TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Poplar Room
Nashville, TN
December 18, 2015

BOARD MEMBERS PRESENT
Nina Smothers D.Ph., President
Will Bunch, D.Ph., Vice President
Kevin Eidson, D.Ph.
Joyce McDaniel, Consumer Member
Rissa Pryse, D.Ph.

STAFF PRESENT
Reginald Dilliard, Executive Director
Stefan Cange, Assistant General Counsel
Devin Wells, Deputy General Counsel
Terry Grinder, Pharmacy Investigator

BOARD MEMBERS PRESENT ELECTRONICALLY
R. Michael Dickenson, D.Ph.
Debra Wilson, D.Ph.

The Tennessee Board of Pharmacy convened on Friday, December 18, 2015, in the Poplar Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the rulemaking meeting was called to order at 9:00 a.m.

Rulemaking Hearing

Mr. 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, 1140-02, 1140-03, 1140-04, 1140-05, 1140-07, 1140-08, 1140-09, 1140-11, 1140-13 and 1140-14. Mr. Cange informed the board that some of the changes in rule 1140-11 concern the controlled substance monitoring database and the board doesn't need to vote on those changes since they are commissioner rules and were added for expediency. The statutes which pertain to those rules take effect on January 1, 2016. Pursuant to T.C. A. §4-5-204 the following is a summary on the factual information on which the amended rule contained in the summary are based: adding new definitions, pharmacy practice in long term care setting, license category, recordkeeping requirements, prohibition on offering financial incentives to transfer prescriptions, rule waivers, fee increase and CSMD access fee for law enforcement, pharmacy collaborative practice and language that deals with pilot programs.

Rule(s) (**ALL** chapters and rules contained in filing must be listed. If needed, copy and paste additional tables to accommodate more than one chapter. Please enter only **ONE** Rule Number/Rule Title per row.)

Chapter Number	Chapter Title
1140-01	Introductory Rules
Rule Number	**Rule Title**
1140-01-.01	Definitions

SS-7037 (July 2014) 1 RDA 1693

1140-01-.03	Application for a Pharmacist License
1140-01-.04	Pharmacy Internship
1140-01-.05	Licensing Examinations
1140-01-.07	Inactive Licenses and License Reinstatement
1140-01-.08	Application for Pharmacy Practice Site, Manufacturer, Outsourcing Facility, Oxygen Supplier and Wholesaler/Distributor Licenses
1140-01-.09	Renewal of Licenses
1140-01-.10	Fees
1140-01-.11	Controlled Substance Registration
1140-01-.13	Standards for Pharmacies and Prescription Department Security
1140-01-.15	Prescription Drugs Dispensed by Health Departments
1140-01-.16	Reserved

Chapter Number	**Chapter Title**
1140-02	Professional Conduct and Responsibilities
Rule Number	**Rule Title**
1140-02-.01	Pharmacists and Pharmacy Interns
1140-02-.02	Pharmacy Technicians

Chapter Number	**Chapter Title**
1140-03	Standards of Practice
Rule Number	**Rule Title**
1140-03-.01	Responsibilities of Pharmaceutical Care
1140-03-.02	Locations of Practice
1140-03-.03	Medical and Prescription Orders
1140-03-.04	Facsimile and Electronic Medical and Prescription Orders
1140-03-.06	Labeling Requirements
1140-03-.08	Repacking
1140-03-.10	Conditions for Delivery or Sell
1140-03-.11	Outdated and Deteriorated Drugs
1140-03-.13	Automated Dispensing Devices
1140-03-.14	Pharmacist in Charge
1140-03-.15	Reference Books
1140-03-.16	Automated Dispensing Devices for Pharmacy Practice

Chapter Number	**Chapter Title**
1140-04	Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites
Rule Number	**Rule Title**
1140-04-.02	Personnel
1140-04-.03	Physical Requirements
1140-04-.04	Prescription Orders
1140-04-.05	Distribution and Control of Drugs
1140-04-.06	Medication Carts
1140-04-.07	Floorstock Drugs
1140-04-.08	Controlled Drugs
1140-04-.09	Emergency and Home Care Kits
1140-04-.10	Unused Drugs, Devices, and Related Materials
1140-04-.11	Take-Home and Leave of Absence Drugs, Devices and Related Materials
1140-04-.12	Drugs Brought Into the Facility
1140-04-.14	Absence of Pharmacist
1140-04-.15	Automated Dispensing Devices in Institutional Practice Sites
1140-04-.16	Emergency Rooms
1140-04-.17	Investigational Drugs
1140-04-.18	Monthly Inspections

Chapter Number	**Chapter Title**
1140-05	Continuing Education
Rule Number	**Rule Title**
1140-05-.02	Reporting System

1140-05-.04	Falsification of Records

Chapter Number	**Chapter Title**
1140-07	Sterile Product Preparation in Pharmacy Practice
Rule Number	**Rule Title**
1140-07-.02	Standards
1140-07-.03	Personnel
1140-07-.04	Physical Requirements

Chapter Number	**Chapter Title**
1140-08	Civil Penalties
Rule Number	**Rule Title**
1140-08-.01	Civil Penalties

Chapter Number	**Chapter Title**
1140-09	Manufacturers, Outsourcing Facilities, Oxygen Suppliers and Wholesalers/Distributors
Rule Number	**Rule Title**
1140-09-.01	Manufacturer, Outsourcing Facility, Oxygen Supplier and Wholesaler/Distributor Licensing
1140-09-.02	Minimum Information Required
1140-09-.03	Minimum Qualifications
1140-09-.05	Minimum Requirements for General Operation

Chapter Number	**Chapter Title**
1140-11	Controlled Substance Monitoring Database
Rule Number	**Rule Title**
1140-11-.01	Definitions
1140-11-.02	Access to Database
1140-11-.04	Submission of Information

Chapter Number	**Chapter Title**
1140-13	Telepharmacy
Rule Number	**Rule Title**
1140-13-.02	Licensing and Renewal

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to http://state.tn.us/sos/rules/1360/1360.htm)

Chapter 1140-01
Introductory Rules

Amendments

Rule 1140-01-.01 Definitions is amended by deleting paragraph (1) in its entirety and substituting the following language, and adding new paragraphs (4), (21), (22) and (23), and is further amended by deleting newly-numbered paragraph (19) in its entirety and substituting instead the following language, so that as amended the new paragraphs shall read:

(1) "ACPE" means the Accreditation Council for 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.

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

(a) hospital and associated clinics;

(b) developmental disability center;

(c) inpatient psychiatric center;

(d) sub-acute care facility; and

(e) university health center.

(21) "Long term care pharmacy practice site" means a pharmacy practice site serving patients within a long term care facility.

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

(a) nursing home

(b) hospice or residential hospice; and

(c) assisted living facility.

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

Authority: T.C.A. §§ 63-10-101, 63-10-102, 6-10-204, 63-10-214, and 63-10-304.

1140-01-.03 Application for a Pharmacist License is amended by deleting paragraphs (2) and (3) in their entirety and substituting instead the following language, and is further amended by adding new paragraph (7), so that as amended, the new paragraphs shall read:

(2) For the purpose of *T.C.A. § 63-10-306(d),* a "recognized" college or school of pharmacy is a college or school of pharmacy which meets the minimum standards of the ACPE and appears in the ACPE "Annual Directory of Accredited Professional Programs of Colleges and Schools of Pharmacy."

(3) No applicant shall be eligible for a license if the applicant has engaged in conduct or suffers a condition which would constitute grounds for revocation or suspension of a license under *T.C.A. § 63-10-305*, unless the applicant can show cause why a license should be issued.

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

Authority: T.C.A. §§ 63-10-101, 63-1-116, 63-10-202, 63-10-204, 63-10-304, 63-10-306, and 63-10-308.

1140-01-.04 Pharmacy Internship is amended by adding new subparagraph (1)(d), so that as amended, the new subparagraph shall read:

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

Authority: T.C.A. §§ 63-10-101, 63-10-102, 63-10-202, 63-10-204, and 63-10-304.

1140-01-.05 Licensing Examinations is amended by deleting paragraph (2) in its entirety and substituting instead the following language, and is further amended by adding new paragraph (5), so that as amended, the new paragraphs shall read:

(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.

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

Authority: T.C.A. §§ 63-10-304 and 63-10-306.

1140-01-.07 Inactive Licenses and License Reinstatement is amended by adding new subparagraph (3)(f), so that as amended, the new rule authority shall read:

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

Authority: T.C.A. §§ 63-10-204, 63-10-304, and 63-10-306.

1140-01-.08 Application for Pharmacy Practice Site, Manufacturer, Outsourcing Facility, Oxygen Supplier and Wholesaler/Distributor Licenses is amended by deleting parts (3)(a)5 and (3)(b)2 in their entirety and substituting instead the following language, and is further amended by adding new paragraph (8), so that as amended, the new parts and paragraph shall read:

(a) 5. Maintain records of prescription orders dispensed to and/or of medication assessments provided to persons residing in Tennessee.

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

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

Tenn. Code Ann. Title 4, Chapter 5.

Authority: T.C.A. §§ 53-11-301, 53-14-104, 53-14-106, 53-14-107, 63-10-203, 63-10-204, 63-10-304, and 63-10-308.

1140-01-.09 Renewal of Licenses is amended by adding new paragraph (3), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 53-11-301, 53-11-302, 63-10-204, 63-10-304, and 63-10-308.

1140-01-.10 Fees is amended by adding new paragraphs (17), (18), and (19), so that as amended, the new paragraphs shall read:

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

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

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

Authority: T.C.A. §§ 4-5-202, 63-10-204, 63-10-216, 63-10-304, and 63-10-308.

1140-01-.13 Standards for Pharmacies and Prescription Department Security is amended by deleting paragraph (3) and only part (3)(g)2 in their entirety and substituting instead the following language, so that as amended the new paragraph and part shall read:

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

2. The pharmacist in charge shall place a key or other access device in a sealed device or vault in a secured place outside of the department. The key or access device may be used to allow emergency entrance to the department. A signature log of persons accessing the pharmacy department using the key or other access device must be maintained on the premises of that pharmacy practice site.

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-01-.15 Prescription Drugs Dispensed by Health Departments is amended by deleting the rule in its entirety, including the rule title, and renumbering the remaining rule.

Authority: T.C.A. §§ 63-10-204, 63-10-205, and 63-10-304.

Newly numbered Rule 1140-01-.15 Reserved is amended by deleting the rule, including its title, in its entirety, and substituting instead the following language, so that as amended, the new rule and new rule title shall read:

1140-01-.15 Pilot Programs.

A licensee of the Board who wishes to undertake a temporary pilot program for the purpose of studying or investigating the impact of a public health initiative, or who wishes to address a recognized health emergency or crisis in the State shall submit a written application for such program to the executive director on a form approved by the Board, who may present such application to the Board for approval. The Board may authorize such a program to take place for a predetermined, temporary amount of time. A program authorized pursuant to this part

may deviate from the board's rules if the Board determines such deviation is crucial to the proposed program and in the best interest of the public health, safety and welfare.

Authority: T.C.A. §§ 63-10-301, 63-10-304, 63-10-305, and 63-10-308.

Chapter 1140-02
Professional Conduct and Responsibilities

Amendments

Rule 1140-02-.01 Pharmacists and Pharmacy Interns is amended by adding new paragraph (18) and renumbering the remaining paragraph, so that as amended the new paragraph shall read:

(18) A pharmacist shall not offer, participate in, or condone the use of pecuniary incentives as a means to encourage a patient or a prospective patient to transfer prescriptions.

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-02-.02 Pharmacy Technicians is amended by deleting paragraph (4), subparagraph (5)(c) in their entirety and substituting instead the following language, and is further amended by adding new paragraph (13), so that as amended the new paragraph and subparagraph shall read:

(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.

(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.

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

Authority: T.C.A. §§ 63-1-116, 63-10-204, 63-10-304, 63-10-306, and 63-10-308.

1140-03
Standards of Practice

Amendments

Rule 1140-03-.01 Responsibilities for Pharmaceutical Care is amended by subparagraph (1)(d) and part (4)(a)1 in their entirety and substituting instead the following language, and is further amended by inserting new part (4)(a)4, so that as amended the new subparagraph and parts shall read:

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

1. Developing a working and collaborative relationship 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

4. Where formally defined, providing patient care services consistent with a collaborative pharmacy practice agreement.

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-03-.02 Locations of Practice is amended by deleting the rule, but not the rule title, in its entirety and substituting instead the following language, so that as amended, the new rule shall read:

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 so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-03-.03 Medical and Prescription Orders is amended by deleting subpart (7)(b)3(i), subparagraph (7)(e), and paragraph (9) in their entirety and substituting instead the following language, so that as amended the new subpart, subparagraph, and paragraph shall read:

(i) Date the order was originally issued and dispensed;

(e) The transfer of schedule III, IV, V, controlled substances are subject to the conditions set forth in C.F.R. 1306.25.

(9) Medical and prescription orders cannot be accepted, solicited, collected or advertised at any location other than a pharmacy practice site for which a license has been issued by the Board, and such pharmacy practice site shall be actively engaged in compounding and dispensing medical and prescription orders. An entity or other non-licensed site which does not dispense drugs directly to patients may accept, solicit, and collect prescriptions for the purpose of medication therapy management or other consultative services related to drug therapy and patient care.

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-03-.04 Facsimile and Electronic Medical and Prescription Orders is amended by deleting subparagraphs (2)(b), (2)(c), (2)(d), (2)(e), and (2)(f) in their entirety, and substituting instead the following language, so that as amended the new subparagraphs shall read:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-03-.06 Labeling Requirements is amended by deleting the rule, but not the rule title, in its entirety and substituting instead the following language, so that as amended the new rule shall read:

The dispensing label for a medical or prescription order shall bear at least the following information: name and address and telephone number of pharmacy practice site; the medical or prescription order serial number, name

of prescriber; name of patient; directions for use; date medical or prescription order originally dispensed, and/or refill date; "poison", "shake", "caution", or other appropriate advisory label; name of product (unless otherwise required by the prescriber); and expiration date of the product (if applicable). This rule shall not apply to medical and prescription orders dispensed by an institutional pharmacy for administration to inpatients of that institution. Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-03-.08 Repackaging is amended by adding new paragraph (5), so that as amended the new paragraph and shall read:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-03-.10 Conditions for Delivery or Sell is amended by adding paragraphs (3) and (4), so that as amended the new paragraphs shall read:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-03-.11 Outdated and Deteriorated Drugs is amended by deleting the rule, but not its rule title, in its entirety and substituting instead the following language, so that as amended, the new rule shall read:

The owner or pharmacist in charge of a pharmacy practice site shall immediately return or destroy all outdated, defective, or deteriorated prescription drugs and devices and related materials; except that the destruction of controlled substances listed in any schedule shall be performed by a Board approved agent or vendor. Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-03-.13 Automated Dispensing Devices is amended by deleting paragraph (3) in its entirety and substituting instead the following language, so that as amended, the new paragraph shall read:

(3) Lot numbers may not be mixed and shall be tracked and stored by the automated device.

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-03-.14 Pharmacist in Charge is amended by deleting paragraph (2), but not its subparagraphs, and substituting instead the following language and is further amended by adding new paragraph (15), so that as amended, the new paragraphs shall read:

(2) It shall be the responsibility of the person, partnership, firm, or corporation holding a pharmacy practice site license issued pursuant to T.C.A. § 63-10-506 306 to notify the Board immediately of:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-03-.15 Reference Books is amended by deleting the rule, but not its title, in its entirety and substituting instead the following language, so that as amended, the new rule shall read:

Each pharmacy practice site shall maintain an adequate reference library (printed or electronic) consistent with its scope of practice. The reference library shall include a current edition of the Tennessee Pharmacy Laws issued by the Tennessee Board of Pharmacy and may include current material regarding the technical, clinical, and professional components of the practice of pharmacy, with particular emphasis in the area in which the pharmacy specializes. Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: T.C.A. § 63-10-304.

Rule 1140-03-.16 Automated Dispensing Devices for Pharmacy Practice is amended by deleting the rule title, but not the rule language, in its entirety, and substituting the following language, so that as amended the new rule title shall read:

1140-03-.16 Centralized Prescription Processing.

Authority: T.C.A. § 63-10-304.

Chapter 1140-04
Institutional and Alternate or Alternative Infusion Pharmacy Practice Sites

Amendments

Rule 1140-04-.02 Personnel is amended by deleting paragraph (1) in its entirety and substituting instead the following language, so that as amended, the new paragraph and new rule authority shall read:

(1) Pharmacist in charge. The practice of pharmacy and the performance of 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, 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.

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-04-.03 Physical Requirements is deleted by adding new paragraph (6), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-04-.04 Prescription Orders is amended by adding new paragraph (2), so that as amended, the new paragraph shall read:

(2) Upon request, the Board may waive selected portions of these requirements so long as any waiver

granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-04-.05 Distribution and Control of Drugs is amended by adding new paragraph (5), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-04-.06 Medication Carts is amended by adding new paragraph (2), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-04-.07 Floorstock Drugs is amended by adding new paragraph (2), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-04-.08 Controlled Drugs is amended by adding new paragraph (5), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 53-11-302, 63-10-204, and 63-10-304.

Rule 1140-04-.09 Emergency and Home Care Kits is amended by adding new paragraph (3), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. § 63-10-304.

Rule 1140-04-.10 Unused Drugs, Devices, and Related Materials is amended by adding new paragraph (2), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-04-.11 Take-Home and Leave of Absence Drugs, Devices, and Related Materials is amended by adding new paragraph (4), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-04-.12 Drugs Brought Into the Facility is amended adding new paragraph (5), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-04-.14 Absence of Pharmacist is amended by deleting part (1)(c)2 in its entirety an substituting instead the following language, so that as amended, the new part shall read:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-04-.15 Automated Dispensing Devices in Institutional Practice Sites is amended by deleting the rule title in its entirety and substituting instead the following language, and is further amended by adding new paragraph (7), so that as amended, the new rule title and paragraph shall read:

1140-04-.15 Automated Dispensing Systems.

(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.

1. 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 off-campus site to be loaded into the machine by personnel designated by the pharmacist-in-charge provided:

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

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

(III) the automated dispensing system uses bar-coding, microchip, or other

technologies to ensure that the containers are accurately loaded in the automated dispensing system;

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

2. 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.

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

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

5. 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.

6. 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.

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-04-.16 Emergency Rooms is amended by adding new paragraph (2), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-04-.17 Investigational Drugs is amended by adding new paragraph (2), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-04-.18 Monthly Inspections is amended by adding new paragraph (13), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Chapter 1140-05
Continuing Education

Amendments

Rule 1140-05-.02 Reporting System is amended by adding new paragraph (5) and is further amended by deleting the existing rule authority and substituting instead the following language, so that as amended, the new paragraph and new rule authority shall read:

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

Authority: T.C.A. §§ 63-10-304 and 63-10-306.

Rule 1140-05-.04 Falsification of Records is amended is by deleting the rule, but not its rule title, in its entirety and substituting instead the following language, so that as amended, the new rule shall read:

Any pharmacist who alters, forges, or falsifies, or causes to be altered, forged, or falsified any information, documents, or records required to be kept or submitted by this Chapter shall be subject to disciplinary action by the Board under T.C.A. § 63-10-305(6).

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Chapter 1140-07
Sterile Product Preparation in Pharmacy Practice

Amendments

Rule 1140-07-.02 Standards is amended by adding new paragraph (7), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304 and 63-10-306.

Rule 1140-07-.03 Personnel is amended by adding new paragraph (7), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-07-.04 Physical Requirements is amended by adding new paragraph (2), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304 and 63-10-306.

Rule Chapter 1140-08
Civil Penalties

Amendments

Rule 1140-08-.01 Civil Penalties is amended by deleting paragraph (1) in its entirety and substituting instead the following language, so that as amended, the new paragraph shall read:

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

Violation	Penalty
T.C.A., Section 63 10 305(1)	$0 - $1000
T.C.A., Section 63 10 305(2)	$0 - $1000
T.C.A., Section 63 10 305(3)	$0 - $1000
T.C.A., Section 63 10 305(4)	$0 - $1000
T.C.A., Section 63 10 305(5)	$0 - $1000
T.C.A., Section 63 10 305(6)	$0 - $1000
T.C.A., Section 63 10 305(7)	$0 - $1000
T.C.A., Section 63 10 305(8)	$0 - $1000

Authority: T.C.A. §§ 63-10-304 and 63-10-305.

Rule Chapter 1140-09
Manufacturers, Outsourcing Facilities, Oxygen Suppliers and Wholesalers/Distributors

Amendments

Rule 1140-09-.01 Manufacturer, Outsourcing Facility, Oxygen Supplier and Wholesaler/Distributor Licensing is amended by adding new paragraph (4), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-204, 63-10-304, and 63-10-306.

Rule 1140-09-.02 Minimum Information Required is amended by adding new paragraph (5), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-204, 63-10-304, and 63-10-306.

Rule 1140-09-.03 Minimum Qualifications is amended by adding new paragraph (3), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Rule 1140-09-.05 Minimum Requirements for General Operation is amended by adding new paragraph (11), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-204 and 63-10-304.

Chapter 1140-11
Controlled Substance Monitoring Database

Amendments

Rule 1140-11-.01 Definitions is amended by inserting new subparagraph (1)(a) and renumbering the remaining subparagraphs, and is further amended by deleting the existing rule authority and substituting instead the following language, so that as amended, the new subparagraph and new rule authority shall read:

(a) "ARCOS" (the "Automation of Reports and Consolidated Orders System") is an automated, comprehensive drug reporting system, created pursuant to 21 U.S.C. § 827 and administered by the United States Drug Enforcement Administration, which monitors the flow of controlled substances from the point of manufacture, through commercial distribution channels, to the point of distribution or sale at the dispensing or retail level.

Authority: T.C.A. §§ 53-10-302 and 53-10-303.

Rule 1140-11-.04 Submission of Information is amended by deleting paragraph (2) in its entirety and substituting instead the following language, so that as amended, the new paragraph (2) shall read:

(2) Prior to January 1, 2016, The information in the database, as required by paragraph one (1) above, shall be submitted at least once every seven (7) days for all controlled substances dispensed during the preceding seven (7) day period. Information submitted after January 1, 2016, with the exception of information reported by veterinarians, shall be submitted for each business day but no later than the close of business on the following day.

Authority: T.C.A. §§ 53-10-303, 53-10-304 and 53-10-305.

Chapter 1140-13
Telepharmacy

Amendments

Chapter 1140-13 Telepharmacy is amended by deleting the chapter title in its entirety and substituting instead the following language, so that as amended, the new chapter title shall read:

Chapter 1140-13 Pharmacy Practice in Federally Qualified Health Centers

Authority: T.C.A. §§ 63-10-601 and 63-10-602.

Rule 1140-13-.02 Licensing and Renewal is amended inserting new paragraph (4), so that as amended, the new paragraph shall read:

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

Authority: T.C.A. §§ 63-10-601 and 63-10-602.

Chapter 1140-03
Standards of Practice

New Rule
1140-03-.17
Collaborative Pharmacy Practice

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1140-03-.17 – Collaborative Pharmacy Practice.

(1) Definitions—In addition to the definitions contained in Tenn. Code Ann. Title 63, Chapter 10, Part 2, the following definitions are applicable to collaborative pharmacy practice:

(a) "Active practice", for purposes of the qualifications of a pharmacist under (4)(b) of this rule, means engagement in paid, unpaid, or volunteer activity which requires a pharmacist's license under Tennessee law, for at least 2,000 hours within the 24-month period immediately preceding the date of the agreement. "Active practice" is not limited to direct patient care and includes supervisory, educational or consultative activities or responsibilities for the delivery of such services.

(b) "Agreement" means the collaborative pharmacy practice agreement.

(c) "Authorizing physician" means a medical doctor or osteopathic physician with an unencumbered Tennessee license who has a direct provider/ patient relationship with the patients served under a collaborative pharmacy practice agreement or who is the supervising physician of an advanced practice nurse or physician assistant who has such direct relationship or who, in the case of a multi-specialty practice, is the representative or chief responsible for particular specialty care within that multi-specialty practice recognized and certified by the American Board of Medical Specialties (hereinafter "ABMS") or the American Osteopathic Association Bureau of Osteopathic Specialists (hereinafter "AOABOS").

(d) "Collaborating prescriber" means the physician, advanced practice nurse or physician assistant who is a party to a collaborative pharmacy practice agreement, who has a direct provider/ patient relationship with the patient served by the agreement and who has prepared the patient specific, drug specific, disease or condition specific plan of care based on a physical examination of the patient where required under these rules.

(e) "Hospice patient" means an individual who has been diagnosed as terminally ill, has been certified in writing by a physician to have an anticipated life expectancy of six (6) months or less and who has voluntarily requested admission to, and been accepted by, a licensed hospice as defined in T.C.A. § 68-11-201.

(f) "Institutional-based pharmacy setting" means a pharmacy located within a hospital or nursing home as defined in T.C.A. § 68-11-201 or an academic health care institution and where the pharmacist is physically present in the facility when exercising prescriptive practices under the terms of a collaborative agreement.

(g) "Patient Care Services" means services rendered by physicians and members of the healthcare profession under their supervision, including advanced practice nurses, physician assistants and pharmacists for the benefit of the patient and which must be within the professional training and experience of the healthcare practitioner and be covered by the collaborative pharmacy practice agreement.

(h) "Routine scope of practice and services" means any patient care service provided by the authorizing physician and their practice in compliance with the respective applicable licensing board's laws, rules, policies and procedures. In addition, the services to be provided by the pharmacist shall be services that the authorizing physician generally provides to his or her patients in the normal course of his or her clinical medical practice. The pharmacist should only provide services to the patients whom the authorizing physician or collaborating prescriber routinely treats in the course of his or her clinical medical practice.

(i) "Unencumbered", for the purpose of this rule, means an active license that is not revoked, suspended or on probation at the time and is not subject to any conditions, restrictions, or limitations imposed by the applicable licensing board, which relate directly to the delivery of health care services. A condition, restriction or limitation directly relates to the delivery of health care services when it prevents a provider from treating certain types of patients or certain types of ailments or injuries, or otherwise limits a provider from fully engaging in the practice which would otherwise be authorized pursuant to his or her license.

(2) Physicians, advanced practice nurses and physician assistants may only engage in collaborative pharmacy practice agreements with pharmacists when an appropriately executed collaborative pharmacy practice agreement has been executed and a written attestation has been filed with the licensing boards for all practitioners participating in the agreement notifying those boards of the existence of such agreement; when the patient or the patient's authorized representative has signed an informed consent that is made a part of the patient record; and in accordance with the authorized care and services contained in the agreement.

(a) Any pharmacist who is a participant in a collaborative pharmacy practice agreement must be provided a copy of said agreement by the director of pharmacy, pharmacist-in-charge, or designated pharmacist in a group.

(b) The written attestation shall include the names of all signatories and practitioners participating in the collaborative pharmacy practice agreement, the date of the Agreement and a description of the scope of the services covered by the Agreement.

(c) In the event that an advanced practice nurse or physician assistant is a party to a collaborative pharmacy practice agreement, the physician with responsibility for supervision and control of that advanced practice nurse or physician assistant must approve and sign the Agreement.

(d) In addition, for those Agreements not involving the institutional-based pharmacy setting, the written attestation shall include a formulary of the categories of drugs and services authorized by the Agreement. The written attestation must be provided to the appropriate licensing boards of the signatories no later than thirty (30) days following the effective date of the Agreement.

(3) No physician, advanced practice nurse, physician assistant or pharmacist may engage in a collaborative pharmacy practice agreement unless each collaborating provider holds an active, unencumbered license in Tennessee and possesses at least one million dollars ($1,000,000) in professional liability insurance coverage per occurrence.

(4) In addition to the other requirements of these rules, a pharmacist must meet one of the following qualifications in order to engage in a collaborative pharmacy practice agreement:

(a) Has been awarded a doctor of pharmacy degree from a program accredited by the Accreditation Council for Pharmacy Education; or

(b) Has been awarded a bachelor of science in pharmacy and been in the continuous, active practice of pharmacy.

(5) Each collaborative pharmacy practice agreement ("Agreement") shall contain the following elements, at a minimum:

(a) Names and Titles of Collaborating Providers. The agreement must contain identification of all pharmacists and all physicians and other prescribers (collectively, "collaborating providers") who

are parties to the Agreement. The Agreement shall state the procedure to be followed to indicate changes in the members of the group(s) participating in the Agreement. Unless expressly stated in the Agreement, changes to the list of collaborating providers bound by the Agreement shall not automatically void the Agreement. When the Agreement involves a group or groups of practitioners, the chief medical officer or medical director, where applicable, and the director of pharmacy or pharmacist-in-charge shall sign the Agreement, and the Agreement shall identify all collaborating providers in one or more addendums. In the case of a healthcare institution with an organized medical staff or a multi-specialty group with more than one ABMS or AOABOS recognized physician specialty, the signature of the authorizing physician representing or responsible for that specialty unit will suffice. Nevertheless, each collaborating provider must affirm understanding and acceptance of the terms of the Agreement by signing an addendum to the Agreement within thirty (30) days of the effective date of the agreement (or within thirty days of employment or association with such multi-specialty group) and all members of the medical staff or group must be provided a copy of the collaborative agreement within fifteen (15) days of execution, with a copy also made available via online access. Signatures may be handwritten, electronic, or any other method authorized by the Board of Pharmacy and the respective licensing board of the signatory.

(b) Authorized Care and Services. The Agreement must contain a provision defining the nature and scope of patient care services and activities, including screening, prevention, assessment, management, and care, authorized or restricted to be provided by the pharmacist(s) under the collaborative pharmacy practice agreement. All care and services authorized to be provided shall be within the routine scope of practice and services delivered by the authorizing physician and the advanced practice nurse or physician assistant, where applicable. All care and services provided, except immunizations, opioid antagonists, and preventive care, must be pursuant to a diagnosis appropriately made and documented by the physician, advanced practice nurse or physician assistant. An Agreement which grants the collaborating pharmacist prescriptive authority, including authority for initiation and discontinuance of drug therapy, must be specifically authorized in the authorized care and services portion of the Agreement and must contain a listing of the drugs or categories of drugs that may be prescribed by the collaborating pharmacist under the terms of the Agreement.

(c) Documentation and Communication. Any patient care services provided by a pharmacist or pharmacists pursuant to a collaborative pharmacy practice agreement will be documented in a patient record accessible by the pharmacist(s) and the collaborating prescriber(s) or communicated in writing to the collaborating prescriber or prescribers within three (3) business days of the service. The Agreement shall describe the methods for maintenance and access to the records by the pharmacist(s) and the prescriber(s), for documentation of services performed pursuant to the Agreement and for communication and feedback between the pharmacist(s) and the collaborating prescriber(s). All such records shall be maintained by the collaborating prescriber(s) and pharmacist(s) for a period of not less than ten (10) years from the date of the last patient contact.

(d) Override Clause. A provision must be included in the Agreement allowing the collaborating prescriber to override the actions taken by the collaborating pharmacist specific to services provided under the Agreement if he or she determines that the override is essential to the optimal health outcomes of the patient, and stating how such overrides shall be documented and communicated to the collaborating pharmacist and the patient in a timely manner, as defined in the agreement.

(e) Expiration, Modification and Termination. The effective date of the Agreement shall be stated in the Agreement. Each agreement must contain a term or expiration date, upon which the agreement will expire if not renewed; however, in any event, all Agreements must be reviewed and updated at least every two (2) years as evidenced by signatures of the parties. Every Agreement must contain a provision stating the process for modification or termination of the agreement by either party. This process shall include written notification to all affected parties when modification or termination is sought. An Agreement may be amended upon mutual approval by the collaborating prescriber, authorizing physician (where applicable) and pharmacist who have been duly authorized to execute, modify, or change the Agreement. Such amendments shall include, at a minimum, a description of the desired change and the effective date of the change. Additional prescriber(s) and additional pharmacist(s) may be added to an existing

participating group through an addendum without affecting the effective date of the agreement. Any amendment executed shall not automatically void the terms and conditions of the existing Agreement unless expressly stated. Amendments to the authorized care and services not involving an institutional-based pharmacy setting which institute substantive additions or reductions to the scope of patient care services provided under the agreement including new therapeutic classes of drugs to the authorized formulary must be provided to the appropriate licensing boards no later than thirty (30) days from the effective date of the amendment.

(f) Automatic Exclusions. A provision must be included in the Agreement which identifies any terms under which a provider will be automatically excluded from participation in the Agreement, which may include but need not be limited to death, suspension, surrender, revocation, or retirement of license; loss or restriction of prescriptive authority; the suspension or revocation of a Drug Enforcement Administration registration; exclusion from any federally-funded health programs, or the formal termination of the supervising relationship between an advanced nurse practitioner or physician assistant and his or her supervising physician. Any Agreement involving an advanced practice nurse or physician assistant participating in a collaborative pharmacy practice agreement shall contain a procedure for immediate notification to the collaborating pharmacist(s) if that supervisory relationship is terminated for any reason.

(g) Quality Assessment. The authorizing physician(s) and pharmacist(s) shall create written measurable and objective performance goals for evaluating the quality of care provided for the patients treated pursuant to the Agreement. The Agreement must provide for such goals and data to be aggregated and reviewed by the participants to the Agreement at least quarterly. Such quarterly review shall include consideration of any changes necessary to the Agreement, authorized formulary, and patient orders, in addition to strategies regarding patient education and medication adherence, increased or improved monitoring of side effects and the need for further screening/ testing. The Agreement shall also provide at a minimum for monthly patient record review by the authorizing physician(s) of at least five per cent (5%) of the patients treated pursuant to the Agreement. The quality assessment review shall be properly documented, retained by the participating parties of the Agreement, and available for review by representatives of the various licensing boards for at least ten (10) years.

(6) The scope of a collaborative pharmacy practice agreement shall NOT include:

(a) Any patient of the collaborating prescriber for whom such collaborating prescriber has not prepared a patient specific, drug specific, disease or condition specific plan of care based on a physical examination of the patient by the collaborating prescriber, with the exception of immunizations and screening/testing which do not require such patient-specific plans, as well as the dispensing of opioid antagonists as defined in T.C.A. § 63-1-152, which require neither a physical examination nor a patient-specific plan;

(b) The management of controlled substances, except by a pharmacist practicing within an institutional-based pharmacy setting or for hospice patients.

(7) A copy of the Agreement, including any addendum, modification or termination shall be accessible at each practice site and shall be made available to the applicable regulatory board for review upon request.

(8) Pharmacists engaging in the collaborative pharmacy practice must utilize an area for in-person, telephonic or other approved consultations with patients that ensures the confidentiality of the communication.

(9) Physicians, advanced practice nurses and physician assistants engaged in a collaborative pharmacy practice agreement shall:

(a) Retain professional responsibility to his/ her patients for the management of their drug therapy;

(b) Establish and maintain a physician-patient relationship with each patient subject to the collaborative pharmacy practice agreement;

(c) Be available at all times through direct telecommunication for consultation, assistance and direction, or shall make arrangements for a substitute physician to be available.

(10) Any pharmacist issuing a prescription order, as defined in T.C.A. §63-10-204(38), or medical order, as defined in T.C.A. §63-10-204 (21), pursuant to an Agreement shall issue the prescription order or medical order in accordance with the requirements set forth in Tenn. Comp. Rules and Regs.1140-03-.03 and within the terms set forth in the collaborative pharmacy practice agreement

(11) All collaborative pharmacy practice agreements authorizing pharmacists to provide services and activities shall include language that ensures compliance with all applicable by-laws, policies, and procedures of that facility.

(12) For patient care services performed by a pharmacist and authorized only pursuant to a collaborative pharmacy practice agreement, the Board of Pharmacy expressly adopts the guidelines, rules, and standards of practice of the Board of Medical Examiners, Board of Osteopathic Examiners, or other Tennessee Health Related Boards, as applicable.

(13) Pharmacists engaged in the collaborative pharmacy practice are strongly encouraged to complete ten (10) hours of the biennially required thirty (30) hours of continuing education in topics related to the clinical practice of pharmacy.

(14) All signatories and other parties engaging in a collaborative pharmacy practice shall be subject to disciplinary action by their licensing boards if the licensee violates the terms of these rules or the terms of the collaborative pharmacy practice agreement. Each board with jurisdiction over any of the signatories to the agreement shall report to the other appropriate board any conduct which it believes to be in violation of any such agreement.

(15) Pharmacists who hold a current federal drug enforcement administration ("DEA") license must complete a minimum of two (2) hours biennially of continuing education related to controlled substance prescribing, which must include instruction in the Department's treatment guidelines on opioids and chronic pain and may include such other topics as medicine addiction, risk management tools, and other topics as approved by the Board of Pharmacy. Such continuing education hours shall be counted toward the pharmacist's mandatory continuing education requirement.

Authority: T.C.A. §§ 63-10-217, 63-10-304, and 63-10-306.

Chapter 1140-11
Controlled Substance Monitoring Database

New Rules
1140-11-.08 Minimum Reporting Requirements for Wholesalers and Manufacturers
1140-11-.03 Fees

1140-11-.01 Definitions
1140-11-.02 Access to Database
1140-11-.03 Fees
1140-11-.04 Alternative Identification of Patients
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1140-11-.06 Practice Sites – Electronic Access
1140-11-.07 Prescriber and Dispenser Responsibilities
1140-11-.08 Minimum Reporting Requirements for Wholesalers and Manufacturers

1140-11-.03 Fees.

(1) A fee of twenty-two dollars and fifty cents ($22.50) shall be paid to the Board for each request from law enforcement processed by Committee staff, unless an alternative arrangement has been agreed to.

(2) A fee of twenty-two dollars and fifty cents ($22.50) shall be paid to the Board for each request from any judge of a participating drug court pursuant to T.C.A. § 53-10-306 processed by Committee staff, unless an alternative arrangement has been agreed to.

Authority: T.C.A. §§ 53-10-303 and 53-10-306.

1140-11-.07 Minimum Reporting Requirements for Wholesalers and Manufacturers.

(1) Wholesalers and manufacturers, as defined in T.C.A. § 63-10-204, shall submit a report of all wholesales and distributions of controlled substances at least once every month and no later than 45 days after the earliest transaction being reported.

(a) Any report submitted pursuant to this rule shall be in the ARCOS format, as specified in the most current version of the "Instructions for Reporting Wholesale Transactions" document, which will be made freely available on the Board of Pharmacy's website or the Controlled Substance Monitoring Database's website.

(b) Any report submitted pursuant to this rule shall be sent to the database or email address specified in the "Instructions for Reporting Wholesale Transactions" document.

(c) Any entity exempt from reporting to the Drug Enforcement Administration pursuant to 21 C.F.R. § 1304.33 shall not be required to submit reports of wholesales and distributions of controlled substances pursuant to this rule.

Authority: T.C.A. § 53-10-312.

New Chapter 1140-14

Long Term-Care Pharmacy Practice Sites

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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.

Authority: T.C.A. §§ 6-10-204(21) and (22), 63-10-304.

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.

Authority: T.C.A. § 63-10-304.

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.

Authority: T.C.A. § 63-10-304.

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.

If a patient residing in a long-term care facility has an existing prescription order for a controlled substance, and a valid prescription is needed from the prescriber to continue that order, a fax or electronic communication containing the required information listed in 1140-03-.03 (4)(a) may be generated by a pharmacist, or pharmacy technician working under the direct supervision of a pharmacist, and communicated to the prescriber. Upon receipt of the communication, the prescriber may complete the prescription order by indicating the name of the patient, name and signature of the prescriber, drug, quantity, and date. The completed prescription order may then be faxed or electronically communicated to the long-term care pharmacy practice site. When received by the long-term care pharmacy practice site, this signed fax or electronic communication shall be considered a valid prescription order.

Authority: T.C.A. § 63-10-304

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.

Authority: T.C.A. § 63-10-304.

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 the 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.

Authority: T.C.A. § 63-10-304.

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 patient's 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 reseal 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 <or = 100units/ml

(vi) Naloxone

(vii) Sodium Chloride for Irrigation

(viii) Sterile Water for Irrigation

(ix) Dextrose 50%

(x) Urokinase 5000units

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

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

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

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

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

patients.

Authority: T.C.A. § 63-10-304.

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.

Authority: T.C.A. § 63-10-304.

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.

Authority: T.C.A. § 63-10-304.

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.

Authority: T.C.A. § 63-10-304.

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.

Authority: T.C.A. § 63-10-304.

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:

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

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

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

(IV) 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.

Authority: T.C.A. § 63-10-304.

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.

Authority: T.C.A. § 63-10-304.

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.

Authority: T.C.A. § 63-10-304.

From the comments received the board made the following changes:

Dr. Eidson made the motion to change the wording in board rule 1140-01-.01 (4) from Automated Dispensing Device to Automated Dispensing System and board rule 1140-04-.15 (7)(a) to state t"Each pharmacy holding an active license with the Tennessee Board of Pharmacy and using automated dispensing systems shall register its automated dispensing system, and provide the physicial location for each automated dispensing device used within the automated dispensing system, 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 system and (d) to state "The registration fee for each automated dispensing system 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 systems, including phsyical address and number of all automated dispensing devices located at each physicial address. Regsitrations for automated dispensing systems msut be renewed every two (2) years. Dr. Bunch seconded the motion. The motion carried.

Dr. Eidson made the motion to accept the changes to board rule 1140-14-.12 (1) to state "Each pharmacy holding an active license with the Tennessee Board of Pharmacy and using automated dispensing systems shall register its automated dispensing system, and provide the physicial location for each automated dispensing device used within the automated dispensing system, 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 system and (9) to state "The registration fee for each automated dispensing system 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 systems, including phsyical address and number of all automated dispensing devices located at each physicial address. Regsitrations for automated dispensing systems msut be renewed every two (2) years. Dr. Bunch seconded the motion. The motion carried.

Dr. Pryse made the motion to accept the changes to board rule 1140-01-.13 (3) to state "The pharamcist in charge shall place a key or other access device in a sealed device or vault in a secured place outside of the department, unless the pharmacy practice utilizes an electronic access device which is capable of restricting and preventing unauthorized access into the pharmacy. A written or electronic record of persons accessing the pharmacy department using the key or other access device must be maintained on the premises of that pharmacy practice site". Dr. Eidson seconed the motion. The motion carried.

Dr. Pryse made the motion to accept the changes to board rule 1140-03-.10 (3) to state" 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 and in strict accordance with 1140-03-.03 (8). Ms. McDaniel seconded the motion. The motion carried.

Dr. Pryse made the motion to accept the changes to board rule 1140-03-.17 (1) to state "Institutional –Based Pharmacy Setting" means any institutional facility or long term care facility, as defined in 1140-01-.01, or an academic health care institution, where the pharmacist is responsible for the care of patients within that facility, including prescriptive practices, under the terms of the collaborative agreement". Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to accept the changes to board rule 1140-03-.17 (2) to state "that the when a patient or patient's authorized respresentative has signed an general consent that is listed in the patient's record, is verifying that the patient is agreeing to participate in service from an health care team including collaborative pharmacy practice with the exception of the institutional based pharmacy setting where such an informed consent is not required". Dr. Bunch seconded the motion. The motion carried.

Dr. Eidson made the motion to accept the changes of board rule 1140-03-.17 (6)(b) to state"The prescribing of controlled substances, except by a pharmacist practicing within an institutional-based pharmacy setting or for hospice patients". Dr. Bunch seconded the motion. Dr. Eidson withdrew the motion. Dr. Eidson to accept the changes of board rule 1140-03-.17 (6)(b) to state The prescriptive authority of controlled substances, except by a pharmacist practicing within an institutional-based pharmacy setting or for hospice patients". Dr. Bunch seconded the motion. The motion carried.

Dr. Pryse made the motion to delete board rule 1140-03-.13 (13) (3). Dr. Bunch seconded the motion. The motion carried.

Dr. Eidson made the motion to accept the changes to board rule 1140-03-.06 to state " The dispensing label for a medical or precription order shall bear at least the following information: name and address and telephone number of pharmacy practice site; the medical or prescription order serial number, name of prescriber; name of presciber; name of patient; direction for use;date medical or prescription order originally dispensed, and/or refill date; "poison", "shake", "caution", or other appropriate advisory label; name of product (if applicable). This rule shall not apply to medical and prescription orders dispensed by an institutional pharmacy or long-term care pharmacy for administration to inpatients of that institutional facility or long-term care facilty, except when medications are dispensed to patients residing in assisted care living facilites. Dr. Bunch seconded the motion. The motion carried.

Dr. Eidson made the motion to accept the changes to board rule board rule 1140-14-.07 (1) (a) 3 to state "The emergency kit shall be sealed or electronically secured by authorized personnel in accordance to established policies. The expiration date of the kit shall be cleary marked on the exterior of the kit or kept electroncially to represent the earliest expiration date of any drug device, or related materials contained in the kits". Dr. Bunch seconded the motion. The motion carried.

Dr. Eidson made the mtoion to accept the changes to board rule 1140-04-.15 (7)(b)1 (ii) to state " The prepackaged cartidges, unit dose package, 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: and (ll) the individual cartridges, unit dose package or containers are transported to the off-campus site in a secure, tamper-evident container;" and board rule 1140-04-.12 (2) (ii) The prepakaged cartridges, unit dose package or containers may be sent to the remote site to be loaded into the machine by personnel designated by the pharmacist in charge provide: and (ll) the individual cartridges, until dose packages or containers are transported to the remote site in a secure, tamper-evident container;". Dr. Bunch seconded the motion. The motion carried.

Dr. Bunch made the motion to accept the changes to board rule 1140-02-.01 (18) to state "A pharmacist shall not offer, participate in, or condone the use of financial incentives as a means to encourge a patient or prospective patient to transfer prescriptions. Dr. Eidson seconded the motion. The motion carried.

Dr. Eidson made the motion to accept the changes to board rule 1140-01-.13 (3) 2 to state "The pharmacist in charge shall place a key or other access device in a sealed device or vault in a secured place outside of the department. The key or access device may be used to allow emergency entrance to the department. A signature log of persons accessing the pharmacy department using the key or other access devices must be maintained on the premises of that pharmacy practice site for two (2) years. Dr. Bunch seconded the motion. The motion carried.

Dr. Eidson made the motion to add to board rule 1140-03-.17 (16) "Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapter 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.Dr. Bunch seconded the motion. The motion carried.

Dr. Bunch made the motion to accept the rules presented as amended. Ms. McDaniel seconded the motion. A roll call vote was taken and the motion carried.

General Discussion

Mr. Cange informed the board that the RFI was sent on December 1, 2015 to all the companies listed on the vendor list for bid. Mr. Cange stated that he did meet with procurement office and asked for a grant proposal for contract for prescription recovery.

Dr. Dilliard informed the board that he has spoken with LexisNexis concerning the printing of new law book. Dr. Dilliard stated that the fee would be $38,000.00 for 3000 or 5000 books. After discussion, Ms. McDaniel made the motion to purchase 5000 books and charge $25.00 per book. The motion died for lack of second. Dr. Eidson made the motion to purchase 5000 law books and to charge $12.00 plus shipping and handling. Dr. Dickenson seconded the motion. The motion carried.

The meeting adjourned at 2:40 p.m.

The minutes were approved and ratified as amended at the January 12-13, 2016 board meeting.