

DRAFT MINUTES

Agency for Health Care Administration (AHCA)

Pediatric Cardiac Technical Advisory Panel (PCTAP or Advisory Panel)

Date: October 15, 2019

Time: 5:00 – 6:30 PM EST

Location: Online Webinar

Members Present: Mel Almodovar, MD; Alfred Asante-Korang, MD; Kak Chen-Chan, MD; Gul Dadlani, MD; Eric Eason, MD; Joel Hardin, MD; David Nykanen, MD; Biagio Pietra, MD; Frank Pigula, MD; Frank Scholl, 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; and Jess Hand, Florida Center.

Interested Parties: Bill Blanchard, MD; Gerold Schiebler, MD; Janet Kreutzer

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

PCTAP Rule and Update Discussion

Florida Center Bureau Chief Nikole Helvey invited questions from members regarding the revised draft rule circulated to the members. Dr. Nykanen noted the following changes:

On page three, item five: the term “cardiovascular revascularization” does not apply to pediatric patients and should be deleted.

Page eight, item four regarding cardiac surgical outcomes, the panel previously agreed to no longer use star ratings. Dr. Scholl suggested this section should simply state “...publish cardiac surgical outcomes to the public on the Society of Thoracic Surgeons website” and not add any further information that may ultimately be changed by the STS. Dr. Eason objected, stating that removing this measure will remove one of the only quality measures from the document and weaken its helpfulness to the public. Dr. Nykanen asked whether the Agency needs specific measures in this rule in order to identify underperforming programs. Mr. Plagge responded that the Agency has the statutory authority to investigate any program for any reason at any time. Members discussed the role of the Panel in investigations and the importance of publicly reported data. Dr. Scholl suggested the rule require that all program data go to the Panel for review. Ms. McKinstry clarified that the rule determines licensure, not the activities of the Panel.

Dr. Asante-Korang suggested a time limit be added to page one item (a). Ms. McKinstry added that there is already rule language regarding licensure that sets a one-year requirement for this clause. Dr. Asante-Korang stated his concern that two years would be a better time limit for new programs to ramp up and meet the rule expectations. Dr. Nykanen responded that there is precedent for placing underperforming programs on probation, rather than removing their license. Ms. McKinstry added that in enforcement, there may be opportunities for flexibility based on extenuating circumstances. Dr. Scholl stated it is important to set a bar and help programs meet that standard and not modify the current language. Dr. Schiebler and Dr. Nykanen agreed it is important the committee not make exceptions in rule to accommodate circumstances of existing member programs. Dr. Hardin stated that the purpose of the committee is not to ensure the survival of any program, but to ensure compliance to standards of care. Dr. Asante-Korang clarified their program hired a surgeon who will begin in February and they will need time to ramp up. Members discussed compliance with the draft rule standards. Ms. McKinstry stated that it will take approximately six months for the rule making to be adopted, and the rule goes into effect upon adoption of the rule.

Dr. Asante-Korang suggested adding to Enforcement (8) that it be added the Agency provide a “reasonable amount of time” clause. Ms. McKinstry provided an overview of 408.811 outlining the Agency’s licensure and inspection policy. Dr. Asante-Korang requested a change to Page 1 item 2 (C) by changing “continue to be met” to “be met” and the effective date changed. Ms. McKinstry responded that programs have a year to come into compliance. Dr. Nykanen argued against changing the deadlines in the draft rule.

Dr. Schiebler asked whether the draft rule has a section on heart lung transplantation. Mr. Plagge noted that transplantation is a separate rule with requirements for adult and pediatrics. Dr. Blanchard requested that a copy of this rule be sent to the members for comment. Mr. Plagge stated he would route the draft through Agency management for approval to circulate.

Surgical Volume Discussion

Members discussed the minimum surgical volume number to be put into rule for pediatric congenital heart programs. Dr. Hardin motioned for the threshold to be set at 100, and members seconded the motion. The members voted as follows:

Arnold Palmer Hospital for Children	David Nykanen, MD, Chair	YES
	William M. DeCampli, MD - <i>Alternate</i>	
AdventHealth for Children(Formerly Florida Hospital for Children)	Frank Pigula, MD	NO
	Bhavya Trivedi, MD - <i>Alternate</i>	
Holtz Children's Hospital	Melvin C. Almodovar	No Representative Attended
	Sethuraman Swaminathan, MD - <i>Alternate</i>	
Joe Dimaggio Children's Hospital	Frank Scholl, MD Vice Chair	YES
	Kak Chen Chan, MD - <i>Alternate</i>	
Johns Hopkins All Children's Hospital	Alfred Asante-Korang, MD	NO
	Jamie Decker, MD - <i>Alternate</i>	
Nicklaus Children's Health System	Redmond Burke, MD	No Representative Attended
Nemours Children's Hospital	Peter Wearden, MD	No Representative Attended
	Gul H. Dadlani, MD - <i>Alternate</i>	
St. Joseph's Children's Hospital	Stephen Langley, MD	YES
	Jeremy Ringewald, MD	
UF Health Shands Children's Hospital	Mark S. Bleiweis, MD	YES
	Biagio Pietra, MD - <i>Alternate</i>	
Wolfson Children's Hospital	Jose' Etedgui, MD	
	Michael Shillingford, MD	YES
At-Large Member Affiliation	At-Large Member Name	
Golisano Children's Hospital SWFL	Eric Eason, DO	NO
Tampa Bay Adult Congenital Heart Disease Center Pediatric Cardiology Associates - Tampa Bay	Joel T. Hardin, MD	YES
MedNax Medical Group	Jorge McCormack, MD	YES

Total Count: 7 Yes, 3 No

Dr. Scholl asked for the rule to clarify that the definition of a case is the yearly denominator number used in the STS mortality analysis.

Public Comment: Dr. Schiebler requested an update on the rule making process. Ms. McKinstry provided an overview of a possible rule timeline. Dr. Schiebler asked for Agency comment on Dr. Blanchard's request for 225,000 in appropriations for the PCTAP. Ms. McKinstry responded that the Agency does not typically comment. Dr. Schiebler requested an update on the status of the at-large alternates. Ms. Helvey responded that the Agency will contact the two physicians suggested by Dr. Schiebler, and recommendations and contact information for a third at-large alternate should be sent to the pctap@ahca.myflorida.com email address. Dr. Schiebler

requested an update on the STS letter. Ms. Helvey stated that a conference call has been scheduled with the Agency, STS and Dr. Scholl. Dr. Schiebler requested a discussion of member term limits. Dr. Nykanen suggested this discussion by on the agenda at next meeting. Dr. Schiebler asked for the status of the Secretary's letter to CMS regarding neonatal pulse oximetry screening results. Ms. Helvey stated the Secretary is reviewing the letter and it will go out soon.

Dr. Blanchard stated that Dr. Eason (who had to leave the meeting early) wanted to schedule a Real Time Reporting Subcommittee. Dr. Nykanen asked that this be an agenda item for the next meeting.

Ms. Janet Kreutzer of St. Joseph Children's Hospital offered to participate in the call to STS. Dr. Nykanen stated his support for her participation.

Members noted that the next full Panel will be December 12, 2019 at 5:00 PM. Future meetings will be the third Thursday of the even months.

Meeting Summary

Member Action Items:

- Member will email recommendations for at-large alternate Panel members to the pctap@ahca.myflorida.com inbox.

Agency Action Items:

- Agency staff will make the following changes to the draft rule:
 - On page three, item five, delete the term "cardiovascular revascularization"
 - The minimum surgical volume will be set at 100 cases minimum annually.
 - The definition of a case is the yearly denominator number used in the STS mortality analysis.

Adjournment: Dr. Nykanen adjourned the meeting at 6:45 PM