

## **DRAFT MINUTES**

Agency for Health Care Administration (AHCA)

Pediatric Cardiac Technical Advisory Panel (PCTAP or Advisory Panel)

Date: July 30, 2020

Time: 5:00 – 6:30 PM EST

Location: Online Webinar

**Members Present:** Mel Almodovar, MD, Alfred Asante-Korang, MD; Kak Chen-Chan, MD; Renato Dubois, MD; Eric Eason, MD; Jose Etedgui, MD; Robert Hannan, MD; Joel Hardin, MD; Jorge McCormack, MD; David Nykanen, MD; Karl Reyes, MD; Jeremy Ringewald, MD; Monica Sanford, APRN; Frank Scholl, MD; Michael Shillingford, MD;

**Staff Present:** Molly McKinstry, Deputy Secretary; Jack Plagge, Manager Outpatient Services Unit; Bill Roberts, AHCA Deputy General Counsel; Nikole Helvey, AHCA Bureau Chief, Florida Center for Health Information and Transparency (Florida Center); Patricia Vidal, Data Dissemination and Communication Manager; Jess Hand and Andrea Bonavia, Florida Center.

**Interested Parties:** Bill Blanchard, MD; Gerold Schiebler, MD; Janet Kreutzer; Jason Rodriguez; Anthony Rossi, MD.

**Call to Order, Welcome and Roll Call:** Dr. David Nykanen welcomed the members, called roll and called the meeting to order.

**Review and Approve February 20, 2020 Full Panel Meeting Minutes:** Dr. Nykanen motioned to approve the minutes. Dr. Schiebler recommended two changes be made. The motion was seconded, and the minutes approved.

### **Rule Workshop Comments:**

Dr. David Nykanen opened the discussion regarding the Table of Contents developed by AHCA staff from the 59A-3.248 Rule Workshop in March 2020. Dr. Nykanen asked for guidance regarding the process of the Rule from AHCA staff. Mr. Jack Plagge, Manager Outpatient Services Unit, provided a description of the Table of Contents and the Agency's formulated responses. Dr. Nykanen asked the members if they would like to proceed with the review of the Table of Contents. Dr. Frank Scholl stated that many of the members were not able to attend the Rule Workshop and suggested additional time be given for each member to thoroughly review the Table of Contents. In addition, Dr. Scholl asked if the members needed to accept the Agency's formulated responses in this meeting and what were the next steps being asked of the Panel. Dr. Scholl requested additional time be given if the members need to provide an acceptance or recommendations to the Agency's responses. Dr. Nykanen and Dr. Michael Shillingford agreed. Deputy Secretary Molly McKinstry stated that the comment responses are recommendations of the Agency, however, feedback regarding the agreeance on, or alterations of, the responses from the Panel are welcomed. Ms. McKinstry stated that once member feedback is provided, the Agency would need to review the feedback and consider how it may

change the Rule. Dr. Gerold Schiebler asked what the most expeditious, appropriate method would be for this process. Ms. McKinstry responded if the Panel is comfortable with the Agency's comment responses and a motion was made to accept them and to proceed; this would be the fastest processes. Ms. McKinstry stated that if the Panel finds issues with some of the responses and would like to provide recommendations, and there is a concurrence to move forward with the recommended changes, that this process would take longer. However, the Agency wants to ensure that the Rule reflects the Panel's intentions. The members and AHCA staff discussed further processes of the Rule. Dr. Nykanen suggested the next full panel meeting be dedicated to the complete review of the Agency's comment responses in the Table of Contents and requested Agency staff provide the members a current copy of the rule as it is written. Dr. Scholl and Dr. Blanchard agreed. Ms. McKinstry recommended also providing the members with the draft rule containing the language changes from the Table of Contents for comparison. Dr. Nykanen agreed and stated that having the comment references from the rule would be useful. The members and AHCA staff agreed on a tentative timeframe of three weeks for the next Panel meeting.

#### **Full Panel Updates:**

**STS:** Dr. Nykanen discussed the status of the STS contracting and stated that STS has yet to provide a budget estimate for the 2019 to 2020 Florida regional based data report, or a 2021 report for the next congenital harvest. Dr. Nykanen stated that development of a contract between STS and the State of Florida may be a long process. Dr. Nykanen also stated that the contract will require each Florida program to sign an agreement to participate in the regional reporting. Dr. Scholl asked if the report format previously agreed upon would still be consistent with the Pennsylvania report. Ms. Nikole Helvey responded that information was correct and that the report format has not changed but that STS is still transitioning into their new data warehouse. Members discussed STS new data reporting methods. Dr. Nykanen requested to keep STS as a standing agenda item until further updates from STS are provided.

**2019 Annual Report:** Dr. Nykanen updated the Panel on the submission of the 2019 Pediatric Cardiac Technical Advisory Panel Annual Report.

#### **Term Limits:**

Dr. Nykanen mentioned Senator Harrell's letter to Secretary Mayhew regarding the interpretation of term limits. Dr. Nykanen stated the intent of the alternate member position was to be a learning position to prepare for when the voting member's terms were fulfilled. Members and AHCA staff discussed term limit language meaning. Ms. McKinstry stated that the Agency is actively working to navigate the intent of the term limit language with the General Counsel office within the Agency's authority within the Statute. Dr. Blanchard stated that the motive of the Panel regarding term limits is to ensure there is continued experience within the primary voters of the Panel. Dr. Nykanen requested for clarity regarding term limits at the next full panel meeting.

### **Site Visits Discussion:**

Dr. Nykanen needed to leave the meeting and Dr. Scholl stepped into the role of Chair. Dr. Scholl asked whether site visits and sovereign immunity comply with the Sunshine Rule. Dr. Schiebler discussed the options for virtual site visits due to the current COVID-19 pandemic. Members discussed site visits and virtual site visits. Dr. Scholl asked for Ms. McKinstry to comment on the topic of site visits. Ms. McKinstry stated that the Secretary is supportive in proceeding, but would like to understand what the content of the site visit would be, the length of visits, the expected outcomes, the expected composition of the visit – is it a single person or multiple persons, how would the Agency be able to communicate and understand what the visit means, and a schedule of site visits. Dr. Scholl requested that at the next full panel meeting (before addressing Rule comments) to have a vote on two items: 1) Adopt the site visits workflow algorithm, and 2) The site visits schedule. Dr. Scholl suggested Dr. Blanchard lead the effort to standardize the site visits and inform AHCA staff and the Secretary of the intent. Dr. Blanchard agreed to gather the information.

**Neonatal Pulse Oximetry:** Dr. Schiebler mentioned Dr. Mark Hudak is now head of a committee to improve data collection for the neonatal pulse oximetry protocol. Dr. Schiebler stated that Dr. Gul Dadlani was appointed as a committee member and should be asked what the progress is on the reporting. Dr. Scholl asked AHCA staff if a quarterly report and representation from this new committee can be provided as outlined by Dr. Schiebler. Ms. McKinstry stated that if the Panel would like a request to come from the PCTAP, AHCA staff can work on a letter on behalf of Dr. Nykanen as the Chair. Ms. McKinstry stated that in terms of AHCA participation, AHCA staff will need to contact CMS to understand what would be involved in this process. Dr. Blanchard asked AHCA staff if the Agency will include the PCTAP fiscal budget needs in the next session. Ms. McKinstry stated she would present this request to the Secretary.

Dr. Jeremy Ringwald asked if the site visit forms were updated. Members discussed site visit materials and methods of material development. Dr. Scholl asked for the members willing to help in material development to email Dr. Blanchard for assignments. Dr. Scholl request that an update regarding the material development be present at the next PCTAP meeting.

**Public Comment:** There was no public comments.

### **Meeting Summary**

#### **Member Action Items:**

- Members will complete the following:
  - Dr. Blanchard will gather information on standardizing site visits
  - Members willing to assist in the development of site visits material will email Dr. Blanchard for assignments.
  - Vote at the next meeting to:
    - Adopt the site visit workflow algorithm
    - Adopt the site visits schedule

**Agency Action Items:**

- Members requested Agency staff speak with Secretary Mayhew regarding the following:
  - Present fiscal budgetary request
- Agency staff will circulate the current copy of the Rule
- Agency staff will circulate the revised copy of the Rule with new language from the Rule Workshop
- Agency staff will formulate a request letter to CMS new committee on behalf of Dr. Nykanen.
- Members requested Agency staff maintain STS update as a standing agenda item
- Members requested Agency staff add to the agenda of the next full panel meeting:
  - Clarity on term limits.
  - Site visit material be presented by Dr. Blanchard.

**Adjournment:** Dr. Scholl adjourned the meeting at 6:01 PM