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TENNESSEE DEPARTMENT OF HEALTH MEMORANDUM

Date: November 6, 2020

To: Shelley Walker, Director of Communications 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

Date of Meeting: December 2, 2020

Time: 9:00 a.m., Central Time

Place: Iris Conference Room

665 Mainstream Drive, First Floor

Nashville, TN 37243

WebEx Event: Due to COVID-19 considerations, please join us in our virtual meeting which is open to the public

using the instructions below.

During the meeting, please join using the information below:

Join online as an attendee:

Meeting Link:

https://tngov.webex.com/tngov/onstage/g.php?MTID=ef884c0159d7ae9305ab3857059557f6b

Join online as a panelist:

https://tngov.webex.com/tngov/onstage/g.php?MTID=e2a65cca0c5d437e6f0972242c0b1b33e

Event Number: 178 388 5244

Event Password: HCF2020

Join the meeting audio conference only

To join the meeting telephonically call the number below and enter the access code.

US TOLL +1-415-655-0003

Event number/Access code: 178 388 5244

Major Item(s) on Agenda: See Attached Agenda

Board members will be participating by WebEx Event.

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 WEBEX MEETING

DECEMBER 2, 2020

IRIS 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. CoPEC Final Draft of Pediatric Emergency Care Facilities Rules-Chapter 1200-08-30 for Board Approval.
 - **REPRESENTATIVE(S):** Natasha Kurth, Executive Director and Dr. Kevin Brinkmann Children's Emergency Care Alliance of Tennessee (CECA TN)
- 3. DIDD Submission of Interpretative Guideline for PSS Agency Survey.
 - **REPRESENTATIVE(S):** Karen Wills, Director, Therapeutic Services Office of Clinical Services
- 4. Home Medical Equipment Licensure Requirement
 - **REPRESENTATIVE(S):** David Baxter, President, Baxter Management

5. Request Rule Changes for Ambulatory Surgery Treatment Centers according to CMS changes.

REPRESENTATIVE(S): Judy Eads, RN Consultant Key Management Associates, LLC

6. Skilled Nursing Facility Drug Disposal According to Tennessee Code Annotated §68-11-241.

REPRESENTATIVE(S): Wanda Lingner, Director, Regulatory Compliance Sharps Compliance, Inc.

7. Statutory CMPs for Unlicensed Facilities according to Tennessee Code Annotated § 68-11-213(i)(1).

REPRESENTATIVE(S): Caroline Tippens, Senior Associate General Counsel, Office of General

- 8. Public Comments.
- 9. Adjourn.

MINUTES

BOARD FOR LICENSING HEALTH CARE FACILITIES

PERFORMANCE ISSUE STANDING COMMITTEE MEETING

DECEMBER 2, 2020

The Board for Licensing Health Care facilities meeting began on December 2, 2020. Mr. Shulman, chair, called the meeting to order.

A quorum roll call vote was taken:

Mr. Louis Caputo – here

Dr. Patricia Ketterman – here

Dr. René Saunders - not here

Mr. Jim Shulman - here

Ms. Gina Throneberry – here (arrived at approximately 9:20am)

Ms. Janet Williford – here

A roll call vote was taken if each board member was able to hear the response given to the roll call:

Mr. Louis Caputo – yes

Dr. Patricia Ketterman – yes

Dr. René Saunders – not here

Mr. Jim Shulman – yes

Ms. Gina Throneberry – yes (arrived at approximately 9:20am)

Ms. Janet Williford – yes

The first item on the agenda was the DIDD submission of an Interpretative Guideline for PSS agency survey. Karen Wills, Director, Therapeutic Services, Office of Clinical Services, was the representative for this item. Ms. Wills spoke to the duplicative surveys mentioned in T.C.A. that Ms. Tippens provided her. Ms. Wills provided further explained DIDDS completes annual quality survey of those providers in the DIDDS program. She stated the survey covers ten (10) domains including health, billing, etc. Ms. Wills stated this survey is announced but the 10% sample reviewed is unannounced. Ms. Tippens emphasized the T.C.A. portion regarding unannounced surveys is law and that a MOU with DIDDS could be developed regarding surveying. Mr. Shulman sought clarification that surveys are completed by both DIDDS and TDH. Ms. Tippens stated two different set of requirements are used in during these respective surveys. She further referenced and summarized case law on unannounced surveys. Mr. Shulman further stated there must be a more efficient process available. He asked Ms. Tippens if this is a problem with other licensed entities. She stated the HME licensure type. The East Tennessee Regional Office (ETRO) staff's thoughts to this process were sought. The regional office stated this is a problem with some of the PSS agencies especially the smaller individually operated agencies. Ms. Wills confirmed the statement made by the ETRO. She further stated DIDDS can do unannounced surveys at any time just as TDH can. Ms. Wills feels if the details of DIDDS and TDH surveys were looked at overlap would be found. Ms. Ketterman asked Ms. Wills what she thinks will work in this situation. Ms. Wills stated she talked with providers and a window of time for survey would be a reasonable process with allowances for extenuating circumstances. Additionally, Ms. Wills indicating looking at the DIDD survey

as a stand in for TDH's annual survey. Ms. Ketterman asked the health surveyors their thoughts. Vincent Davis, Director of the Office of Health Care Facilities, asked the ETRO surveyors to respond. The ETRO stated surveyors work from a schedule, reach out to providers to schedule a survey, and do take some on a case by case basis due to extenuating circumstances. Mr. Davis asked how this would work for a complaint. The regional office representative stated not many complaints are received on PSS agencies. There was discussion regarding establishment of a process to set-up an unannounced survey visit and if a provider is not available develop a procedure to address which is more useful of everyone's time. Ms. Tippens urged the standing committee members to think about precedent with this issue. Mr. Caputo stated this was a difficult situation and voiced concern over establishing a precedent. He also asked if this would expand to other license types. All standing committee member concurred with Mr. Caputo's sentiment. Mr. Shulman recognized if this is not addressed then will continue to be a problem. Ms. Tippens cautioned to tread lightly and to address each situation on a case by case basis. Mr. Shulman stated the committee's recommendation is for no action to be taken at this time. The response to the full Board will include that the item was reviewed, there was concern of setting a precedent, and it will be monitored in the future.

The second item for discussion was the Home Medical Equipment licensure requirement. Mr. David Baxter, President Baxter Management, was the representative for this item. He spoke to the prescription for dispensing and a lot of HME products without this. He requested that he'd like to tie in to the NSC standards for home medical equipment (HME) provider requirements. Mr. Shulman asked Ms. Tippens if they could be on NSC standards and not have TN licensure. Mr. Baxter stated that other states have adopted the NSC requirements. He further focused on the mail order requirements for HME providers. Ms. Tippens stated that the Board adopted rules and regulations to allow mail order within the definition in the HME rules and regs. Mr. Shulman asked if HME rules and regulations been compared to other states. Ms. Tippens stated these regulations were last updated in 2019 with the mail order language added around 2017. Mr. Shulman recognized this as a complicated issue with many technology changes affecting this licensure type. Ms. Tippens focused the discussion on the item at hand which was to adopt NSC standards. Committee members had additional questions. Mr. Shulman stated the committee needs to dig further to determine a need for changes to the HME rules and regulations. Mr. Baxter stated the physical location requirement was put in place to protect Tennessee based companies. Mr. Shulman asked who would lead a discussion on HME statutory history and rule history. Ms. Tippens stated a task force could be developed to include all interested parties and would require a sunshine notice. Ms. Shulman asked about convening with a smaller group then move to a larger task force. Ms. Tippens again encouraged the committee to remain focused on the issue at hand. Mr. Shulman addressed members stating he doesn't know enough to decide today. He asked the members of the committee their thoughts. They collectively decided nothing to be done at this time. Mr. Shulman asked if a taskforce would be helpful for this item. He stated he and Ms. Tippens could work together to look at the issue then bring back their findings to the committee for a second look. All agreed that the issue needs more information and would be willing to be on a taskforce to further discuss this item and to keep the item on the PI Standing Committee agenda.

The third item on the agenda was the request for rule changes to the ambulatory surgical treatment center (ASTC) regulations according to recent CMS changes. Ms. Judy Eads was the representative for this item. Paige Proffitt, Michael Powers, and Mike Bivens representing the Tennessee Ambulatory Surgery Center Association (TASCA) also addressed the Board on this item. Ms. Eads summarized the request to align the state licensing regulations with CMS regulations. Mr. Shulman asked if a change in state regulations had to occur. Ms. Eads stated it did not. She indicated when she worked with the state the goal was to align state regulations with federal regulations. Ms. Eads further stated she did

not work with CMS on this regulatory change. She indicated that TASCA worked with CMS. Ms. Eads stated this change would be helpful in the accreditation process. Ms. Proffitt with TASCA stated accrediting bodies regulate hospital transfer agreements and privileges of MDs at hospitals. She referenced the one-page document provided to the Board. Ms. Proffitt stated that Tennessee would be the first to make state licensure changes if this is approved by the Board. She requested that the committee not to make changes at this time as this keeps the state licensure regulations aligned with the accrediting bodies' requirements. Mr. Powers, TASCA Board member, stated that it would be burdensome to make changes to transfer agreements as there are processes in place. A change in the history and physical requirements would also be burdensome if implemented. Mr. Shulman asked why these changes were made at the federal level. Ms. Proffitt stated these changes relieve burden on administration and providers. Ms. Eads pointed out the CMS history and physical changes do not eliminate the facility assessing a patient prior to survey. Mr. Shulman stated the consensus of the standing committee was for no changes to be made to the ASTC rules and regulations.

The fourth item for discussion was the Skilled Nursing Facility Drug Disposal according to TCA 68-11-241. Ms. Wanda Lingner, Ms. Kathryn Kane-Neilson and Ms. Lindsey Murrile-Hawkins of Sharps Compliance, Inc. were the representatives for the item. Ms. Linguer had concern regarding the destruction language in the Nursing Homes rules because the bin isn't destroyed on the Nursing Home site. Ms. Lingner asked if a statement could be made to confirm that the disposal and destruction/destroy are same in meaning. Ms. Tippens stated that the terms are used interchangeably. Ms. Lingner asked if a statement could be given confirming the terms disposal and destruction/destroy convey the same meaning as they have nursing home customers with concern, they would not meet the nursing home rule if a disposal bin/box is used. Mr. Puri spoke to the item. He spoke of the provision in the federal requirements allowing collection receptacles in long-term care facilities which includes disposal receptacles. Mr. Puri stated from THCA's perspective this is an issue of wording. His presentation of the following recommendation, for purposes of compliance placement of unused drugs in a closed system meets the language of the current rule, is on behalf of THCA. Dr. Ketterman asked who surveys this and Ms. Reed stated that the state surveys nursing homes per the rule regarding destroy vs disposal. Mr. Puri stated the DEA does a thorough survey of entities providing the disposal/destruction bin. Dr. Ketterman asked if an IG could be drafted for this. Ms. Tippens agreed with the language and to have the IG state that it meets language of destroyed on premises. Mr. Puri added to the IG that it isn't a requirement to have a disposal system. Dr. Ketterman made a motion to have an IG drafted for Nursing Home rule 1200-08-06-.06(6)(o); Ms. Williford seconded.

A roll call vote was taken:

Mr. Caputo – yes Dr. Ketterman – yes Dr. Saunders – yes Mr. Shulman – yes Ms. Throneberry – yes Ms. Williford – yes

The motion was approved.

The fifth item for discussion was consideration of statutory CMPs for unlicensed facilities according to TCA §68-11-213(i)(1). Ms. Tippens presented the item. She asked for an interpretation of the CMP to be assessed. Is the intent of the statute to be \$5,000 max for a penalty of operating an unlicensed facility

or \$5,000 per day. Ms. Tippens stated that the Attorney General's office asked for this to be opined by the Board. Mr. Shulman asked if there was a document to be referenced. Ms. Tippens stated that she could develop an IG per the Board vote/decision. Ms. Ketterman interprets as a daily fine up to \$5,000. All members agreed with her interpretation. Ms. Ketterman made a motion that each day of violation is a fine up to \$5,000 per day; Ms. Williford seconded.

A roll call vote was taken:

Mr. Caputo – yes Dr. Ketterman – yes Dr. Saunders – yes Mr. Shulman – yes Ms. Throneberry – yes Ms. Williford – yes

The motion was approved.

The last item for discussion was the waiver of late fees for Fresenius Kidney Care Community Dialysis (ESRD #255). Ms. Reed gave the background of the facility's request. The rationale for the facility's request to waive the late fee was due to the effects of Hurricane Zeta. Mr. Caputo made a motion to waive the late fees for the facility due to Hurricane Zeta; Ms. Williford seconded.

A roll call vote was taken:

Mr. Caputo – yes Dr. Ketterman – yes Dr. Saunders – yes Mr. Shulman – yes Ms. Throneberry – yes Ms. Williford – yes

The motion was approved.

Ms. Tippens made the standing committee members aware of a possible need for a December Board meeting in order to hear items around the everchanging COVID-19 situation.

The meeting was adjourned.