



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**

Date: August 28, 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: September 14, 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.



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**

**SEPTEMBER 14, 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-July 25, 2017 – Performance Improvement Issue Standing Committee Meeting.
3. Ambulatory Surgical Treatment Center (ASTC) Rules and Regulations 1200-08-10-.01(7)(b) ASTC definition.

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

4. Other Discussion(s).
5. Public Comments.
6. Adjourn.

MINUTES
BOARD FOR LICENSING HEALTH CARE FACILITIES
PERFORMANCE IMPROVEMENT ISSUE (PI) STANDING COMMITTEE MEETING
September 14, 2017

The Board for Licensing Health Care Facilities' Performance Improvement Issue (PI) Standing Committee meeting began on September 14, 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 July 25, 2016 PI Standing Committee meeting minutes. **Dr. Saunders made a motion to approve the minutes; seconded by Ms. Throneberry. The motion was approved.**

The first item for discussion was continuation of the standing committee's deliberation on ambulatory surgical treatment (ASTC) rule, 1200-08-10-.01(7)(b), for the ASTC definition concerning four hours or less under anesthesia. Ann Reed, Director of Licensure, recapped this item from the last PI Standing Committee. She stated the discussion of the last meeting was ongoing concerning a facility which was cited on annual survey for state licensure, but not on the federal survey and additional information was requested and to be provided by the facility representative bringing the issue before the standing committee, Office of General Counsel (OGC), and Gina Throneberry. Patti Cotton, representing Parkwest Plastic Surgery Center, presented to the standing committee. After the last meeting, further work was done including review of the state rules and regulations to determine the inception of the four hour rule. Ms. Cotton stated the rule was originally adopted in 1992. Caroline Tippens, OGC, stated the original rule was actually adopted in 2003. She stated she did a review of the ASTC rule history and has that information. Ms. Tippens gave a background to the federal rules and state rules with the years that amendments were made and the language these included. She indicated in 1982 the federal requirements stated the period following convalescence from a procedure should be no longer than four hours and anesthesia be no longer than 90 minutes. Ms. Tippens stated the former language still exists in the federal requirements, but the method of survey changed looking at different requirements to the expected duration of surgeries to be less than 24 hours. She stated this was codified in Appendix L of the State Operations Manual. Ms. Tippens stated 1977 the Board first had rules for ASTCs. The language did not initially begin with the four hour anesthesia language. In late 1992, an amendment for the 24 hour length of stay was added. In 2000, an amendment was added putting in place a 12 hour duration of stay, but may be longer if approved by attending physician, medical director, or anesthesiologist, but no longer than 24 hours. Ms. Tippens re-stated the current four hour rule language was instituted during a 2003 amendment to the ASTC rules. Ms. Cotton stated she did not do that in depth research, but surrounding states to Tennessee follow the federal requirement of 24 hours

for procedures. Mr. Shulman asked why the current Tennessee rule is in place. Ms. Tippens stated she did not know and could not find public comments when the rule was amended. She further stated the change may have been tied to the 1982 federal requirement and that she spoke with CMS who stated this requirement is still on the books, but not used for survey purposes. Ms. Cotton provided a letter from Covenant Hospital's administrator which indicates a desire for these types of procedures (plastic surgery) to be in an outpatient setting and not in the hospital. She further stated a description of the lengthier surgeries performed at Parkwest Plastic Surgery Center could be provided to standing committee. Ms. Tippens presented the option of an interpretative guideline (IG) and a change in the rule. Ms. Reed interjected agreement with Ms. Tippens rule change statement. At this point, through internal discussion in the Office of Health Care Facilities (OHCF) the recommendation is to follow the federal guidelines for 24 hour procedure time and to change the rule. Dr. Saunders wanted it to be considered that the ASTC rule applies to other types of surgery and stated is it best for patients to be under anesthesia for greater than six hours. She stated no information has been provided by anesthesiologist on the standard of care. Dr. Saunders asked if a general surgeon performing a surgery for eight hours is this something the Board would be comfortable with. Ms. Tippens stated the state rules may be more restrictive than the federal rules; then Ms. Cotton stated the state rules are more restrictive than the federal rules and the focus should be on the 12 hour discharge rule versus the four hour anesthesia requirement. Ms. Cotton stated this rule directly impacts Dr. Smith's practice especially since the hospital will not allow longer plastic surgery procedures to occur there. She stated Dr. Smith has no other alternative. Dr. Saunders stated that is a business decision of the hospital. She further stated the committee was charged with looking at the term 'routinely' in the rule. Ms. Tippens did not want to define routinely due to too many definitions. She further stated a waiver was not a good option even a waiver specific to plastic surgery centers. Ms. Throneberry stated safety is met via consultation of anesthesia and the surgeon. She stated patients are vetted highly before surgery is conducted. She stated decision should be made by the surgeon in consultation with anesthesia per the ASTC's policies and procedures with oversight by the ASTC's governing body. Ms. Throneberry also stated that anesthesia may start prior to the surgical procedures so the four hour clock starts then. She also thinks a waiver of the rule is a bad idea and that a rule change would be best. She stated only two states have the strict four hour rule, Pennsylvania and Tennessee. Mr. Shulman asked why did 48 others make this change and why did the federal rule change. Ms. Throneberry stated some states' chose not to have a requirement like the federal requirement and other states changed their requirements to match the current federal requirement. Ms. Tippens stated based upon her conversation with CMS the change in the federal rule was driven by payment. Mr. Shulman indicated a hearing could be held to determine the safety of the proposed rule change – Tennessee Medical Association, anesthesiologists, physicians, hospitals to testify. Ms. Williford asked if data on safety rates of longer anesthesia times was available. Dr. Smith stated the data shows no correlation of such. He stated numerous articles are out on safety and these state there is better safety in outpatient settings. Dr. Saunders provided a reference to the 2006 JAMA (Journal of American Medical Association) article on facial plastic surgery and that no greater complications were associated with lengthier surgical timeframes. She further stated this is only one article and only one specialty addressed. Dr. Saunders states a hearing may be in order to hear testimony of other providers. She stated another surgeon such as a general surgeon may think the current timeframes are appropriate. Dr. Saunders stated it is not the best practice to take one ASTC's request to apply to all ASTCs that may provide other types of specialties. Dr. Smith stated he is not the spokesperson for all other ASTCs. He stated the ASTC's medical team works together and it is their responsibility to determine and maintain the safety of patients. Dr. Saunders stated the length of time of anesthesia is not a relevant term any longer; it is the entire process that is relevant. Dr. Smith informed the standing committee that his ASTC serves as a training location for an anesthesia school. He stated that other centers and colleagues are performing surgeries longer than four hours and the

reason for being here before the standing committee is due to a deficiency cited during his last state survey. Dr. Smith stated he and Ms. Cotton have not found a rationale for the four hour anesthesia timeframe. Ms. Shulman stated with the information of other plastic surgeons doing the same thing have other ASTCs been cited for this deficiency. Ms. Reed stated no. Mr. Shulman if this were looked at more closely during a survey would there be more citations. Ms. Reed stated if this was a targeted regulation then yes probably. Mr. Shulman stated again that testimony from other physicians and anesthesiologist could address the safety concerns. He stated I would not want your facility to continue to be cited while this group tries to sort this out. Mr. Shulman stated to determine the correct safety parameters testimony by physicians, anesthesiologists, etc. will need to occur. Ms. Tippens again stated to the committee that all the other states have enacted state rules based upon the federal requirements and the CMS representative informed her via e-mail that the change of the federal requirements was based upon payment. Dr. Saunders stated why should state rule language be based upon the federal payment process and its impact on federal rules. Ms. Tippens stated to mirror the federal regulations creates consistency. Dr. Saunders asked how many ASTCs have been cited for this rule over the past 10 years. Ms. Reed stated this could be found by searching the survey system used by the Office of Health Care Facilities and is not aware of this being cited since 2006 which is when Ms. Reed began in this position. Dr. Saunders asked if the facility has submitted a POC. The provider stated yes a POC has been submitted and accepted, but there is still debate over what the term 'routinely' means. The facility could be cited again for this same deficiency as the facility will be surveyed again. Dr. Saunders asked what percentage of Dr. Smith's cases go over the four hour requirement – 30%. Dr. Smith stated this percentage has been consistent over his entire practice. Ms. Tippens stated an IG would be the appropriate way to go at this time for all ASTCs. Mr. Shulman not certain the committee is comfortable with an IG being developed before a hearing is held. Ms. Tippens stated without the IG facilities will continue to be cited under this rule. Dr. Saunders stated set a hearing date for testimony on possible changes to this rule and do not take action on the item at this time. Mr. Shulman asked what will occur to this facility if continued citing of this deficiency. Ms. Reed stated if the facility shows to have continued noncompliance then the facility will ultimately be brought before the full Board for disciplinary action. Mr. Shulman discussed granting a timed waiver. **Dr. Saunders made a motion for the facility to comply with their plan of correction (POC) until a final decision can be made by the full Board and to table the discussion with a full hearing before the committee; seconded by Ms. Williford.** Discussion ensued with Ms. Throneberry asking for (a) of the same rule to be changed. She identified this as also being a problem. Ms. Tippens stated this could be done. Mr. Shulman suggested reviewing the entire rule for needed revisions. Ms. Tippens asked if a surveyor was on the phone and if any thoughts to the issue. The East Tennessee Regional Office (ETRO) Administrator, Tamra Turberville, addressed the committee regarding the citation of this rule for ASTCs. She stated she was not aware of any prohibitions to the four hour requirement, but this was not under her purview. Ms. Turberville stated the issue with 'routinely' was the facility intentionally scheduling surgeries that would take more than four hours. She stated this deficiency is not often cited, but in Parkwest Plastic Surgery's case the surgeries that were greater than four hours were intended to be over four hours evidenced by waivers signed by those patients. She further stated the four hour rule has not historically been a problem. Dr. Saunders asked how surveys are conducted for ASTCs. Ms. Turberville stated a sample of cases conducted in the last six months is chosen for review. Dr. Saunders asked Ms. Turberville if she had a problem with the current rule, she stated no. Ms. Throneberry stated words are being minced, but the time is for duration of anesthesia. Ms. Turberville stated the surveyors pull the pre-operative paperwork which would show the actual anesthesia time. Dr. Smith stated this is getting into an entire outpatient surgery charge and he is not able and nor willing to speak for all ASTCs. It was clarified that Dr. Smith's facility is currently in compliance and will be surveyed at a next annual survey time. Craig Parisher, Facilities Construction Director, suggested a timed waiver for Parkwest Plastic Surgery Center

to protect the facility until the issue is resolved. Mr. Shulman stated this is a good idea as well as Ms. Tippens and Dr. Smith. **Mr. Shulman offered as an amendment to the current motion a timed waiver to allow the routinely four hours or less anesthesia requirement to be waived for six months for Parkwest Plastic Surgery Center.** Dr. Smith stated there is still debate over what 'routinely' means. He stated he has cases scheduled that will go over the four hour requirement. He stated the definition of 'routinely' for the last twenty years was that occasional cases go over the four hour requirement. Dr. Saunders stated Dr. Smith is deliberately scheduling surgeries that require anesthesia for more than four hours and that was the issue with the survey office. Dr. Smith stated the regional office just stated that some cases may go over the four hour anesthesia requirement and meet the 'routinely' term. He also offered again that other plastic surgery centers do go over the four hour anesthesia time requirement. Mr. Shulman stated surveyors can be set loose to find those facilities that do this, but this will be difficult for the surveyors to do. He further stated the Board is now on notice of this occurring in ASTCs performing plastic surgery. Ms. Tippens stated the offered amendment should be removed from the original motion as Dr. Saunders will not support and needs to be done as a separate motion. Mr. Shulman stated the committee is now back to the original motion with Ms. Tippens stating to table Dr. Saunders' motion. **Mr. Shulman made a motion to table the original motion without amendment; 2nd by Ms. Williford. The motion was approved.** **Mr. Shulman made a motion to allow a timed waiver allowing the routinely four hours or less for anesthesia requirement to be waived for six months for Parkwest Plastic Surgery Center; seconded by Ms. Williford. Two yes (Mr. Shulman and Ms. Williford) votes and one no (Dr. Saunders) vote. The motion was approved.** **Mr. Shulman made another motion to conduct a hearing before the standing committee to address ASTC rule 1200-08-10-.01(7)(a-c) within three months; seconded by Ms. Williford. The motion was approved.** Ms. Throneberry did not vote on any aspect of this discussion.

The standing committee meeting was adjourned.