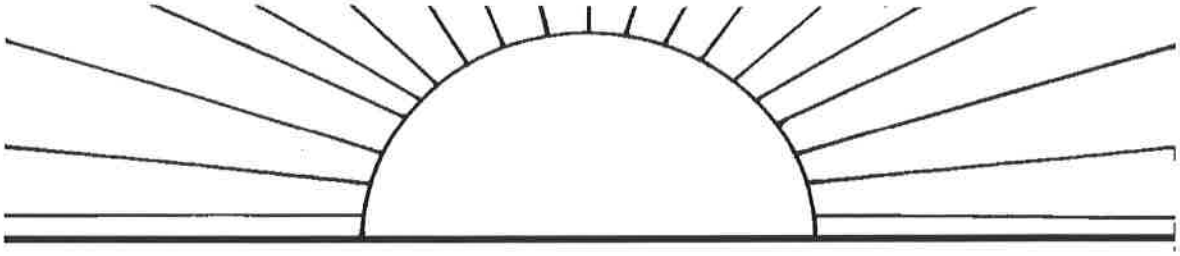

The Tennessee Open Meetings Act passed by the General Assembly in 1974 requires that meetings of state, city and county government bodies be open to the public and that any such governmental body give adequate public notice of such meeting.

TENNESSEE DEPARTMENT OF HEALTH
MEMORANDUM
SECOND AMENDED

Date: December 2, 2016

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-Education and Performance Improvement Issue Standing Committee Meeting
(Call-in Number: 1-888-757-2790 passcode: 457462#)

Date of Meeting: December 12, 2016

Time: 9:00 a.m. – 2:00 p.m., CST

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
EDUCATION AND PERFORMANCE IMPROVEMENT ISSUE STANDING COMMITTEE

DECEMBER 12, 2016
POPLAR CONFERENCE ROOM, FIRST FLOOR
9:00 a.m. – 2:00 p.m.

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

A. EDUCATION AND PERFORMANCE IMPROVEMENT ISSUE STANDING COMMITTEE

1. Call the Meeting to Order and Establish a Quorum.
2. Development more Nurse Aide Rule Language.
3. Other Discussion(s).
4. Public Comments.
5. Adjourn.

B. PERFORMANCE IMPROVEMENT ISSUE STANDING COMMITTEE

1. Call the Meeting to Order and Establish a Quorum.
2. AARP/THA Proposed Caregiver Rule Language for Hospital Rules.
3. Development of Sentinel Event Quality Measures Improvement Guidelines Regarding Public Chapter 1003.
4. HME Regulation Discussion(s):

   (a) All American Medical Supplies, LLC, Memphis
   -Steven King, Chief Compliance Officer, Executive Vice President

(b) Prism Medical Products, Elkin, NC
-Ken Reel, Executive Vice President

(c) A1 Diabetes & Medical Supply, Inc., Memphis
-Lucas Matheny, Chief Compliance Officer, Mark Cullen, Attorney, Cullen Law Firm and Julie Elkin, Elkin Law Office

5. Revision for the Trauma Brain Injury Residential Homes Rules 1200-08-37 Related to Public Chapter 984.

6. Legislative Intent/Reasoning for General Hospital Discontinuation of OB Services Requirement for a Certificate of Need (CON).

7. Other Discussion(s).

8. Public Comments.

9. Adjourn.

MINUTES
BOARD FOR LICENSING HEALTH CARE FACILITIES
PERFORMANCE IMPROVEMENT ISSUE STANDING COMMITTEE MEETING
December 12, 2016

The Board for Licensing Health Care Facilities' Performance Improvement Issue (PI) Standing Committee meeting began on December 12, 2016. Jim Shulman served as chair for this meeting.

A quorum roll call vote was taken:

Mr. Jim Shulman – here
Mr. John Marshall – here
Ms. Janet Williford – here
Dr. René Saunders – here

A quorum was established.

The first item for discussion was AARP/THA's proposed caregiver rule language for the hospital regulations. Ann Reed gave background to this agenda item. She stated it was first presented to the Board at the September 2016 meeting with the full Board voting to move to the PI Standing Committee for further discussion and review. Revised rule language has been provided by AARP based upon the September 2016 Board meeting discussion. AARP presented to the standing committee the rule language with noted changes which were based upon Board comments. It was stated this language is present in many states. It was further noted that THA supports the presented language changes. Dr. René Saunders questioned the unpaid caregiver and private residence language. AARP stated this language was requested by THA to be included. AARP indicated no issue with the caregiver designation as paid vs unpaid, but THCA did have an issue and wanted the clarification. Linda Estes with THCA addressed the standing committee. She stated the regulation will cover who takes orders, instructions for the patient which would be family members, friends, or paid caregivers. Dr. Saunders stated does the term unpaid need to go away. Ms. Estes stated the intent of the language was for those who are paid or are family and acting as caregivers. John Marshall stated this only applies in a hospital setting so the caregiver wouldn't be paid. Dr. Saunders doesn't feel unpaid has to be in the rule language. Mr. Marshall suggested the inclusion of paid and unpaid to the language. THA representative states this language is being submitted to formalize the process in a hospital setting. The THA representative further stated that THA doesn't care whether the term paid vs unpaid is in the language. Jim Shulman stated does paid vs unpaid caregiver make a difference. Ms. Estes stated it may not. She also stated there are many new requirements from CMS for nursing homes relative to caregivers. It was stated again this language is only for the hospital setting and once a patient is discharged to the nursing home these regulations wouldn't apply. A nursing home representative would be involved in the discharge process for a patient at that point and would address if the patient requests outside of the proposed caregiver rules. Stacia Vetter with NHC stated the language helps prevent a healthcare organization from being a caregiver for a patient. She stated the federal requirements dictate who will be responsible once the patient is in another licensed facility. Ms. Estes wants clarity that other healthcare facility residency is not part of this rules' intent. Mr. Shulman stated move phrase from #2 of the proposed rule language to #1. Dr. Saunders unsure this was needed felt the language presented is self-explanatory. Mr. Shulman can see legal confusion down the road if language left as is. AARP's

conversation with THCA representative felt ease with designation of patient representative once the patient needs to go to a nursing home from their home. Dr. Saunders felt this was a different situation and would not apply to the current rules being proposed. Mr. Shulman stated the associations need to continue to work with this language. Gayla Sasser requested clarity to the rule on notification of patient's discharge from the hospital. She further stated all hospitals she has had contact with do this. Ms. Sasser feels this doesn't support the unpaid term and that family may be out of state and depend upon a home care organization employee. Paul Boyd, Board for Licensing Health Care member, approached the standing committee asking if this truly needed codifying in rule if it already occurs. AARP gave the scenario of a patient with family out of state or responsible person is working and these individuals are unable to participate in the discharge receipt of instructions. It was asked if other tools are currently available and it was indicated that no there are not. **Mr. Marshall made a motion to approve the rule language with change of the term unpaid; seconded by Dr. Saunders.** Mr. Shulman stated there may need to be further discussion on the clarity of the language. **The motion was approved.**

The second item for discussion was the development of sentinel event, quality measures, and improvement guidelines regarding Public Chapter (PC) 1003. Ms. Reed gave background to this item. It was first presented to the full Board at the September 2016 meeting and was moved to the standing committee for further consideration. Ms. Reed also recapped a meeting that was held by the Office of Health Care Facilities (OHCF) and TASCA. She also stated the former OHCF Unusual Incident Reporting System interpretative guidelines were shared with OGC and provided to the standing committee for review. Kyonzté Hughes-Toombs, OGC, stated to the standing committee that the full Board adopted the CMS definition for sentinel event. The work of the standing committee is to develop quality measures. Jeff Teague, Planned Parenthood of Middle and East Tennessee, addressed the Board. He stated his facility uses the states licensure rules for ambulatory surgical treatment centers (ASTC) and some of the guidelines provided by TASCA. Mr. Teague stated there are very few surgical abortions performed at his facility more are medication induced. He stated only 3 to 4,000 surgical abortions are performed each year. Dr. Saunders started the committee discussion by using the TASCA list of guidelines to determine what should be included as a quality measure. It was determined the following would be starting quality measures – wrong site/wrong patient/wrong procedure, patient burn, patient fall, safe surgery checklist used, flu vaccination, volume data, normathermia, consumer survey, anesthesia complication, documentation informed consent, transfer to hospital, adverse incidents related to procedure, and inability to perform procedure. Dr. Saunders felt IV antibiotics should be included, but Planned Parenthood indicated their facility only uses oral antibiotics. Planned Parenthood also stated to the standing committee that for every termination that is performed a form for the Tennessee Department of Health's (TDH) Vital Statistics is completed. This form indicates what is done with the fetal tissue. Mr. Teague stated no abortion facilities in TN sell or donate fetal tissue. Dr. Saunders informed the standing committee that Office Based Surgery Suites (OBS) must report certain adverse events such as transfer to ER, unplanned admit, discovery of foreign object during surgery, wrong site/surgery, and death. She further stated if too many adverse events are seen this would be a concern and an investigation would be needed. Ms. Hughes-Toombs stated the recommendations would be 'prettied-up' and provided to the full Board at the February 2017 meeting. **Mr. Shulman made a motion to accept the quality measures in order to comply with PC 1003 and send this back to the full Board for approval; seconded by Mr. Marshall. The motion was approved.**

The third item for discussion was revision of the Traumatic Brain Injury (TBI) Residential Home rules, 1200-08-37 related to PC 984. Ms. Reed gave background to the item stating state statute was changes creating the need for change to the TBI regulations. She stated it removed the single family home

language and changed the language to residential home. Caroline Tippens, OGC, pointed out the rule language changes made are per TCA change which includes redefine TBI, fee schedule implementation, and removal of the eight bed limit. Dr. Saunders asked why not start the fee schedule at $1080. Ms. Reed stated the fee schedule in the rules is the same fee schedule that is used for all facility types with an unlimited number of beds. **Dr. Saunders made a motion to approve the rule language changes for the TBI rules and move to the full Board; seconded by Janet Williford. The motion was approved.**

The fourth item for discussion was legislative intent/reasoning for general hospital discontinuation of OB services requiring a certificate of need (CON). Mr. Reed provided background to this item. The item was first introduced to the full Board at the September 2016 meeting. During that discussion, the full Board requested the item to be moved to the PI Standing Committee for further discussion and research of the intent of the statute change. Ms. Hughes-Toombs stated she met with Senator Sexton the author of the legislation that removed the requirement for a CON by a hospital when discontinuing OB services. She stated it was recognized that the OHCF's Board does not approve or review hospitals for the need of a service. Senator Sexton indicated the Board may ask for an exit plan and notification by a hospital of the discontinuation of the OB services. Ms. Hughes-Toombs further stated OHCF can't tell a facility they cannot discontinue OB services. Dr. Saunders asked why must a hospital submit an exit plan; what is gained by a provider who discontinues the service? Ms. Hughes-Toombs stated if this is in the rule and the hospital doesn't provide it is held responsible. The Board can approve a presented plan. Mr. Marshall offered insertion of language in the hospital rules that if OB services are discontinued a plan to implement the discontinuance must be present. He further stated surveyors could review and ask for upon survey. It was also stated that these questions should be brought to the full Board. Ms. Reed brought to the standing committee the issue that the hospital rules require a general hospital designation to have OB services and asked about what steps to take regarding this. **Mr. Marshall made a motion to remove OB services from the general hospital rule; seconded by Dr. Saunders**. Dr. Saunders then questioned why are hospitals are designated. Ms. Reed stated these rules have been in place at least since 2006 and she was not aware of the intent of the rule regarding designations. Mr. Shulman wanted to know why the legislation was put forth. Ms. Hughes-Toombs stated to reduce obstacles for a hospital to discontinue OB services. **The motion was approved by a vote of three to one (Dr. Saunders).**

The last item for discussion was home medical equipment (HME) regulations with respect to the following facilities – All American Medical Supplies, LLC; Prism Medical Products; and A1 Diabetes & Medical Supply, Inc. Ms. Reed provided background to this agenda item. She stated the issue at hand is the interpretative guideline (IG) concerning delivery of equipment and mail order company providers. She stated the three providers here today have issues with the face to face delivery requirement in light of being mail order companies. It was determined that each provider would address the standing committee. All American Medical presented first to the standing committee. Representative for the facility was Juliet McBride who joined by phone. She stated to the standing committee mail order companies coordinate with physician offices to supply equipment to patients at their place of residence. All American provides equipment, TENS unit, under CMS' competitive bidding program. Ms. McBride stated the patients' physician has a face to face with the patient at which time instruction is given including an instruction sheet. All American has a call in center as well for patients to access. Patients are provided with a manufacturer handout to the appropriate use of the product that is a custom and normal way of furnishing information of the product. *Ms. McBride stated no other licensing authority exempted mail order or unique licensure type with rules and regulations don't require in-state presence and in-home assessment/education/training.* She also stated the Interstate Commerce is being violated by the restriction placed on out of state providers doing business in Tennessee. Ms. McBride also asked

about the use of the statute that allows accreditation to show a facility meets the state's licensure standards. Lynette Towns, OHCF surveyors, stated this provider had numerous deficiencies upon survey. Ms. Tippens stated she found Tennessee has the most stringent HME rules during her research. Mr. Shulman stated this issue has been before this Board in the past. Ms. Tippens stated a rule should be in place to define mail order. Prism Medical Supply's representative addressed the standing committee. He stated the same issue is had with Prism which is the in-home assessment/education/training requirement. He further stated Prism has an open survey due to the application of the current HME rule and IG on delivery. He believes a quick fix of the IG would resolve the issue. A rule indicating qualified to deliver and do assessment on equipment to include the physician making the assessment or a home health agency. A physician statement showing the training should suffice to meet assessment/education/training. A1 Diabetes and Medical Supply next addressed the Board. Lucas Matheny was the representative for this facility. He stated A1 has a CMS contract to provide diabetic equipment. Mr. Matheny stated his agency does not provide the glucose meters and surveyor findings support this. He also stated A1 may provide diabetic test strips. A1 uses a physician attestation statement as Prism does to indicate patients have been educated and trained on their equipment. Mr. Matheny stated that A1 contacts patients seven days after the equipment has been sent. If needed, A1 conferences in the patient's physician to ensure medical needs are met. Mr. Matheny stated A1 Diabetics only provides diabetic meters and supplies these to patients in Tennessee and this has been made clear in past communications with the state agency. Ms. Reed instructed Mr. Matheny to submit a determination for licensure to her office with specific description of the equipment the agency provides. She further stated the OHCF via the survey process had been made informed A1 also provided C-Pap machines which do meet the definition of home medical equipment. A1 stated the National Supplier Clearinghouse (NSC) shows a requirement for licensure when blood glucose meters are a delivered item. Ms. Reed stated she just provided update information to NSC and that blood glucose meters were not indicated as a requirement for a HME license. Ms. Hughes-Toombs stated a change can be made to the IG to address training indicating it does not need to be done by a person. Mr. Marshall asked if the physician attestation holds validity. Ms. McBride stated her client does not deliver products that are complicated such as oxygen concentrators. Dr. Saunders felt the language is written for the sole purpose to have someone instruct a patient in person. OGC recognizes certain equipment is not in the same in the scope of risk. It was stated that TENS units are sold over the counter (OTC). This was verified by A1 and identified as being the same type of machine as ordered by a physician when a licensed HME providers. Mr. Shulman stated OGC has a language recommendation to address. He also stated it is a concern with a patient can go to CVS to buy the same equipment defined as HME in the HME rules. The representative for Prism explained why FDA label for physician order is found on certain equipment and is explicit to physician instruction. He further stated feels the instruction by an agency employee would infringe on this requirement. Ms. Tippens advised the Board that the following items are to be addressed – amend rules to define mail order and waive current regulations for these three providers. Mr. Shulman expressed the need to know what qualifies HMEs to begin sending equipment out to the public. Ms. Tippens stated the FDA approves the equipment for patient use then it gets into the stream of commerce. Mr. Shulman stated there will be some other item to come along that will be designated as medical equipment. It was also stated that the payor source drives what is home medical equipment to some degree. Ms. Tippens stated the Board could follow Alabama's rules on mail order and HME licensure. Ms. Reed asked about the requirement for a physical presence. OGC stated this would still be required, but in-home training would be excluded for mail order providers via the new rule. A1 and Prism stated as a licensed provider in this state their agencies take care of the in-home assessment requirement. Ms. Tippens encouraged the standing committee to adopt the Alabama mail order definition with the exclusion for in-home training.

The discussion on physical location was brought up again regarding mail order. Ms. Tippens assured that the proposed language adopted from Alabama will not remove the licensed physical location that Tennessee requires.

Dr. Saunders made a motion to adopt OGC proposed mail order definition with exclusion for rulemaking; seconded by Mr. Marshall. Ms. Reed asked how to address the three facilities with outstanding deficiencies. The standing committee stated develop an IG to address the issue until rulemaking is concluded and effective. Mail order suppliers of home medical equipment are excluded from in-home training except for those agencies that provide lifesaving equipment such as oxygen and respiratory equipment. Mr. Shulman stated this tables the outstanding deficiencies for the three facilities. **Dr. Saunders made a motion to approve the above stated IG; seconded by Ms. Williford. The motion was approved.**

The standing committee meeting was adjourned.