

Draft Comments for Panel Review
59A-3.248, Pediatric Cardiac Programs
March 2020 Workshop

Item	Rule Reference	Commenter	Comment	Agency Response
1	3.248 (1)	Steve Ecenia, representing Nemours Children’s Hospital	No grandfathering clause for existing programs. Now they must meet these guidelines, but for years they’ve been providing these services at a high quality of care. What if they do not meet those volumes at the license renewal time & CEO cannot sign the attestation? What happens? Do they shut down? May they never open another program again? No due process for challenging decision, no timeframe for coming into compliance.	<p>Grandfathering</p> <p>Hospitals currently providing services described in this rule are authorized to continue to provide those services. Clarification added to rule.</p>
	3.248(1)	Crystal Stickle, Interim President, Florida Hospital Association	Concerned that there is no grandfathering or phase-in provision for existing providers as the rule provides that a hospital authorized to provide pediatric cardiac catheterization and angioplasty, and pediatric open heart surgery prior to July 1, 2019 must meet the requirements of this rule.	
	3.248(1)	Thomas Panza, Esq. representing the Public Health Trust of Miami-Dade County	Agency should incorporate an explicit grandfathering provision. Suggest: (a) A hospital authorized to provide pediatric cardiac catheterization and angioplasty, and pediatric open-heart surgery prior to July 1, 2019, <u>shall be issued a license for its existing pediatric cardiac catheterization, angioplasty, and pediatric open-heart surgery programs. The hospital must meet the requirements of this rule, except it will have two years from the date this rule is adopted to meet the minimum volume requirements listed in subsection (2)(b) below. A hospital’s failure to meet the minimum volume requirements listed in subsection (2)(b) during this two-year period may not be considered when deciding whether to renew the hospital’s license.</u>	
2	3.248(1)	Diane Godfrey, AdventHealth	What if a provider with good outcomes falls just 10 short on volume? What is the due process?	<p>Enforcement</p> <p>Clarification added to rule. Covered under current law. See Item 27</p>
3	3.248(1)(a)	Thomas Kmetz, President, John Hopkins All Childrens Hospital	When would the volume requirements need to be met? In the Oct 2019 minutes someone stated 1 year to come into compliance, but it is not in the rule. How would this work with 2 year volume requirements. Recommend: all programs in place prior to July 2019 to be permitted to come into compliance by the first renewal after the rule is effective or allow 1 year grace period for all programs.	<p>Enforcement</p> <p>Clarification added to rule. Subsection 395.1055(8), Florida Statutes states: Any licensed facility which is in operation at the time of promulgation of any applicable rules under this part shall be given a reasonable time, under the particular circumstances, but not to exceed 1 year from the date of such promulgation, within which to comply with such rules.</p>

Draft Comments for Panel Review
59A-3.248, Pediatric Cardiac Programs
March 2020 Workshop

4	3.248(1)(c)	Sean Frazier, representing Nicklaus Children’s Hospital	Supports insistence that volume requirements must be met to maintain licensure	Volume Requirements
	3.248(1)(c)	Dr Saima Ahrab, MD, Nicklaus Childrens Hospital	Volume is extremely important. Important to define thresholds that matter. There is a lot of data out there that supports volume to maintain skills and expertise for all providers.	No Change. The rule includes volume as approved by the panel.
5	3.248(2)(a)1	Thomas Panza, Esq. representing the Public Health Trust of Miami-Dade County	Add this additional sentence onto the end of (2)(a): “Rapid mobilization” is defined as the ability to contact and begin assembling the cardiovascular surgery team within the requisite timeframe;	Emergency Response Review pending technical advice. Clarification added to rule to emphasize response time to begin services and care.
6	3.248(2)(b)	Sean Frazier, representing Nicklaus Children’s Hospital	Term “pediatric cardiac and adult congenital procedures”. Clarification of “procedures” is necessary. A single operation may involve several surgical procedures, but should only be counted as one procedure.	Volume Requirements No change. The rule describes reportable cardiac catheterization procedures.
	3.248(2)(b)1.	Crystal Stickle, Interim President, Florida Hospital Association	Clarification needed with respect to the definition of <i>cardiac catheterization procedure</i>	
	3.248(2)(b)	Jacqueline Hernandez, Nicklaus Children’s Hospital	How many adult procedures may be counted? There should be a specific amount of adult congenital or a specific amount of both of pediatric & adult congenital to meet volume requirement.	Volume Requirements
	3.248(2)(b)	Sarah Naumowich, President, St Josephs Hospital	A facility should be allowed to count all procedures toward the volume requirement. Procedures counted should not be limited by age of patient.	No change. The volume requirements do not specify separate requirements for pediatric and adult congenital patients. Procedures on adults who are not adult congenital patients cannot be counted.
	3.248(2)(b)	Steve Ecenia, representing Nemours Children’s Hospital	Often hospitals have different practitioners for adult vs, pediatric. Allowing adult procedures to satisfy pediatric volumes has the propensity to lower quality of care. Recommend a lower volume requirement and only permit pediatric procedures to be counted.	Subsection 395.003(6)(a), Florida Statutes authorizes specialty children’s hospitals to provide pediatric cardiac services to congenital heart disease patients age 18 years and older for continuity of care. Each hospital’s governing board, though policies and procedures and credentialing of the organized medical staff oversees the level of care provided to patients. Practitioners should only accept patients for which they have been granted privileges.
7	3.248(2)(b)	Thomas Panza, Esq. representing the Public Health Trust of Miami-Dade County	Include language in this Rule that allows a licensed pediatric cardiac program to enter into a corrective action plan if it fails to meet the minimum volume requirements listed in subsection (2)(b)	Enforcement Clarification added to rule. Covered under current law. Refer to item 27.
8	3.248(2)(b)	Sean Frazier, representing Nicklaus Children’s Hospital	Supports minimum volume requirements. Literature that supports minimums:	Volume Requirements

Draft Comments for Panel Review
59A-3.248, Pediatric Cardiac Programs
March 2020 Workshop

			<p>OPPAGA report Sarah Burki & Charles D. Fraser, <i>Larger Centers May Produce Better Outcomes: Is Regionalization in Congenital Heart Surgery a Superior Model</i>, Pediatric Cardiac Surgery (2016) Sara K. Pasquali, et al, <i>Association of Center Volume with Mortality & Complications in Pediatric Heart Surgery</i>, Pediatrics, Vol. 129, No. 2, (Feb 2012) Tara Karamlou, et al, <i>Surgeon & Center Volume Influence on Outcomes After Arterial Switch Operation</i>, Annals of Thoracic Surgeons, Vol 98 (2014) Welke, K.F. et al, <i>The Complex Relationship between Pediatric Cardiac Surgical Case Volumes and Mortality Rates in National Database</i>, J. Thoracic Cardiovasc. Surg. No. 137 (2009) Michael L. O’Byrne, et al, <i>Effect of Center Catheterization on Risk of Catastrophic Adverse Event Following Cardiac Catheterization in Children</i>. American Heart Journal, Vol 169 (2015)</p>	No change. The rule includes volume as approved by the panel.
9	3.248(2)(b)4	Sarah Naumowich, President, St Josephs Hospital	The word “index” should be inserted in front of “cardiac surgical procedures” to denote procedures as index operations. This will ensure the data only includes the 1 st cardiovascular case of each episode of care, not any revisions or subsequent procedures. Which will lead to an objective definition & standardize the threshold. Also this info comes straight from the STS report.	<p>Volume Requirements</p> <p>Review pending technical advice. Clarification added to rule pending recommendation from the panel.</p> <p>Note: surgical procedures are listed in (2)(c).</p>
	3.248(2)(b)4	Jacqueline Hernandez	Specify type of surgical procedures: Impact vs. nonimpact procedures. Recommend that it should be “impact” procedures.	
	3.248(2)(b)4	Sean Frazier, representing Nicklaus Children’s Hospital	Term “cardiac surgical procedures”. Clarification of “procedures” is necessary. A single operation may involve several surgical procedures, but should only be counted as one procedure.	
	3.248(2)(b)4	Liz Dudek, Florida Hospital Association	Procedure is defined in definition section. How would multiple procedures within one session be counted toward volume?	
10	3.248(2)(b)4	Steve Ecenia, representing Nemours Children’s Hospital	<p>The minimum volume requirement is arbitrary, has no relation to quality of care, and acts as a barrier to new programs.</p> <p>Existing programs do not meet that number and will be unable to maintain the program.</p> <p>There is no scientific literature that supports this number. In fact, the American Board of Thoracic Surgeons recommends minimum of 50.</p>	<p>Volume Requirements</p> <p>No change. The rule includes volume as approved by the panel.</p>

Draft Comments for Panel Review
59A-3.248, Pediatric Cardiac Programs
March 2020 Workshop

			Data does not support minimum volume requirements: Society of Thoracic Surgeons data (on public website) from Jan 2015 – December 2018 shows the highest volume providers had higher observed mortality rates & the lower volume providers had lower observed mortality rates than expected. Instead use the following for quality measures: surgical volume, mortality/morbidity numbers, & staff capabilities.	
	3.248(2)(b)4	Dr Peter Wearden, Director, Cardiac Center, Nemours Children’s Hospital	The minimum volume lacks any scientific merit. There is some consensus that volume is a weak surrogate for quality. He believes volume exceeds what any center meets in the state of Florida. We must use scientifically valid ways of determining quality. This minimum volume requirement may prevent new and superior programs from originating. There is always a growth period in the beginning & no provision to help those new programs to come online.	
11	3.248(2)(c)5.-7.	Thomas Panza, Esq. representing the Public Health Trust of Miami-Dade County	Suggest: 5. Repair or reconstruction of intrathoracic vessels, <u>and</u> 6. <u>Emergency intra-cardiac catheterization for interventions, including septostomy, and</u> 7.6. Treatment of cardiac trauma.	Service Capability Added to the rule.
12	3.248(2)(c)6.	Liz Dudek, Florida Hospital Association	References “treatment of cardiac trauma”. Does that require a center to be a pediatric trauma center? If so, that would impact many programs as the ability to get additional trauma centers in the state is very limited.	Terminology - Trauma Clarification added to rule. A hospital providing pediatric cardiac services must be capable of providing care to the most seriously ill patients, including cardiac injury. Rewording the requirement to avoid confusion with trauma center designation.
	3.248(2)(c)6	Crystal Stickle, Interim President, Florida Hospital Association	The FHA asks that Agency to clarify the meaning of the capability to treat ‘cardiac Trauma’; is this a medical term or does it require the hospital to be a designated pediatric trauma center? If the latter, there are limited designated pediatric trauma centers and no reasonable likelihood that additional pediatric trauma center can be added under the existing rule.	
13	3.248(2)(d)	Sarah Naumowich, President, St Josephs Hospital	Modify or remove the requirement for ambulatory care clinics to be located on the hospital premises as it is not critical for patient safety.	Ambulatory Care Removed on-site requirement.
	3.248(2)(d)	Thomas Panza, Esq. representing the Public Health Trust of Miami-Dade County	Suggest: (d) Ambulatory care clinics serving pediatric cardiac conditions and adult congenital heart disease patients must be located on the hospital premises <u>or, if located off-site from a hospital, it must be part of a program with an on-site pediatric cardiac clinic and must:</u>	

Draft Comments for Panel Review
59A-3.248, Pediatric Cardiac Programs
March 2020 Workshop

14	3.248(3)	Thomas Panza, Esq. representing the Public Health Trust of Miami-Dade County	Suggest: <u>3. Adult congenital cardiac services must be under the direction of a physician board certified by the Adult Congenital Heart Disease Sub-board of the American Board of Internal Medicine.</u> <u>4. The dedicated intensive care unit or component within a unit for pediatric acquired or congenital heart disease patients must be under the direction of a board-certified pediatric intensivist.</u>	Personnel Director qualifications for ICU added to rule. Note: Draft NICU rules require NICU levels III and IV must be under the direction of a neonatologist. This is consistent with AAP guidelines. Level III and IV NICUs must also have specialists available for consultation including pediatric intensivists.
15	3.248(3)(a)2.	Sean Frazier, representing Nicklaus Children’s Hospital	Strike “and by the International Board of Heart Rhythm Examiners”. This is not a requirement in (3)(a)3. and not needed as an additional requirement here.	Personnel No change. Rule reflects panel’s recommendation
16	3.248(3)(b)3.	Thomas Panza, Esq. representing the Public Health Trust of Miami-Dade County	Suggestion: <u>At least one pediatric cardiovascular surgeon must be board certified or eligible by the American Board of Thoracic Surgery, specialty certification in congenital cardiac surgery, and readily available in a timely manner (within 30 minutes).</u>	Emergency Response No change. Response timeframes for catheterization laboratory and surgery are already established in this rule.
17	3.248(3)(b)7.a.	Thomas Panza, Esq. representing the Public Health Trust of Miami-Dade County	Suggestion: <u>Pediatric cardiologists, at least one of whom is readily available in a timely manner (within 30 minutes);</u>	
18	3.248(3)(b)7.e.	Thomas Panza, Esq. representing the Public Health Trust of Miami-Dade County	Suggestion: <u>Pediatric intensivists, preferably with cardiac focused training, at least one of whom is available in-house 24 hours per day to care for intensive care unit patients; and</u>	Personnel No change
19	3.248(3)(c)	Thomas Panza, Esq. representing the Public Health Trust of Miami-Dade County	Suggestion under Nursing Staff: 1. Correct the spelling of registered and add the following: <u>“Special training” shall include certifications, education, or at least two years of experience in the techniques and skills described herein.</u> 2. Correct the spelling of registered 3. <u>Registered Nurses in the cardiac intensive care unit will have completed training with validated competencies in caring for congenital heart patients.</u>	Personnel Added to the rule.
20	3.248(3)(d)	Thomas Panza, Esq. representing the Public Health Trust of Miami-Dade County	Add ‘ECMO specialists’ to the list of professionals	Personnel No change.

Draft Comments for Panel Review
59A-3.248, Pediatric Cardiac Programs
March 2020 Workshop

21	3.248(4)	Crystal Stickle, Interim President, Florida Hospital Association	The FHA asks for confirmation that existing programs would be subject to the building codes in place at the time of their initiation of the program; rather than current building codes.	Physical Plant Clarification added to rule.
	3.248(4)	Diane Godfrey, AdventHealth	Wondering if something needs to be in place for existing programs. Will they need to come up to current codes? How long would they have?	
22	3.248(4)	Thomas Panza, Esq. representing the Public Health Trust of Miami-Dade County	Add the following sentence: <u>All hospitals providing pediatric cardiac services must have a dedicated intensive care unit or component within a unit for pediatric acquired or congenital heart disease patients, which includes facilities for prolonged reverse isolation when required.</u>	Physical Plant No change. Refer to section (2) Quality of Care for minimum service requirements.
23	3.248(5)(c)1	Thomas Panza, Esq. representing the Public Health Trust of Miami-Dade County	Correct spelling of ‘dimensional’	Format Correction has been made to the rule.
24	3.248(6)	Diane Godfrey, AdventHealth	What kind of policies and procedures would a pediatric open heart program need to do rapid transport of pediatric patients?	Emergency Transportation Clarification added to rule.
	3.248(6)	Thomas Panza, Esq. representing the Public Health Trust of Miami-Dade County	Add on to the end of the sentence: <u>for any service the hospital is unable to perform.</u>	
25	3.248(7)(a)	Thomas Panza, Esq. representing the Public Health Trust of Miami-Dade County	Remove from the sentence: including the Anesthesia Model	Data Registry No change. Rule reflects the Panel’s recommendation
26	3.248(7)(a)4.	Judy Morris, Nicklaus Children’s Hospital	Clarification needed for surgical procedures. Look at that and define appropriately.	Data Registry Clarification added to rule. Exception if STS doesn’t publish data; New programs with limited data.
27	3.248(8)	Steve Ecenia, representing Nemours Children’s Hospital	Does not meet 395.1055(12)(c) There is nothing in this section that establishes specific steps to be taken by the Agency & licensed facilities when facilities fail to meet the minimum requirements within a specified time, including time required for detailed case reviews and corrective action plans.	Enforcement References to 408 part II and 395 Part I added to rule. Clarification added to rule specifying suspension or revocation of the pediatric cardiac program are possible sanctions afforded in statute for non-compliance with this rule. Subsections 395.1065(2) and (3), Florida Statutes describes possible administrative action the Agency may take for noncompliance with licensure requirements.
	3.248(8)	Thomas Panza, Esq. representing the Public Health Trust of Miami-Dade County	Add after the last sentence in (8): <u>In addition to the enforcement procedures listed in rule 59A-3.253, F.A.C., the following shall also apply: hospitals with existing pediatric cardiac programs that fail to meet the minimum volume requirements listed in subsection (2)(b) as part of their re-licensure, must submit a corrective action plan that must be approved by the Agency. Once the Agency approves the corrective action plan, the hospital must come into compliance with the minimum volume requirements listed in subsection (2)(b) within two years of the date that the corrective</u>	

Draft Comments for Panel Review
59A-3.248, Pediatric Cardiac Programs
March 2020 Workshop

			<p><u>action plan was approved. Nothing in this subsection shall limit the Agency's authority to immediately terminate a hospital's pediatric cardiac program's license if it presents a danger to the public.</u></p>	<p>See also sections 408.813-817, and 408.831, F.S. In addition, Subsection 395.1055(14), Florida Statutes allows the Agency Secretary to request announced and unannounced site visits and receive recommendations from the Pediatric Cardiac Technical Advisory Panel based on the findings of the site visits.</p>
--	--	--	--	---