

2017 Tennessee Board of Pharmacy Rules Update Synopsis

[CLICK HERE](#) or visit http://share.tn.gov/sos/rules_filings/11-14-16.pdf to access the document referred to below that contains all the updates to the Tennessee Board of Pharmacy Rules. Look for the newly updated rules to be posted on the Board of Pharmacy website soon.

Page 4: Important Definitions Added and/or Amended (1140-01-.01)

- "**Automated Dispensing System**" means a mechanical or electronic system outside the premises of an institutional or long-term care pharmacy that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.
- "**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.
- "**Long term care pharmacy practice site**" means a pharmacy practice site serving patients within a long term care facility.
- "**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.
- "**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.

Page 6: Updates Fee Structure with Addition of Two New Paragraphs (1140-01-.10)

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

Pages 6-7: New Rule Permitting Board Approved Temporary Pilot Programs (1140-01-.15)

- “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.**”

Page 7: New Rule Prohibiting Incentivizing and/or Inducing Prescription Transfers (1140-02.01)

- “A pharmacist **shall not incent or induce the transfer of a prescription** absent the exercise of professional judgment.”
 - The intent of this was to encourage patients to use one pharmacy instead of utilizing multiple pharmacies to obtain gift cards or other incentives.

Page 7: Updates Current Tech-Check-Tech Rule Allowing Verification of Automated Dispensing Systems (1140-02-.02)

- “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.”

Pages 8-9: Update Clarifies Labeling Requirements for Medications Dispensed to Patients in Assisted Living Facilities (1140-03-.06)

- “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 facility, **except when medications are dispensed to patients residing in assisted care living facilities.**”

Page 12: Update Allows for Electronic Documentation of After-Hour Access to Institutional Pharmacy Practice Sites (1140-04-.14)

- “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.”

Pages 12-13: New Rule for Off-Campus Automated Dispensing Systems (1140-04-.15)

- “Each pharmacy holding an active license with the Tennessee Board of Pharmacy and using automated dispensing systems **shall register each automated dispensing system** with the Tennessee Board of Pharmacy. Each pharmacy **shall maintain a list of the physical locations of all automated dispensing machines in its systems**, whether such systems are located in the same facility as the licensed pharmacy, or not, **and shall be responsible to pay a registration fee, as defined in 1140-01-.10 (\$300)** (for each automated dispensing system, which the licensed pharmacy is responsible for and which is located in an institutional facility.)”
- “The **pharmacist in charge** of the institutional pharmacy practice site shall be designated to be **accountable** for this automated dispensing system.”
 - “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:”
 - “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.”
 - “The **prepackaged cartridges, unit dose packages 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:**”
 - “**a pharmacist verifies** the cartridge or container has been properly filled and labeled;”
 - “the individual cartridges, unit dose packages or containers are **transported** to the off-campus site **in a secure, tamper-evident container;**”
 - “the **automated dispensing system uses bar-coding, microchip, or other technologies** to ensure that the containers are accurately loaded in the automated dispensing system;”
 - “all drugs to be stocked in the automated dispensing system shall be **delivered** to the off-campus site **by the institutional pharmacy.**”
 - “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.”
 - “All containers of **medications stored** in the automated dispensing system shall be packaged and **labeled** in accordance with federal and state laws and regulations.”
 - “All aspects of **handling controlled substances shall meet the requirements** of all state and federal laws and regulations.”
 - “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.”
 - “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.”

- “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.**”
- “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 physical address and number of devices located at each physical address. Registrations for automated dispensing systems must be renewed every two (2) years.”

Page 17: Establishes Submitting Daily CSMD Information (1140-11-.04)

- “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.**

Pages 17-22: New Rules for Collaborative Pharmacy Practice Agreements (CPPA) (1140-03-.17)

(The information presented below creates a good starting point for those interested in forming a CPPA, but the full board rule should be referenced to ensure compliance)**

- Who can enter into a CPPA
 - A CPPA can be between pharmacist(s) and prescriber(s) OR pharmacist(s) and the chief medical officer, medical director, or a designated physician in an organized medical group
 - If with Advanced Practice Nurse (APN) or Physician Assistant (PA), then supervising physician must approve and sign the CPPA
- Pharmacist Qualifications
 - Has been awarded a doctor of pharmacy degree from a program accredited by ACPE; OR
 - Has been awarded a bachelor of science in pharmacy and been in the continuous, active practice of pharmacy
- Practice Site Requirements
 - Pharmacists engaging in a CPPA must utilize an area for in-person, telephonic or other approved consultations with patients that ensures communication confidentiality
- Professional Liability
 - Physicians, advanced practice nurses, physician assistants and pharmacists engaged in a CPPA must have an unencumbered TN license and at least \$1 million in professional liability insurance coverage per occurrence
- Notification to Boards
 - A written attestation filed with the licensing boards for all practitioners participating in

the agreement must be provided to the appropriate licensing boards of the signatories no later than thirty (30) days following the effective date of the Agreement

- Must include names of prescribers, any supervising physicians for mid-level prescribers, and a formulary of the categories of drugs and services (except in institutional-based settings)
- 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
- Minimum Required Elements for a CPPA
 - **Names and Titles of Collaborating Providers**
 - Physicians, advanced practice nurses and physician assistants engaged in a collaborative pharmacy practice agreement shall:
 - Retain professional responsibility to his/ her patients for the management of their drug therapy;
 - Establish and maintain a physician-patient relationship with each patient subject to the collaborative pharmacy practice agreement;
 - Be available at all times through direct telecommunication for consultation, assistance and direction, or shall make arrangements for a substitute physician to be available.
 - Attestation must include names of providers and scope of services
 - **Authorized Care and Services**
 - CPPA must define the nature and scope of patient care services and activities (authorized or restricted) to be provided by the pharmacist
 - The prescriber or prescribers entering into the agreement retain the ultimate authority regarding scope of services provided by pharmacists
 - All care and services to be provided shall be within the routine scope of the authorizing physician or APN/PA, where applicable
 - A list of the drugs or categories of drugs must be created if given prescriptive authority
 - The scope of a CPPA shall NOT include:
 - 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 services involving immunizations or preventive care, 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;
 - Prescriptive authority for controlled substances, except for a pharmacist practicing within an institutional-based pharmacy setting or for hospice patients
 - **Documentation and Communication**
 - Any patient care services provided by a pharmacist(s) must be documented and communicated to the prescriber(s) within three (3) business days
 - Must maintain records for ten years from the date of last patient contact

- **Override Clause**
 - The prescriber or prescribers entering into the agreement must have authority to override the actions taken by the collaborating pharmacist
- **Expiration, Modification and Termination**
 - Must be reviewed and updated every two years or agreement will expire
- **Automatic Exclusions**
 - Includes situations that automatically exclude a provider (i.e. death, loss of license, etc.)
- **Quality Assessment**
 - Must include measurable and objective performance goals for evaluating the quality of care provided to patients by the pharmacist on a quarterly basis
 - Every month, the authorizing physician shall also review at least five percent (5%) of the patient records seen by the pharmacist
- Pharmacist Prescribing Requirements
 - 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 1140-03-.03 and within the terms set forth in the collaborative pharmacy practice agreement
 - Pharmacists who hold a current federal 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

TPA and its practice societies, as well as the TPA ad hoc Ambulatory Care/Collaborative Practice Committee, will continue to support and encourage the implementation of collaborative pharmacy practice models. More information and resources on collaborative pharmacy practice will be available soon, but in the meantime, TPA members can access examples of collaborative pharmacy practice agreements by [CLICKING HERE](#) or visiting the Tennessee Society of Pharmacists (TSP) page on the TPA website.

Pages 23-31: Establishes New Chapter for Long Term-Care Pharmacy Practice (1140-14)

- A new chapter was created to distinguish long term-care pharmacy practice from retail pharmacy practice. Most of the language is copied from 1140-04, but one major difference includes:
 - Existing prescriptions for controlled substances can be renewed via fax (1140-14-.04)