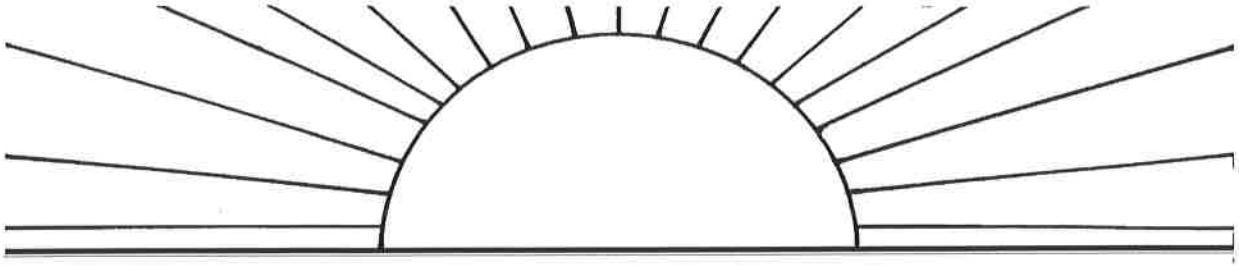

The Tennessee Open Meetings Act passed by the General Assembly in 1974 requires that meetings of state, city and county government bodies be open to the public and that any such governmental body give adequate public notice of such meeting.

TENNESSEE DEPARTMENT OF HEALTH
MEMORANDUM
AMENDED

Date: July 21, 2017

To: Woody McMillin, Director of Communication and Media Relations

From: Wanda E. Hines, Board Administrator

Name of Board or Committee: Board for Licensing Health Care Facilities- Performance Improvement Issue Standing Committee Meeting
(Call-in Number: 1-888-757-2790 passcode: 152602#)

Date of Meeting: July 25, 2017

Time: 9:00 a.m. – 12:00 noon

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

TENNESSEE DEPARTMENT OF HEALTH

JOHN J. DREYZEHNER, MD, MPH
COMMISSIONER

BILL HASLAM
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

JULY 25, 2017
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. Approval of Minutes – December 12, 2016 – Performance Improvement Issue Standing Committee

3. **PENTEC HEALTH, INC., NASHVILLE**
This home health agency is seeking to waive two provisions: Home Health Services Rule 1200-08-26-.06(2) regarding a written summary report for each patient must be sent to the attending physician at least every 62 days and Home Health Services Rule 1200-08-26-.06(3)(b) regarding plan of care of a patient must be reviewed by attending physician and agency personnel as the severity of the patient's condition at least once every 62 days. Pentec's believes their staffing plan and existing policies for management of medical plans of care and nurse reporting meets the intent of the standards.

REPRESENTATIVE(S): Michelle Hiidel, RN and Karen Boyer, RN

4. **NATIONAL BIOLOGICAL CORPORATION, NOLENSVILLE AND THE RICHMOND LIGHT COMPANY, NOLENSVILLE**
National Biological Corporation and Richmond Biological Corporation both are home medical equipment facilities are seeking to waive the following Home Medical Equipment Rules: 1200-08-29-.04(7)-(8) and 1200-08-29-.06(5)(c)- Physical Location; 1200-08-29-.04(9) – Charity Care Statement; 1200-08-29-.06(2) – Infection Control; 1200-08-29-.06(4)(a),(f), 1200-08-29-.06(4)(b), 1200-08-29-.06(6)(c)-Equipment Management; 1200-08-29-10-Infectious and Hazardous Waste; and 1200-08-29-11-Records and Reports. Both businesses are based in Ohio and have applied for licensure in Tennessee.

REPRESENTATIVE(S): Michael Kaufman, Vice President and Chris Puri, Attorney

5. National HealthCARE Corporation (NHC) proposed language for nursing home rules 1200-08-06-.06 from the NF Drug Disposal Rules for SB 1320 – PC 355.

6. The Tennessee Committee on Pediatric Emergency Care (CoPEC) is currently working on revising the Standards for Pediatric Emergency Care Facilities Rules 1200-08-30. CoPEC is requesting guidance on revisions to the rules and interpretative guidelines/licensure survey to reflect current standards of care.

   REPRESENTATIVE(S): Kevin Brinkmann, M.D. and Cristina Estrada, M.D., Co-Chair CoPEC Standards Committee

7. Ambulatory Surgical Treatment Center (ASTC) Rules and Regulations 1200-08-10-.01(7)(b) ASTC definition.

   REPRESENTATIVE(S): Patti Cotton and Dr. Steven J. Smith

8. Other Discussion(s).

9. Public Comments.

10. Adjourn.

MINUTES
BOARD FOR LICENSING HEALTH CARE FACILITIES
PERFORMANCE IMPROVEMENT ISSUE (PI) STANDING COMMITTEE MEETING
July 25, 2017

The Board for Licensing Health Care Facilities' Performance Improvement Issue (PI) Standing Committee meeting began on July 25, 2017. Jim Shulman served as chair for this meeting.

A quorum roll call vote was taken:

Mr. Jim Shulman – here
Ms. Janet Williford – here
Dr. René Saunders – here
Ms. Gina Throneberry – here
Ms. Patricia Ketterman – not here

A quorum was established.

The first item before the committee was consideration for approval of the December 12, 2016 PI Standing Committee meeting minutes. **Dr. Saunders made a motion to approve; seconded by Ms. Williford. The motion was approved.**

The first item for discussion was Pentec Health, Inc., Nashville. This home health agency appeared before the full Board at the June 2017 meeting requesting to waive two home health agency rules, 1200-08-26-.06(2) regarding the written summary report for each patient to be sent to the attending physician at least every 62 days and 1200-08-26-.06(3)(b) regarding plan of care of a patient to be reviewed by the attending physician and agency personnel as the severity of the patient's condition at least every 62 days. The full Board voted to move this item to this standing committee for consideration and further review. Pentec representatives provided information on other state requirements for plan of care intervals. Four states, Colorado; Maine; New Hampshire; and Virginia, provided waivers to Pentec allowing for a yearly plan of care review. Thirty-two states' regulations allow for an annual plan of care review. Pentec encountered four states that would not consider a waiver of their requirements for less than yearly plan of care reviews. Mr. Shulman questioned why the licensure rules call for a 62 day requirement. Ms. Reed stated these requirements mirror the federal requirements for home health providers. Ms. Williford gave further reasoning of the 62 day timeframe stating this coincides with the physician recertification of the patient's plan of care. Dr. Saunders doesn't understand the difficulty in complying with the rules. Pentec representatives stated it is not more complicated, but the agency receives push back from their patients' physicians when asking for signatures on duplicate documents. The standing committee further asked if the waiver were granted would changes in a patient's condition be addressed. Pentec assured nurses do a two page assessment of the patients when visits are made and the physicians know immediately what is going on with patients. Ms. Throneberry asked if the assessment was done electronically or by paper. Pentec representatives stated both and it becomes a part of the medical record of the patient. Mr. Shulman wanted to know more about the intrathecal pumps and the care of such. Pentec stated the pump is the size of a hockey puck usually implanted in the abdomen. There is a pencil eraser sized access port on the pump and the catheter tubing is spaghetti sized. Nurses access the port to start medications, empty the pump and begin new

medications, and use a device to 'read' the pump for medication administration. Pentec representatives stated medication changes are usually made every 60 days, but some may be as soon as every two weeks or as far out as every six months. Mr. Shulman also wanted to know why other states have approved a waiver. OGC and OHCF administrative staff did not know the reason. He further stated he is willing to look at a waiver if just a paperwork issue. Dr. Saunders again voiced that she did not see the need for the waiver. Ms. Tippens asked Pentec if opioids were administered through the pumps. Pentec representatives stated yes, Fentanyl; Morphine; Dilaudid; and Baclofen an antispasticity medication. Non-opioid medications are also used. Patients may give themselves a boost of medication, but this is programmed into the pump. Nurses can see the history of the patients' use of medications. Ms. Tippens asked how the medications get to the patients' place of residence. Pentec representatives stated the medication is delivered to the nurse who then takes to the patient and has the patient to sign for the medication. Ms. Tippens made it known to the standing committee members that the Commissioner of Health was opposed to the use of opioids via this method and wrote a letter to Health Services and Development Agency opposing the CON application of Pentec. **Dr. Saunders made a motion to deny the waiver requests; seconded by Ms. Throneberry.** Discussion ensued with Mr. Shulman asking how a patient would know something was wrong with the medication and pump. Pentec representatives stated the pump would alert with a beeping sound within the body. Mr. Shulman asked for follow-up information on why some other states granted waivers. **Pentec was agreeable to provide. The motion to deny the waiver requests was approved.**

The second item for discussion was National Biological Corporation, Nolensville and The Richmond Light Company, Nolensville. These home medical equipment (HME) licensure applicants appeared before the Board at the June 2017 meeting requesting a waiver of numerous HME regulations. The full Board voted to move this item to this standing committee for consideration and further review. Chris Puri, attorney, represented these two HME applicants during this PI Standing Committee meeting. He presented opening comments which included an introduction of the two licensure applicants, when they were established, their location, and a summary of the waiver requests to include consideration and determination of whether licensure as a HME provider was needed. Kenneth Oif a representative for both licensure applicants provided information on phototherapy which included the type of light used and diseases treated by this therapy. Mr. Puri presented to the standing committee that after the waiver request letter was written it was found that these two companies may not meet the HME licensure requirement. He felt this was due to the specific reference in the definition of home medical equipment to neonatal phototherapy device. Mr. Puri felt the specificity of this equipment listing overrode the general rule definition related to the caution statement. He further stated there is no legislative history on the HME statutes. Dr. Saunders asked if the equipment provided by the two licensure applicants contained the caution statement referenced in the rule. Mr. Oif stated yes. Dr. Saunders stated the two licensure applicants meet the definition of HME set forth by the legislature. Mr. Shulman asked for a description of how the provider operates. Mr. Oif stated the agency would receive an MD order, ship the product to the patient which requires an approximate 10 minute set-up, no patient education is provided, and the patient follows the physician orders they received. He also informed the standing committee the 48 other states granted waivers or determined National Biological and Richmond Light Company were not HME providers. Dr. Saunders asked if TennCare pays for the provided equipment. Mr. Oif stated he didn't believe so, but that certain private insurance does plus Medicare. He further stated that once the equipment is provided in Tennessee maybe TennCare will provide reimbursement. Mr. Oif stated the therapy has been available for 20 years in Tennessee, but in physician offices and hospitals. He stated the use of phototherapy offers financial efficacy versus medication therapy. He also stated there is less risk associated with phototherapy than with medication usage. The greatest risk would be sunburn. The standing committee agreed National Biological and

Richmond Light Company are HME providers. Ms. Reed directed the standing committee to the numerous waiver requests of each provider. Mr. Shulman stated a motion should be made and voted upon regarding the determination these two entities should be licensed as HME providers. **He made a motion to find this photo equipment to be a HME device and National Biological and Richmond Light Company require licensure; seconded by Dr. Saunders. The motion was approved.** Mr. Puri informed the committee of another recently licensed HME, Respritech, that sought waivers due to the agency's service model which is similar to National Biological and Richmond Light Company. **Mr. Shulman moved to grant waiver of all applicable rules for the two entities in order to allow licensure.** Ms. Tippens interjected asking Mr. Puri if Respritech asked for a waiver of the same rules as National Biological and Richmond Light Company. Mr. Puri stated no. **Dr. Saunders seconded Mr. Shulman's motion. Mr. Shulman amended his motion to grant waiver of the list of rules as provided by in the power point presented by the provider. Dr. Saunders accepted the amendment.** Discussion ensued regarding the waiver request of rule 1200-08-29-.11(3) which addresses patient record requirements. **Mr. Shulman made an amendment to remove this rule from the waiver request; seconded by Dr. Saunders.** Ms. Reed sought clarification about the administrator rule waiver request and the term modified as shown in the power point of the provider. Mr. Puri stated the provider will have someone acting as the administrator, but wants to waive 1200-08-29-.01(2)(a-c) which is the specific requirements to be an administrator of a HME. Discussion continued regarding the waiver request of rule 1200-08-29-.04(9). Ms. Reed stated this is a statutory requirement and that a facility must have the required statement available. Ms. Tippens stated this signage doesn't have to be posted since the public does not enter the location. OGC's determination is the requirement is not applicable since the public doesn't visit and is only a housing location for the equipment. Further discussion revolved around the placement of such a statement to the websites of the two providers. Ms. Reed questioned the request to waive rules 1200-08-29-.05(1)(b) and 1200-08-29-.06(6) since these address being compliant with federal, state, and local anti-discrimination laws and aspects of the federal requirements for the provision of HME equipment and services. Mr. Puri stated the providers would comply with those aspects. It was also identified during the discussion that aspects of the rule 1200-08-29-.06(6) would not be applicable to the providers as these rules address wheeled mobility devices. **Mr. Shulman made a friendly amendment to remove these two rules from the list of waiver requests; seconded by Dr. Saunders.** Ms. Reed questioned if the waiver requests for the disaster preparedness should be looked at more closely. Dr. Saunders felt that since this is not life-saving equipment it is not an essential set of rule language. Ms. Reed stated she was thinking more along the lines of a detriment occurring to the patient relative to a malfunction. The standing committee stated this would not be an issue. **Mr. Shulman then made a motion to accept all amendments. The motion was approved. Mr. Shulman stated a motion to accept the list of waiver requests found on the providers' power point with all friendly amendments is on the table with a call for a vote. The motion was approved.**

The third item for discussion was National Healthcare Corporation's (NHC) proposed language for nursing home rule, 1200-08-06-.06 regarding nursing facility drug disposal based upon Public Chapter (PC) 355. Stacia Vetter with NHC spoke on PC 355 which allows nursing facilities to develop a repository for donated drugs and to develop rules via emergency rulemaking. Current nursing home rules require medications to be destroyed, but new rules per the PC would allow for a way to put drugs in a repository including nursing facilities having to follow DEA requirements. Jeremy Davis, TDH Assistant Commissioner, addressed the standing committee regarding this topic. He stated controlled substances and REMS would not be a part of the repository, but may go to the repository to be destroyed. Dr. Saunders questioned what REMS included, but Mr. Davis was not certain. It was imparted the standing committee members that repository rules are not in place yet and would be under the purview of the Pharmacy Board. Dr. Saunders voiced concern that the repository rules are not in place. She also voiced

concern over the suggested rule revision language found at (n) and (o). Dr. Saunders felt it was not clear if these two rules are an option or both are required. It was determined this language should be clarified. Many other suggestions were given on how to word the clarified language. The standing committee members questioned if approval of the Board or committee was needed to move this language forward. Ms. Tippens stated no approval was needed to move forward with an emergency rulemaking hearing. The committee wanted clarity in the suggested rule language relative to record of where medications go. Donna Smith, Regional Administrator Middle Tennessee Regional Office (MTRO), informed the standing committee that this is a common issue with facilities and comes to the department via complaints. No approval was granted to the suggested rule language change, but further work to be done on the rule language.

The fourth item for discussion was The Tennessee Committee on Pediatric Emergency Care (CoPEC) request for guidance on revision to rules and interpretative guidelines to reflect current standards of care. Dr. Kevin Brinkmann presented to the standing committee on this agenda item. He indicated the first item to consider was a waiver request of the following items on the current pediatric emergency care facility (PECF) table in the PECF regulations: laryngoscope handle and blades, omit requirement for 1 & ½ straight or Miller blade; omit Bretylium; omit Ipecac; omit Sodium Bicarbonate 7.5%; omit Butterflies, size 19 gauge; tracheostomy tube sizes – size range is inappropriate, recommend changing requirement to tracheostomy tube sizes 3 to 6; urinary catheterization, Foley 6-14 Fr – 6 Fr Foley size is not commercially available, recommend a 6 Fr feeding tube as compliant; omit requirement for oxygen blender; and change requirement for Activated Charcoal from EED to EH for all facility levels. Dr. Brinkmann stated these items are either out of date or no longer the standard of practice. Mr. Shulman asked will there be items to replace the requested omitted items. Dr. Brinkmann stated yes to ensure good pediatric care will be provided. **Dr. Saunders made a motion to develop an interpretative guideline (IG) exempting the listed items from the rule requirements until the revised rules have been passed; seconded by Mr. Shulman. The motion was approved.** Dr. Brinkmann then asked the standing committee if CoPEC should continue with the current composition of the IGs developed for the PECF regulations. The standing committee stated to continue with the current practice and no changes to be made.

The final item for discussion was ambulatory surgical treatment center (ASTC) rule 1200-08-10-.01(7)(b) in the ASTC definition section. Patti Cotton, attorney, presented the request regarding an IG of the term 'routinely' in the ASTC definition. She stated on past surveys of her client's facility it was noted that surgeries occurred that lasted longer than the four hour minimum requirement, but no citation was issued. Ms. Cotton stated she is fearful the surveyors' application of the rule has changed as her client was cited for this on the most recent survey of the facility. Ms. Cotton informed the standing committee that 70% of her client's cases are four or less hours under anesthesia and feels this meets the 'routinely' requirement. Mr. Shulman asked how long the facility has been doing these types of procedures. Dr. Steven Smith stated he had been in practice for 24 years. He further stated ASTCs in the Knoxville area have been performing surgeries longer than the four hour duration for a while. Ms. Cotton stated the four hour anesthesia requirement is difficult to apply to plastic surgery cases. No adverse outcomes have been noted at Parkwest Plastic Surgery relative to the greater than four hour anesthesia. Dr. Smith stated there is no abnormal blood loss related to the procedures he performs. Ms. Cotton further stated that Dr. Smith's facility meets the Governor's value based care initiative. Dr. Saunders asked what the definition of 'routinely' is. Ms. Tippens stated she talked with Ms. Smith, MTRO Regional Administrator, and it was determined surveyors need guidance on this. The next question is how 'routinely' should be measured by percentages or number of cases. Discussion ensued with the standing committee indicating the need to address this rule as it applies to all ASTCs and this would

require further work. Ms. Cotton then asked the standing committee to consider a waiver of the rule for Parkwest Plastic Surgery, but continue to work on the issue for all other ASTCs. Dr. Smith stated that the provision of anesthesia has changed and improved over the years. Mr. Shulman recommended working with the Tennessee Ambulatory Surgical Center Association for data on this item. Ms. Reed asked Dr. Smith if he felt the four hour rule was out dated. Dr. Smith stated yes. Ms. Reed suggested the provider to bring back supporting documentation for an increase in the four hour anesthesia and documentation of current practices relative to surgery in an ambulatory setting. Mr. Shulman stated the item should be tabled for more discussion and that more questions need to be addressed. He further stated it needs to be determined what should be done, a waiver; IG; or a new rule. Dr. Saunders made a motion to table this item; seconded by Mr. Shulman. The motion was approved.

The standing committee meeting was adjourned.