or device and with additional information that may be required by the staff to prevent misunderstanding or risk of harm to the patients.
8. Removal of any drug, device, or related material from the emergency kit shall be pursuant to a valid medical or prescription order and must be documented by established policy which may include patients identification, name of the drug, strength, amount, date, time, and identification of the authorized individual removing the drug.

9. When an emergency kit is opened for any reason, the pharmacy practice site shall be notified, and the kit shall be restocked and resealed within a reasonable time so as to prevent risk of harm to patients.

10. A pharmacy technician holding an active registration with the Tennessee Board of Pharmacy and employed by the pharmacy may restock and resealed the emergency kit with items prepared and checked by a pharmacist at the pharmacy.

(2) Home Care Kits.

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

1. A home care kit may contain:

- (i) Sodium Chloride for Injection 0.9% Bacteriostatic
- (ii) Sterile Water for injection Bacteriostatic or Preservative Free
- (iii) Epinephrine injection 1mg/ml
- (iv) Diphenhydramine
- (v) Heparin Flush \leq 100units/ml
- (vi) Naloxone
- (vii) Sodium Chloride for Irrigation
- (viii) Sterile Water for Irrigation
- (ix) Dextrose 50%
- (x) Urokinase 5000units
- (xi) Any other legend drug as approved by the board.

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

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

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

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

1140-14-.08 UNUSED DRUGS, DEVICES, AND RELATED MATERIALS.

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

1140-14-.09 TAKE-HOME AND LEAVE OF ABSENCE DRUGS, DEVICES, AND RELATED MATERIALS.

(1) All prescription drugs prescribed for and **released** to patients who are on leave of absence from the **long-term care** facility must be **released** in accordance with the **long-term care facility's** policies and procedures.

(2) All prescription drugs prescribed for and dispensed to patients who are being discharged from the **long-term care** facility must be dispensed with labeling in accordance with 1140-3-.06.

(3) The pharmacist in charge in coordination with the medical and nursing staff of the facility shall establish policies and procedures to assure that this process meets state and federal guidelines appropriate for the facility.

1140-14-.10 RECALLS.

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

1140-14-.11 ABSENCE OF PHARMACIST.

(1) **Long-term care pharmacy** practice site.

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

(b) After Hours Drug Provision. When a **long-term care** pharmacy practice site is closed, access to prescription drugs shall be by locked cabinet(s), automated dispensing machines or other enclosure(s) constructed and located **within the long-term care facility**, to which only personnel authorized by the pharmacist in charge, in coordination with the medical and nursing staff, may obtain access. Access should be sufficiently secured to deny entry to unauthorized persons by force or otherwise. Those practice sites utilizing automated dispensing devices for after hours drug provision shall meet the requirements of rule 1140-14-.12.

1140-14-.12 AUTOMATED DISPENSING SYSTEMS IN LONG-TERM CARE PRACTICE SITES.

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

(1) Each pharmacy holding an active license with the Tennessee Board of Pharmacy and using automated dispensing systems shall register each automated dispensing device, and its physical location, with the Tennessee Board of Pharmacy. Each pharmacy shall be responsible to pay a registration fee, as defined in 1140-01-.10, for each automated dispensing device, which the licensed pharmacy is responsible for and which is located in a long-term care facility.

(2) The pharmacist in charge of the long-term care pharmacy practice site shall be designated to be accountable for this automated dispensing system.

(a) The filling/stocking of all medications in the automated dispensing system shall be completed by a pharmacist or pharmacy technician under the direct supervision of a pharmacist, except as provided below:

(i) If the automated dispensing system uses removable cartridges or containers to hold drugs, the prepackaging of the cartridges or containers shall occur at the provider pharmacy unless provided by an FDA approved repackager.

(ii) The prepackaged cartridges or containers may be sent to the remote site to be loaded into the machine by personnel designated by the pharmacist-in-charge provided:

(A) a pharmacist verifies the cartridge or container has been properly filled and labeled;

(B) the individual cartridges or containers are transported to the remote site in a secure, tamper-evident container; and

(C) the automated dispensing system uses bar-coding, microchip, or other technologies to ensure that the containers are accurately loaded in the automated dispensing system.

(D) All drugs to be stocked in the automated dispensing system shall be delivered to the remote site by the provider pharmacy.

(b) A record of medications filled/stocked into an automated dispensing system shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.

(c) All containers of medications stored in the automated dispensing system shall be packaged and labeled in accordance with federal and state laws and regulations.

(d) All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.

(e) The automated dispensing system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated dispensing system, all in accordance with existing state and federal law.

(f) The automated dispensing system shall provide a mechanism for securing and accounting for wasted medications or discarded medications in accordance with existing state and federal law.

(g) The pharmacist **in charge** will work collaboratively with healthcare professionals to ensure that appropriate controls and monitors are utilized to provide information that drugs dispensed were for the correct patient and that pilferage is identified and resolved.

(3) All persons authorized to have access to these automated devices shall have documentation that they have successfully completed a training program that teaches them to perform the functions they perform with the automated device.

(4) Automated dispensing systems shall be used only for the furnishing of drugs and devices and related materials or other products related to the care of patients of that **long-term care** facility; and

(5) At the time of removal of any drug or device or related material from the device, it shall automatically make a record, to be retained by the pharmacy for a minimum of two (2) years, indicating:

- (a) the date and time of removal of the drug or device or related material;
- (b) the name, strength, dosage form, and quantity of drugs or devices or related material removed;
- (c) the identification of the patient for whom the drug or device or related material was ordered; and
- (d) the identification of the person authorized to remove the drug or device or related material from the device.

(6) The pharmacist in charge or designee is responsible for determining how access codes or other methods of access to automated devices are assigned.

(7) The facility shall have policies and procedures approved by the pharmacist in charge in coordination with members of the nursing and medical staff for the points outlined in this section for automated dispensing devices.

(8) Nothing in this section shall be interpreted to authorize the stocking of controlled substances in automated dispensing systems, except when done in a manner consistent with federal controlled substance rules and regulations.

(9) The registration fee for each automated dispensing device shall be determined by the Tennessee Board of Pharmacy and listed in 1140-01-.10. The Board shall maintain a list of registered automated dispensing devices, including physical address and number of devices located at each physical address. Registrations for automated dispensing devices must be renewed every two (2) years.

1140-14-.13 INVESTIGATIONAL DRUGS.

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

1140-14-.14 INSPECTIONS.

The pharmacist in charge shall be responsible (personally or by qualified designee) for documented inspections, **at minimum quarterly**, of all drugs, devices and related materials **dispensed by the long-term care pharmacy practice site and delivered to the**

long-term care facility. Records of such inspections shall be dated, signed and maintained so as to be readily retrievable at the pharmacy practice site for at least two (2) years. These inspections must assure the following:

- (1) thermolabile drugs are stored at the proper temperature;
- (2) drugs, devices and related materials requiring special storage conditions to ensure their stability are properly stored;
- (3) there are no outdated or deteriorated drugs, devices or related materials;
- (4) all drugs, devices and related materials are properly labeled;
- (5) emergency drugs, devices and related materials are properly stored; and
- (6) medicine cabinets, carts and storage areas are accessible to authorized personnel only.

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