

DRAFT MINUTES

Agency for Health Care Administration (AHCA)

Pediatric Cardiology Technical Advisory Panel (PCTAP or Advisory Panel)

Date: December 13, 2018

Time: 5:30-6:30 P.M. EST

Location: Online Webinar

Members Present: Eric Ceithaml, MD; Eric Eason, MD; Joel Hardin, MD; Kristine Guleserian, MD; David Nykanen, MD; Jeremy Ringewald, MD; Frank Pigula, MD; Frank Scholl, MD; Peter Wearden, MD; Kak Chen Chan, MD; Eliot Rosenkranz, MD; Gul Dadlani, MD; Sathuriman Swaminathan, MD;

Staff Present: Jack Plagge, Manager Outpatient Services Unit; Nikole Helvey, AHCA Bureau Chief, Florida Center for Health Information and Transparency (Florida Center); Patricia Vidal, Data Dissemination and Communication Manager; Jess Hand and Carolyn Everett, Florida Center.

Interested Parties: Gerold Schiebler, MD; Bill Blanchard, MD; Tony Rossi, MD; Ron Kanter, MD; Curt DeGross, MD; Jeffrey Jacobs, 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 November 29, 2018 PCTAP Meeting Minutes: Dr. Gerold Schiebler submitted to the Agency a list of corrections pertaining to the November 29, 2018 meeting minutes. Dr. Nykanen motioned to approve the minutes with the changes included. The motion was seconded and the minutes approved.

PCTAP Discussion:

Dr. Jeff Jacobs expressed his gratitude and dedication to the Panel and stated his appreciation for his seven years serving as panel Chair. Dr. Jacobs ceded the floor to Vice Chair Dr. David Nykanen to Chair the meeting.

STS Letter Update

Ms. Nikole Helvey stated that the Agency staff submitted a letter to The Society of Thoracic Surgeons (STS) (per Panel discussion) and received an informal email response requesting more details regarding how the data should be displayed. Staff agreed to write up a more detailed request and submit this request to STS for a detailed cost analysis. Dr. Schiebler suggested PCTAP members be in attendance on calls with STS. Dr. Nykanen, Dr. Scholl, Dr. Wearden, Dr. Langley and Dr. McCormack all agreed to participate in the STS calls. Members requested that Agency staff re-circulate the previous STS letter to members. Panel members also requested that Agency staff contact the aforementioned members for participation in any upcoming STS meetings.

Volume Document Discussion

Ms. Patricia Vidal stated that there were only three responses to the working document approval survey submitted to members. Ms. Vidal stated that one of the survey comments indicated an unwillingness to approve the document before all edits were completed. Dr. Nykanen led a discussion of the electrophysiology and cardiac catheterization volume standards. Dr. Schiebler noted that during previous discussions members suggested a cardiac catheterization volume standard of 100 cases, of which 50 cases would be interventional (except for myocardial biopsies). Dr. Schiebler also stated that volume standards previously suggested by Dr. McCormack and Dr. Kanter were 30 electrophysiology cases, of which 18 would be ablations. Dr. Langley asked what data, if any, formed the basis of the catheterization volume numbers. Dr. Nykanen clarified that no significant data exists that recommends a certain volume standard for cardiac catheterization. Dr. McCormack added that the situation is similar for electrophysiology volume data, which is based upon a survey query of electrophysiologists conducted by the Pediatric Electrophysiology Society. Dr. Eason inquired about the data obtained from IMPACT on complication rates and radiation times. Dr. Nykanen responded that a letter has not been sent yet to the American College of Cardiology (ACC) but that more work will be done on catheterization data at a future meeting.

Dr. Nykanen stated he created a list of suggested data parameters that he would like to share the list with members of the PCTAP in advance of the next meeting. Dr. Wearden and Dr. Nykanen discussed whether there should be a volume requirement for cardiac catheterization in the working document. Dr. Wearden noted that selecting a number that is not based on scientific data could be problematic. Dr. Schiebler noted that Certificate of Need (CON) legislation includes volume requirements for other measures and that legislation tends to support volume standards. Dr. Nykanen noted that volume is a widely used measure within the cardiac community. Dr. Wearden responded that he supported publishing volume, but was concerned with assigning quality interpretations of volume that is not based on scientific data. Dr. McCormack expressed concern for the star rating system review voted upon at the previous (11/29) meeting since it depends on external review. Dr. Wearden responded that the star system would be based on scientific data and Dr. Nykanen noted the star system is not a ranking system. Dr. Nykanen called for a motion on volume standards for cardiac catheterization laboratory as follows: cardiac catheterization volume standard of 100 cases of which 50 cases are interventional (except for myocardial biopsies); and an electrophysiology volume standard of 30 cases of which 18 are ablations. Dr. McCormack seconded the motion and a roll call vote was taken by Agency staff. The results of the vote were eight in favor and three opposed (Dr. Wearden, Dr. Langley and Dr. Eason). One seat did not have a representative present (Nicklaus Children's Hospital). The motion passed with a majority vote.

Dr. Schiebler requested that on line 86 the word "finding" be plural so that the line reads "annual findings".

Dr. Schiebler requested the working document include the sovereign immunity language he previously submitted to the Agency. Dr. Scholl made a motion to include this language and there were no votes opposed.

Dr. Scholl made a motion to include regularly scheduled site visits in the working document. Dr. McCormack and Dr. Blanchard stated support for the inclusion of site visit language in the working document. Dr. Nykanen proposed a motion that the site visit committee consist of (at minimum) a non-invasive pediatric cardiologist, an invasive pediatric cardiologist and a pediatric cardiac surgeon, all of whom practice in Florida. Dr. Scholl suggested that the language for the site visit motion be as follows: that site visits should occur at least every three years for each pediatric cardiac surgery program in Florida; that the site visit be conducted by a team that consists of multidisciplinary professionals licensed to practice within the state; and that this multidisciplinary team be proposed by the Chair and/or vice chair of the PCTAP. Dr. McCormack seconded the motion. Dr. Wearden stated that although he is not opposed to site visits, he is concerned that competitors regulating each other could be problematic. Dr. Nykanen and Dr. Schiebler responded that the panel went to great lengths in the past to make sure direct competitors were not involved in one another's site reviews. Dr. Langley asked why members of the site review panel must be from within the state. Dr. Scholl clarified that these are not paid visits and it is impractical to include out-of-state participants. Dr. Langley asked for clarification as to how site visits differ from the STS review. Dr. Scholl clarified that STS is only auditing surgical data for accuracy, whereas site visits are comprised of a multidisciplinary team of professionals who would tour a facility and review cases for educational and collaborative purposes.

Dr. Schiebler stated that he could like to include language in the document which states that the Panel will propose a budget each year to fund the expenses of the panel. Dr. Nykanen agreed that this language should be included in the document. There were no objections.

Dr. Schiebler noted that the statute is silent on the appointment of alternates for the at-large members and proposed that language be included in the document requesting the Secretary appoint alternates to the three at-large members. There were no objections.

Dr. Nykanen summarized the meeting: He stated that the volume for catheterization and electrophysiology had been decided; surgical volume will be measured using the 2 star system voted upon during the 11/29 meeting; language concerning sovereign immunity, site visits and budgetary requests and alternates for at-large members will be included in the document. Dr. Nykanen asked Agency staff to work with him on the draft working document to circulate to members prior to the next meeting. Dr. Schiebler asked that the agenda for the next meeting include an election of a permanent new Chair and Vice Chair (action item). Dr. Nykanen requested that nominations be submitted to pctap@ahca.myflorida.com.

Nominations were made during the meeting as follows: Dr. Nykanen stated his willingness to serve as Chair. Dr. Scholl nominated Nykanen as Chair and this nomination was seconded. Dr.

Nykanen recommended Dr. Scholl as Vice Chair and Dr. Ceithaml seconded the recommendation. Members agreed to make additional recommendations via email as previously stated. Members agreed that they will vote on the Chair and Vice Chair at the next publicly scheduled meeting.

Ms. Helvey noted that the next meeting will likely be at the end of January and a doodle poll will be circulated to members to select a date. Dr. Nykanen stated he would like to finalize the working document and elect the next leadership at the next meeting.

Public Comment: Dr. Scholl stated his personal thanks to Dr. Jacobs for his work and dedication to the PCTAP as a member and as Chair. Dr. Scholl noted that Dr. Jacobs' hard work has benefitted the children of Florida. Dr. Blanchard agreed and affirmed his gratitude to Dr. Jacobs as a champion of transparency in Florida.

Member Summary:

- Dr. Nykanen will submit to Agency staff the list of suggested data parameters that he would like Agency staff to share with members of the PCTAP in advance of the next meeting.
- Members will submit recommendations for Chair and Vice Chair to the pctap@ahca.myflorida.com inbox.

Agency Next Steps:

- Agency staff will apply Dr. Schiebler's edits to the November 29, 2018 meeting minutes
- Agency staff will add Dr. Bill Pietra and Dr. Langley to the list of attendees
- Agency Staff will add Dr. Pietra's comments to Dr. Scholl's discussion on 2-star system to say he thinks the document will need to include some volume standards but supports the 2-star system discussed at the November 29, 2018 meeting minutes.
- Agency staff will forward the 11/29/2018 meeting minutes to Dr. Eason
- Agency staff agreed to circulate the letter sent to STS to PCTAP members.
- Agency staff will edit the working document to include volume standards for cardiac catheterization laboratory as follows: cardiac catheterization volume standard of 100 cases of which 50 cases are interventional (except for myocardial biopsies); and an electrophysiology volume standard of 30 cases of which 18 are ablations.
- Agency staff will edit line 86 of the working document so that the word "finding" is plural and reads "annual findings".
- Agency staff will add to the Working Document the language previously submitted by Dr. Schiebler concerning sovereign immunity, a budgetary proposal for PCTAP, and at-large alternates
- Agency staff will add to the working document the language concerning site visits approved during the meeting.
- Agency staff will work with Dr. Nykanen on a draft of the Working Document to circulate to members prior to the next meeting.

- Agency staff will include a vote for the Chair and Vice Chair on the agenda for the next meeting.
- Agency staff will circulate a Doodle Poll with proposed dates for the next meeting in January.
- Agency staff will include the finalization of the working document and the election of a new chair and vice chair on the agenda for the next meeting.

Adjourn: Dr. Nykanen adjourned the meeting at 6:34 p.m.

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