



The Tennessee Sunshine Law Passed by the General Assembly in 1974 requires that meetings of state, city and county government bodies be open to the public and that any such governmental body give adequate public notice of such meeting. Open meeting notices can also be accessed at <https://www.tn.gov/hsda/health-care-facilities/hcf-board/hcf-board/meeting-schedule.html>

HEALTH FACILITIES COMMISSION
MEMORANDUM
SECOND AMENDED

Date: December 14, 2022
From: Wanda E. Hines, Board Administrator
Name of Board or Committee: Board for Licensing Health Care Facilities-Emergency Called Board Meeting-Rulemaking Hearing
Date of Meeting: December 15, 2022
Time: 9:00 AM., Central Standard Time
Place: 665 Mainstream Drive, Conference Room C, Nashville, TN 37243
Major Item(s) on Agenda: *See attachment.*

BOARD MEMBERS WILL PARTICIPATE ELECTRONICALLY

Link to Live Video Stream:
Rural Emergency Hospital Rulemaking

Microsoft Teams meeting
Join on your computer, mobile app or room device
[Click here to join the meeting](#)
Meeting ID: 253 657 802 195
Passcode: hyNqZo
[Download Teams](#) | [Join on the web](#)
Or call in (audio only)
[+1 629-209-4396,,700902848#](#) United States, Nashville
Phone Conference ID: 700 902 848#
[Find a local number](#) | [Reset PIN](#)
[Learn More](#) | [Meeting options](#)

This memo shall be forwarded from individual programs to the Public Information Office on the 15th day of the preceding month. The Public Information Office will prepare the monthly list of meetings within the Department and have ready for distribution to state media by the 28th day of the preceding month.



LOGAN GRANT
EXECUTIVE DIRECTOR

CAROLINE TIPPENS
DIRECTOR, LICENSURE & REGULATION

*THE MISSION OF THE HEALTH FACILITIES COMMISSION IS TO
PROMOTE ACCESS TO QUALITY, COST-EFFECTIVE HEALTHCARE IN TENNESSEE*

AGENDA

BOARD FOR LICENSING HEALTH CARE FACILITIES
EMERGENCY CALLED BOARD MEETING – ELECTRONIC RULEMAKING HEARING

DECEMBER 15, 2022

9:00 a.m.

PLEASE REMEMBER TO SILENCE YOUR ELECTRONIC DEVICES
WHEN THE BOARD IS IN SESSION

1. Call the Meeting to Order and Establish a Quorum.
2. Discussion(s):
 - A. Rural Emergency Hospital (REH) Rulemaking Hearing.
 - B. DYNASPLIT SYSTEMS, INC.; KNOXVILLE – (HME #1251)
Determination of need for continued licensure as a home medical equipment provider based upon provided equipment. If determined that licensure is needed, a waiver request of the physical location requirement is sought.

REPRESENTATIVE(S): Mark Hepburn, Executive Vice President and Steve Stolborn,
Compliance and Contract Manager.

- C. BUFFALO RESPIRATORY THERAPY/HAYEK MEDICAL DEVICES; BUFFALO, NY (POTENTIAL HME LICENSEE)

Hayek Medical Devices is a global ventilator manufacturer/distributor partnering with Buffalo Respiratory Therapy to provide ventilators and related services to individuals. A current patient of Monroe Carell, Jr. Children's Hospital at Vanderbilt and who resides in Tennessee needs this ventilator for use at home. Buffalo Respiratory Therapy/Hayek Medical Devices does not currently have a home medical equipment (HME) license in Tennessee nor a physical location. Determination that the proposed physical location by Buffalo Respiratory Therapy/Hayek Medical Devices meets the physical location requirement is needed.

REPRESENTATIVE(S): Daniel Quigley, Hayek Medical Devices and Joe Polito, Buffalo Respiratory Therapy

3. Adjourn.

**BOARD FOR LICENSING HEALTH CARE FACILITIES
EMERGENCY CALLED BOARD MEETING
ELECTRONIC RULEMAKING HEARING
DECEMBER 15, 2022**

The Board for Licensing Health Care Facilities Emergency Called Board Meeting- Rulemaking Hearing began on December 15, 2022. Dr. Christopher D. Wilson, chair, called the meeting to order.

A quorum roll call vote was taken:

Mr. Christopher D. Wilson, Chair—here
Mr. Paul Boyd – here
Mr. Louis Caputo – here
Dr. Howard Daniel Clark – not here
Ms. Patsy Carihfield – not here
Mr. Joshua Crisp – here
Mr. James Dunn – here
Dr. Julie Jeter – not here
Ms. Patricia Ketterman – not here
Mr. Tom Marshall – not here
Mr. Bobby Meadows—here
Mr. Roger Mynatt – here
Dr. Sherry Robbins – here
Dr. Jennifer Tatum-Cranford—here
Ms. Gina Throneberry – here
Dr. Monica Warhaftig – not here

A quorum roll call was established.

Rulemaking Hearing

The first item is the emergency rulemaking hearing: Chapter Number 0720-14 – Standards for Hospitals. Mr. Nathaniel Flinchbaugh, Deputy General Counsel stated the emergency rules are amended by definitions is amended by deleting paragraph (23) in its entirety and substituting instead the following language and is further amended by adding new paragraphs (82) and (83), and renumbering the remaining paragraphs accordingly, so that as amended, new definition language.

Mr. Flinchbaugh read the new definition language and authority to do so into the record. Dr. Kevin Brinkmann, Chair of the Committee on Pediatric Emergency Care the facility subcommittee just wanted to speak about the Pediatric Emergency Care Facility rules that COPEC advising the Board. In this set of rules there is a tier system of pediatric care that the rules provide for and at the lowest level there is a facility that a hospital can self-designate as a basic facility. In the rules for this does require a physician be available for thirty (30) minutes but does not require a physician to be onsite 24/7 and it is recognized the importance a nurse practitioners play in providing health care for our citizens in Tennessee especially children and not requiring a physician to be onsite at the hospital does provide flexibility for a hospital administration if they choose to become a rural emergency hospital to have a nurse practitioner to provide that front line emergency care for pediatrics and the supervising physician just be available. CoPEC is here to support all hospitals and their pediatric level of care and the emergency preparedness for the kids.

Mr. Caputo asked Dr. Brinkmann if he would limit to pediatric providers or any family practitioner. Dr. Brinkman express it could be any mid-level provider should that emergency medicine be their scope of practice. Dr. Robbins questioned with the mid-level provider and getting them to a specialist available and she felt a nurse practitioner doesn't have any emergency level training. Ms. Tippens referred Dr. Robbins under the subsection (82) is mirrored under the CMS federal regs. **Mr. Dunn made a motion to approve the rules as written; Mr. Meadows seconded. The motion was approved by roll call vote.**

HME MEMO

Mr. Flinchbaugh discuss and explain the memo regarding physical location required for Home Medical Equipment (HME) Providers. He explained that Tenn. Code Ann. § 68-11-226 requires that a provider of home medical equipment services has a principal place of business outside this state shall maintain an office or place of business within this state. Statutory requirements cannot be waived by an action of the Board for Licensing Healthcare Facilities. All providers must comply with Tenn. Comp. R. & Regs. 0720-30-.06(5) – Physical location. The Board, in the past, has approved physical locations in this State, such as a provider's employee's home office through Board–30-.04(7) issued Interpretative Guidelines. Further the facility, must also comply with Tenn. Comp R. & Regs 0720-30-.02(4) regarding inspections as well as Tenn. Comp R & Regs. 0720-30-.04(7) and T.C.A. §§68-11-201, et seq. Post in the main public entrance.

Mr. Flinchbaugh stated in the past, the Board has also considered waivers for the following regulations, provided that the facility's office does not provide patient care: T.C.A. Comp R & Reg. 0720-30-.04(8) requires "No smoking signs" and Tenn. Comp R. & Regs. 0720-30-.04(9) that a provider develops a concise statement of its

charity care policies and post those publicly. The Board may wish to consider contingent licensure requiring and approving physical location and all applicable Board waivers as are deemed necessary. However, this Board is indeed within their authority for waiving their current rules and the following items will be discussed regarding these rules.

DYNASPLIT SYSTEMS, INC., KNOXVILLE – HME #1251

Dynasplit Systems, Inc., Knoxville is questioning the need to maintain a physical location. Their products have served patients of all ages and conditions across the country for regaining range of motion after joint contracture, surgery, and numerous other indications. No other state in this county in which they do business does not require a physical location. This company is seeking a determination if their company having a physical location is needed or if a waiver is required. Representative(s) is Mr. Mark Hepburn, Executive Vice President and Steve Stolborn, Compliance and Contract Manager.

Mr. Hepburn explained his company's history and his company is accredited by CMS and is licensure as a HME in Tennessee. He has a question regarding the physical location requirement. Dynasplit currently has a physical location in Knoxville. Mr. Flinchbaugh explained to Mr. Hepburn that the Board cannot waive a statutory rule but can change the physical location waiver. It doesn't have to be a storefront location, but the regional manager is willing to use their person address to use their personal home and the home will be surveyed by surveyors on unannounced visits. Mr. Hepburn would like for his regional manager to be able to use their home which will save overhead cost of having an office. **Mr. Mynatt made a motion to approve this change of address to a home office and waive the signage requirements; Mr. Boyd seconded. The motion passed.**

HAYEK MEDICAL DEVICES, BUFFALO, NY (HME)

Hayek Medical Devices is a global Ventilator manufacturer/distributor. This company manufacturer their patented and unique biphasic cuirass ventilator (BCV). This ventilator is a proprietary, multi-function tool that requires expert attention and care of a highly trained Respiratory Therapist in the home. Hayek Medical Devices do not provide BCV for mass DME distribution in the United States (or Tennessee) to ensure patient safety and proper use. A request from Monroe Carell, Jr. Children's Hospital at Vanderbilt for this type of ventilator to be sent for home use could not be fulfilled due to the DME regulations in Tennessee. Hayek Medical Devices in Buffalo, NY has not successfully received a license from Tennessee due to the regulation requirement of having a physical location. This company is requesting for an exception to this regulation to provide access to our life-saving ventilator to the infant at Vanderbilt and many others to come.

Representative(s) is Daniel Quigley, Hayek Medical Devices and Joe Polito, Buffalo Respiratory Therapy.

Mr. Joe Polito explained this company has gotten a referral to set up a person in Tennessee to use their equipment and they is asking for the Board to help and explain what they need to do to set up a location. Mr. Polito stated a physical location will not benefit the patient, but they would like to be able to go to someone's home to set a person up for a ventilator. This company only wanted to provide this ventilator for a child. Mr. Flinchbaugh explained if Mr. Polito like to set up a home address. Mr. Quigley stated they do not have anyone to be able to use a home for an office. Mr. Flinchbaugh stated they will have to get a home office or office within thirty (30) working day. Mr. Polito stated he will be getting a physical space for an office. **Dr. Robbins made a motion to approve the conditional license requirements to meet within thirty (30) working days; Mr. Mynatt seconded. The motion was approved. Mr. Mynatt also made a motion to waive the signage requirements; Dr. Robbins seconded. The motion passed unanimously.** Mr. Flinchbaugh informed Mr. Polito their thirty (30) days will start immediately and Ms. Reed informed Mr. Polito he also needs to reapply with the new address. Mr. Polito agreed to the terms.

The meeting was adjourned.