

The Tennessee Open Meetings Act 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.

# TENNESSEE DEPARTMENT OF HEALTH MEMORANDUM SECOND AMENDED

Date:

August 6, 2019

To:

Shelley Walker, Director of Communication and Media Relations

From:

Wanda E. Hines, Board Administrator

Name of Board or Committee: HCF/Performance

CF/Performance Improvement

Issue St

Standing

Committee Meeting

(Call-in Number: 1-888-757-2790 passcode: 516730)

**Date of Meeting:** 

August 16, 2019

Time:

9:00 a.m., CDT

Place:

Poplar Conference Room

665 Mainstream Drive, First Floor

Nashville, TN 37243

Major Item(s) on Agenda:

See attachment.

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.

PH-1850 (Rev. 3/79)

RDA N/A



### LISA PIERCEY, MD, MBA, FAAP COMMISSIONER

BILL LEE GOVERNOR

THE MISSION OF THE TENNESSEE DEPARTMENT OF HEALTH IS TO PROTECT, PROMOTE AND IMPROVE THE HEALTH AND PROSPERITY OF PEOPLE IN TENNESSEE

#### **AGENDA**

## BOARD FOR LICENSING HEALTH CARE FACILITIES PERFORMANCE IMPROVEMENT ISSUE STANDING COMMITTEE MEETING

**AUGUST 16, 2019** 

POPLAR CONFERENCE ROOM, FIRST FLOOR 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. RESPIRONICS, INC., DBA PHILIPS RESPIRONICS AND RESPIRONICS COLORADO, INC., COLORADO

This potential applicant as a home medical equipment provider in Tennessee is seeking an interpretation and/or waiver of twelve (12) provisions of the HME Regulations 1200-08-29 including the physical location regulation. Respironics, Inc., is requesting to be consistent with previous waiver approvals that were granted to home medical equipment provider RespirTech in May 2016 and to National Biological Company in October 2017. This provider will offer to consumers a product known as "Simply Go Mini" which is a portable oxygen concentrator as well as other durable medical equipment. Respironics' "Simply Can Mini" will be delivered to patients only through mail order delivery. The product is also not covered under Medicare and/or Medicaid. Like the related company, RespirTech, all equipment-related problems and returns are handled through company support resources and not at the physical location in Tennessee.

REPRESENTATIVE(S): Chris Puri, Attorney

3. SANDERLING DIALYSIS OF NASHVILLE, NASHVILLE #233

Discussion regarding the usage of CCHT/facility staff as a caregiver in home dialysis training.

REPRESENTATIVE(S): Dr. Jerome Tannerbaum

4. CHOW Application Disciplinary Action Requirements.

REPRESENTATIVE(S): Ann Reed, Director of Licensure and Chris Puri, Attorney

5. Office of Health Care Facilities staff request for IG for Professional Support Services (PSS) Rule 1200-08-34-.06(2)(b) regarding 'physician' term. Apply 'physician' IG for ACLF rule.

REPRESENTATIVE(S): Ann Reed, Director of Licensure

- 6. Other Discussion(s).
- 7. Public Comments.
- 8. Adjourn.

#### **MINUTES**

### BOARD FOR LICENSING HEALTH CARE FACILITIES PERFORMANCE IMPROVEMENT ISSUE STANDING COMMITTEE MEETING

#### **AUGUST 16, 2019**

The Board for Licensing Health Care Facilities' Performance Improvement Issue Standing Committee meeting began on August 16, 2019. Mr. Jim Shulman, Chairman, called the meeting to order.

A quorum roll call vote was taken:

Dr. Patricia Ketterman-here

Dr. Rene Saunders-here

Mr. Jim Shulman-here

Ms. Gina Throneberry-here

Ms. Janet Williford-here

A quorum was established.

The first item for discussion was Repironics, INC., DBA Philips Respironics and Repironics Colorado, INC. Ms. Ann Reed, Director of the Board for Licensing Health Care Facilities, gave background to the agenda item that was presented at the June 5, 2019 Board meeting. Repironics submitted a waiver of Home Medical Equipment regulations. Mr. Chris Puri presented for Repironics. Mr. Puri discussed rules and regulations the facility was requesting to waive and Ms. Keri Woodman demonstrated the functionality of the SimplyGo Mini. Mr. Shulman asked the facility to recap previous waivers granted to sister agency-Respirtech. Respirtech were granted same waivers with exclusion of a few. Respirtech provides a percussion vest. Mr. Puri stated there is groundwork for approval of these rule waivers. Ms. Woodman explained the product and that patients that purchase the product have a Home Medical Equipment provider for their oxygen, but would need a prescription to purchase out of pocket and receive product. Dr. René Saunders mentioned that she would feel more comfortable with in person interactions with life sustaining equipment. The committee requested FDA information to confirm whether the equipment was considered "life sustaining/life supporting". Mr. Shulman made a motion to bring back item with FDA information related to equipment before the October Board Meeting; Ms. Ketterman seconded. During this time, Ms. Caroline Tippens researched product class provided by Repironics' representatives. Per FDA, the product was listed a "non-life sustaining/non-life supporting" device. Mr. Shulman withdrew his motion. Dr. Saunders made a motion to approve each waiver request individually; Dr. Saunders withdrew motion. Mr. Shulman made a motion to approve waiver requests in mass with amendments provided by Ms. Tippens; Ms. Gina Throneberry seconded. The motion was approved with a 4 to 1 vote. (Dr. Saunders-no vote)

The second item for discussion was Sanderling Dialysis of Nashville. Ms. Reed gave background to item specific regulations for CCHT to be considered as a caregiver in End State Renal Dialysis rules. Clay Byrd and Dr. Tannenbaum represented for Sanderling. Sanderling agreed with state that unlicensed or non-certified persons couldn't provide home dialysis services in the home but requested to allow CCHT's to

perform dialysis in the home. Ms. Tippens referred to documents referencing all states and the use of Patient Care Technicians in CMS rules. CMS and State doesn't recognize CCHT's or CCHT programs in TN. Mr. Shulman stated the Board wasn't empowered to allow CCHT to perform certain functions without the supervision of a registered nurse in the home but able to perform in the center. Mr. Shulman told Dr. Tannenbaum to take the CCHT issue to legislation, to the Board of Nursing in context of the nurse practice act and if the rule was changed to then come back to this Board. No motion needed. Sanderling understood the position of the Board. Ms. Reed asked the committee if the current ESRD regulations allowed performance of in-home dialysis only in an individual's home. She indicated there is a current ESRD licensure application for such model. She requests guidance for proper licensure for this prospective applicant. Ms. Reed asked does this model meet the state licensure requirements for an ESRD or another licensure type such as a home health agency. Committee members instructed staff to research and bring this back to the Board and/or standing committee.

The third item for discussion was the CHOW application disciplinary action requirements question. Ms. Reed gave background of item which was previously presented in December by administrative staff. At that time, Mr. Puri offered to research other state applications. Mr. Puri presented a memo showing several good indicators to recognize the facility as an operator. Mr. Shulman made a motion to proceed using the recommendation in the presented memo to revise CHOW application, share with applicable parties, and present at the October Board Meeting; Ms. Janet Williford seconded. Motion was approved.

The fourth item for discussion was the Office of Health Care Facilities staff request for IG for Professional Support Services (PSS) Rule 1200-08-34-.06(2)(b) regarding 'physician' term and to use the IG approved for specific ACLF rules. Ms. Reed gave background to the request. Surveyors are finding this issue on survey of PSS agencies; rule language which has been approved by Board for PSS rules show physician and the allowance of advance practice nurse, etc to fill that requirement. Mr. Shulman made a motion to add PSS to ACLF 'physician' term IG and move to full Board in October 2019; Ms. Williford seconded. Motion was approved.

Mr. Shulman made motion to adjourn the standing committee meeting. Meeting was adjourned.