OPPAGA Review of Tertiary Health Services Licensing Standards

Report No. 19-11 Date: November 2019



November 2019

## OPPAGA Review of Tertiary Health Services Licensing Standards

### **EXECUTIVE SUMMARY**

The Agency for Health Care Administration administers the certificate of need program, which requires certain health care facilities to obtain state authorization before constructing new facilities or offering certain new or expanded services. Chapter 2019-136, *Laws of Florida*, eliminated certificate of need review for general hospitals, comprehensive rehabilitation, specialty hospitals, and tertiary health services effective July 1, 2019.

Prior to this legislation, tertiary health services were defined as health services that, due to their high level of intensity, complexity, specialized or limited applicability, and cost, should be concentrated in a limited number of hospitals to ensure the quality, availability, and costeffectiveness of such services. Tertiary health services

#### **REPORT SCOPE**

Chapter 2019-136, Laws of Florida, directs OPPAGA to study federal requirements and other states' licensure statutes and rules governing the provision of tertiary health services and to recommend best practices, including volume requirements, applicable, regarding the establishment of standards licensure for such programs.

include comprehensive rehabilitation; neonatal intensive care units; pediatric cardiac catheterization; pediatric open heart surgery; and organ transplantation.

Tertiary health services licensure standards involve a complex array of detailed requirements across a number of categories, such as volume, outcomes, and professional competencies of staff. While there is consensus that volume of patients is positively related to successful outcomes for tertiary health services, studies do not provide consistent minimum volume recommendations. Studies have concluded that numerous factors, in addition to volume, are related to quality of tertiary health services.

Federal licensure requirements are relevant for comprehensive rehabilitation and organ transplants but not for other tertiary health services. Other states' licensure standards for tertiary health services vary considerably and do not provide reliable information on best practices. Professional medical associations are a primary source of best practices for tertiary health services licensure standards. These entities develop recommendations on best practices for specific types of care or high-risk patients based on collaboration among experts and review of the latest medical research. Recommendations for the Agency for Health Care Administration and the Legislature to consider as the state is developing licensure standards for tertiary health services are largely based on the standards and guidelines provided by the multiple professional medical associations relevant to each tertiary health service.

### BACKGROUND

The Agency for Health Care Administration (AHCA) administers the certificate of need (CON) program, which requires certain health care facilities to obtain authorization from the state before constructing new facilities or offering certain new or expanded services. CON programs were designed to restrain health care costs and provide for directed, measured planning for new services and facilities. Many CON laws across the U.S. were put into effect by the National Health Planning and Resources Development Act of 1974. The federal mandate was repealed in 1987, and while several states have since discontinued their CON programs, most have retained some form of a CON program.

Florida's CON program was established in 1973 and has been reformed several times during the past 15 years. For example, CON review has been eliminated for establishing home health agencies, adult cardiac catheterization and open heart surgery services, and hospital burn units. The Legislature imposed limitations on CON issuance for community nursing home beds. Most recently, Chapter 2019-136, *Laws of Florida*, eliminated CON review for general hospitals, comprehensive rehabilitation, specialty hospitals, and tertiary health services effective July 1, 2019.<sup>1</sup>

Prior to this legislation, tertiary health services were defined as health services that, due to their high level of intensity, complexity, specialized or limited applicability, and cost, should be concentrated in a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such services. Tertiary health services include

- comprehensive rehabilitation;
- neonatal intensive care units (NICUs);
- pediatric cardiac catheterization;
- pediatric open heart surgery; and
- organ transplantation.<sup>2,3</sup>

The CON requirements for these tertiary health services are defined in Rules 59C-1.032 through 59C-1.044, *Florida Administrative Code*. While the 2019 law repealed CON review for the five categories of tertiary health services, it allows the licensure aspect of existing rules for three of the five services to remain in effect until AHCA adopts new licensure rules; this provision is applicable to comprehensive rehabilitation, NICUs, and organ transplantation.<sup>4,5</sup> There do not appear to be any current applicable licensure standards for creation or expansion of pediatric catheterization or pediatric open heart surgery services.

<sup>&</sup>lt;sup>1</sup> Health care facilities that remain subject to CON review after the passage of Ch. 2019-136, *Laws of Florida.*, include hospices, skilled nursing facilities, intermediate care facilities for the developmentally disabled, and the establishment of Class II, III, and IV hospitals. However, effective July 1, 2021, the law eliminates the requirement of CON review for Class II, III, and IV hospitals. Class II hospitals include children's and women's hospitals; class III hospitals include specialty medical, rehabilitation, and psychiatric and substance abuse hospitals; and class IV hospitals are specialty hospitals restricted to offering Intensive Residential Treatment Facility Services for Children.

<sup>&</sup>lt;sup>2</sup> Per the 2018 version of s. 408.032(17), *F.S.* 

<sup>&</sup>lt;sup>3</sup> Tertiary health services may also include medical or surgical services that are experimental or developmental in nature to the extent that the provision of such services is not yet contemplated within the commonly accepted course of diagnosis or treatment for the condition addressed by a given service.

<sup>&</sup>lt;sup>4</sup> Chapter <u>2019-136</u>, Laws of Florida and s. <u>408.0455</u>, F.S.

<sup>&</sup>lt;sup>5</sup> AHCA has issued <u>supplemental licensure information</u> to inform hospitals about the parts of the CON rules they must continue to meet for new or expanded tertiary health services while AHCA drafts licensure rules. These guidelines are available for <u>comprehensive rehabilitation services</u>; neonatal intensive care beds; heart transplant services; liver transplant services; kidney transplant services; bone marrow transplant services; and <u>lung, heart and lung, pancreas and islet cells, and intestines transplant services</u>.

### LICENSURE STANDARDS FOR TERTIARY HEALTH SERVICES

# Volume is one of several measures related to quality of tertiary health services

Tertiary health services licensure standards involve a complex array of detailed requirements across a number of categories. These categories may include patient or procedure volume requirements, procedure outcomes, staff professional competencies, available hours of facility operation, availability of equipment, and many others. Additional standards may specify facility infrastructure requirements, such as co-location with necessary services or facility stratification and coordination of care, including protocols for referral and transportation of patients, as a means to ensure that patients receive the necessary level of care within a system of limited medical resources. There is broad consensus among professional medical associations and academic researchers that volume and quality are positively related in tertiary health services. However, there is little agreement on specific minimum volume threshold requirements for many tertiary health services. Researchers and professional medical associations identify several factors other than volume that are important to consider in developing best practices to ensure quality of tertiary health services.

There is consensus among researchers that volume of patients is positively related to successful outcomes for tertiary health services. Volume is viewed as a proxy for quality and expertise because large volumes enhance opportunities for surgeons to practice critical, high-risk surgeries, and developing skills and perfecting techniques leads to better outcomes.<sup>6</sup> Minimum volume requirements can create a selective referral process in which better performance creates a demand that increases volume, which, in-turn, increases quality of outcomes.<sup>7</sup> Studies have suggested that higher volume medical centers have, on average, better short-term and long-term patient survival rates.<sup>8</sup> For example, the American College of Surgeons concluded that there is wide variation in adjusted mortality rates at lower volumes versus higher volumes for teams performing adult heart procedures.

Academic studies do not provide consistent minimum volume recommendations but do identify several other factors related to tertiary health service quality. Many academic studies have assessed the relationship between volume and patient outcomes for various tertiary health services. While there is consensus among researchers that volume and quality are positively related for tertiary health services, studies have not established consistent minimum volume recommendations for tertiary health services. Many of these studies have estimated the relationship between volume and quality but have used widely different ranges of volumes to define low, medium,

<sup>&</sup>lt;sup>6</sup> Bashore, et al., "2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update," *Journal of the American College of Cardiology* 2012; 59:2221–305.; Alhamad, et al., "Transplant Center Volume and the Risk of Pancreas Allograft Failure," *Transplantation 101*(11), 2017: 2757; Nguyen, et al., "The Volume-Outcome Relationship in Critical Care: A Systematic Review and Meta-Analysis," Chest 148(1), 2015: 79-92; Sonnenberg, et al., "Association of Kidney Transplant Center Volume With 3-Year Clinical Outcomes," *American Journal of Kidney Diseases*, 2019.

<sup>&</sup>lt;sup>7</sup>Nguyen, et al., 2015; Sonnenberg, et al., 2019; Wehby, et al., "Very Low Birth Weight Hospital Volume and Mortality—An Instrumental Variables Approach," *Med Care 50*(8), 2012: 714-721.

<sup>&</sup>lt;sup>8</sup> Grimm, et al., "The Influence of Institutional Volume on the Incidence of Complications and Their Effect on Mortality After Heart Transplantation," *The Journal of Heart and Lung Transplantation 34*(11), 2015: 1390-1397; Barbas, et al., "The Volume-Outcome Relationship in Deceased Donor Kidney Transplantation and Implications for Regionalization," *Annals of Surgery 267*(6), 2018: 1169-1172.

and high volume centers.<sup>9</sup> Therefore, it is not possible to compare the results of such studies in terms of minimum volume requirements to ensure quality of a tertiary health service. For example, recent studies of adult heart transplantation thresholds for high volume transplant centers range from 9 to 48 or more procedures per year; adult liver transplants studies' thresholds for high volume centers range from 21 to 176 or more procedures per year; and pediatric lung transplant studies' thresholds for high volume range from 4 to 11 or more procedures per year. (See Appendix A for more detail on the ranges used by these studies to define center volumes.)

Studies on the relationship between volume and quality of tertiary health services have also identified several other factors that influence patient outcomes, in addition to volume. Specifically, these studies highlight factors such as patient demographics and health characteristics; hospital and center-specific characteristics, such as ICU type, staffing ratios, and teaching hospital status; the surgeon's skill of surgery; and others.<sup>10,11</sup>

### Other states provide limited information on best practices for licensure standards; professional medical associations offer the most comprehensive recommendations to ensure service quality

OPPAGA reviewed the tertiary health services licensure standards and best practices, where applicable, established by federal agencies, other states, and professional medical associations. We examined licensure requirements across four main categories: quality measures, staffing measures, facility and/or staff availability, and equipment. Federal requirements are applicable to only two tertiary health services—organ transplants and comprehensive rehabilitation. Other states' licensure standards for tertiary health services vary widely and do not provide reliable best practice information. Professional associations provide the most comprehensive and reliable recommendations for best practices for tertiary service licensure standards. Some professional associations have identified evidence-based minimum volume recommendations for two tertiary health services, pediatric cardiac catheterization and pediatric open heart surgery, but not for the other tertiary health services.

<sup>&</sup>lt;sup>9</sup> Alhamad, et al., 2017; Arnaoutakis, et al., "Institutional Volume and the Effect of Recipient Risk on Short-Term Mortality After Orthotopic Heart Transplant," *The Journal of Thoracic and Cardiovascular Surgery* 143(1), 2012: 157-167; Barbas, et al., "The Volume-Outcome Relationship in Deceased Donor Kidney Transplantation and Implications for Regionalization," *Annals of Surgery* 267(6), 2018: 1169-1172; O'Byrne, et al., "Effect of Center Catheterization Volume on Risk of Catastrophic Adverse Event After Cardiac Catheterization in Children," *American Heart Journal* 169(6), 2015: 823-832.; Russo, et al. "Post-Heart Transplant Survival is Inferior at Low-Volume Centers Across All Risk Strata," *Circulation* 122, suppl\_1, 2010: S85-S91; Starling, R.C., and Xanthopoulos, A., "Are Outcomes Related to Left Ventricular Assist Device Center Volume?: Too Complex to Answer," JACC: Heart Failure 5(10), 2017: 700-702.

<sup>&</sup>lt;sup>10</sup> Nguyen, et al., 2015; Sonnenberg, et al., 2019; Scully, et al., "Waiting List Outcomes in Pediatric Lung Transplantation: Poor Results for Children Listed in Adult Transplant Programs," *The Journal of Heart and Lung Transplantation 36*(11), 2017: 1201-1208; Hayes et al., "Transplant Center Volume and Outcomes in Lung Transplantation for Cystic Fibrosis," *Transplant International 30*, 2017: 371–377.

<sup>&</sup>lt;sup>11</sup> Burki, S., and Fraser Jr., C. D., "Larger Centers May Produce Better Outcomes: Is Regionalization in Congenital Heart Surgery a Superior model?," Seminars in Thoracic and Cardiovascular Surgery: *Pediatric Cardiac Surgery Annual 19*, 2016: 10-13.

#### Federal requirements primarily apply to comprehensive rehabilitation and organ transplants.

Federal requirements for hospitals to participate in Medicare are the only federal requirements that apply across all five tertiary health services. The Centers for Medicare and Medicaid Services (CMS) establishes requirements that are applicable to the comprehensive rehabilitation tertiary service. In addition, hospitals that provide organ transplants must meet extensive additional requirements established by CMS and the Organ Procurement and Transplantation Network (OPTN).

**Other states' licensure standards for tertiary health services vary considerably and do not provide consistent, reliable information on best practices.** As of February 2019, 35 states and the District of Columbia have some form of certificate of need program in place; three states have a variation of a CON program; and 12 states have no CON program in place.<sup>12</sup> States we reviewed that have CON programs that apply to tertiary health services have volume requirements for some but not all tertiary health services, and these volume requirements vary across states.<sup>13</sup> While CON states provide examples of volume requirements, the intent of their volume thresholds could be either for quality or to limit facilities' capacity to meet demand. Because the volume necessary to maintain quality may differ from the volume necessary to achieve efficiency, it is difficult to identify volume standards among CON states that could serve as best practices for ensuring tertiary service quality.

 $<sup>^{\</sup>rm 12}$  Puerto Rico and the Virgin Islands each have an active CON program.

<sup>&</sup>lt;sup>13</sup> We reviewed requirements for six states that had CON programs: Illinois, Maryland, Massachusetts, New York, North Carolina, and Ohio.

#### Exhibit 1 As of February 2019, 12 States Did Not Have a Certificate of Need Program



Source: National Conference of State Legislatures at http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx.

In addition, we reviewed the tertiary health service licensure requirements of six states that do not have a CON program for tertiary health services—California, Colorado, New Hampshire, Pennsylvania, Texas, and Utah.<sup>14</sup> Among these states, we did not identify consistent licensing standards across all tertiary health services. Some of the states reported that they do not have separate licensing standards for each tertiary health service and that these services are covered under general hospital licensing requirements. Those that established licensing standards for a tertiary health service often set differing expectations for areas such as staff qualifications. While three states (Pennsylvania, Texas, and Utah) reported that they use professional association standards for their neonatal care standards, none of the six reported that they had established volume requirements for tertiary health services. [See Appendices B through E and G.]

Another consideration when using other states' standards to identify best practices is that the standards may have been subjected to a rule promulgation process that involved gathering feedback from stakeholders and negotiating revisions.<sup>15</sup> The outcome of such activities may be a set of rules that has been modified to meet the needs of that state's stakeholders. Officials that we interviewed from other states that do not have a CON process reported that they made changes to their rules during the rule promulgation process as a result of stakeholder input.

<sup>&</sup>lt;sup>14</sup> OPPAGA reviewed six states that do not have a CON program and are comparable to Florida on one or more of the following factors: number of teaching hospitals; percentage of individuals covered by Medicaid, Medicare, or who are uninsured; population size; and portion of the state that is rural.

<sup>&</sup>lt;sup>15</sup> For example, Ch. 120, *F.S.*, provides that state agencies propose a set of rules and hold rule workshops. Stakeholders affected by the proposed rules provide feedback to the agency, and the agency may then modify the rules to accommodate stakeholder input.

Although there are volume requirements for graduate medical education, these only apply to teaching hospitals and are used to ensure appropriate levels of training. The Accreditation Council of Graduate Medical Education (ACGME) provides minimum standards for teaching hospitals and for residents and fellows for certain tertiary health services, including pediatric cardiac care and specific types of transplantations (heart, heart and lung, liver, and kidney). These standards include minimum volume levels for the teaching hospital and for resident and fellow professional experience and also include minimum volume levels for particular procedures. However, these standards are intended to ensure that teaching hospitals have the minimal volume necessary to provide residents and fellows the appropriate level of training and are not applicable to general acute care hospitals as an assurance of tertiary health service quality.

**Professional medical associations are a primary source of best practices for licensing most tertiary health services.** Based on our review of standards among federal entities, other states, and professional organizations, we concluded that professional medical associations should be considered the primary source for identifying state licensing standards for all tertiary health services except organ transplants. These organizations have developed criteria or recommendations for ensuring quality in the provision of specific types of medical procedures, including all tertiary health services except organ transplants; for organ transplants, we referred to the extensive federal requirements for these procedures.

Professional medical associations develop technical advisory panels of leading experts to collaborate on best practices for specific types of care or high-risk patients. Many of these organizations use data established through registries and conduct research on best practices. Several of these organizations have developed criteria or recommendations for specific types of medical procedures, including neonatal and pediatric care.<sup>16</sup> For example, in 2012, the American Academy of Pediatrics (AAP) updated its policy for NICU level classifications to reflect the overall evidence for risk-appropriate care, which the AAP and the American College of Obstetricians and Gynecologists (ACOG) incorporated into their *Guidelines for Perinatal Care, Eighth Edition.*<sup>17</sup> Exhibit 2 lists professional medical associations that have made recommendations for standards applicable to tertiary health services.

<sup>&</sup>lt;sup>16</sup> Accrediting and certification organizations utilize standards developed by technical advisory committees to develop certification standards, performance measures, and data collection for a number of health care services.

<sup>&</sup>lt;sup>17</sup> Three states we reviewed use professional medical association guidelines in their NICU standards. Pennsylvania uses the AAP/ACOG 2017 Eighth Edition guidelines in its hospital licensing standards; Texas references parts of AAP/ACOG 2012 Seventh Edition guidelines in its reviews; and Utah references in statutes the 2010 Sixth Edition. In addition, Utah uses The Facility Guidelines Institute (FGI)—2010 *Guidelines for Design and Construction of Health Care Facilities*. Pennsylvania uses most current versions of and the FGI—*Guidelines for Design and Construction of Hospitals* and FGI—*Guidelines for Design and Construction of Outpatient Facilities*, while Utah references the 2010 edition.

#### Exhibit 2 Several Professional Medical Associations Have Recommended Standards for Tertiary Health Services

Tertiary Health Service	Professional Medical Associations
Comprehensive Rehabilitation	Association of Rehabilitation Nurses
	American Occupational Therapy Association
	American Speech-Language-Hearing Association
	American Physical Therapy Association
	Academy of Neurologic Physical Therapy
Neonatal Care	American Academy of Pediatrics
	American College of Obstetricians and Gynecologists
	Association of Women's Health, Obstetrics, and Neonatal Nurses
	National Association of Neonatal Nurses
Pediatric Cardiac Catheterization	American Academy of Pediatrics
	American College of Cardiology Foundation
	Society for Cardiovascular Angiography and Interventions
	Society of Thoracic Surgeons
	Society for Vascular Medicine
Pediatric Open Heart Surgery	American Academy of Pediatrics
	American College of Surgeons
	American Heart Association

Source: OPPAGA analysis of guidelines and recommendations from professional medical associations.

### FLORIDA'S TERTIARY HEALTH SERVICES

The following sections provide details for each of Florida's five tertiary health services, including summaries of federal requirements (where applicable), other states' licensure standards and practices (where there are examples of best practices), and professional medical association recommendations. In some cases, we compare Florida's current CON rules to professional association recommendations. (See Appendices B through E and G for additional details in each of these areas.)

#### **Comprehensive Rehabilitation**

Florida defines comprehensive medical rehabilitation inpatient services as an organized program of integrated intensive care services provided by a coordinated multidisciplinary team to patients with a variety of severe physical disabilities.<sup>18</sup> Services include physical and occupational therapy and speech-language therapy. Licensure standards for these services are embedded in current Agency for Health Care Administration rules. In addition, because Florida requires facilities to participate in Medicare and Medicaid, the state inherently follows Centers for Medicare and Medicaid Services guidelines regarding quality measures, quality of staffing, availability, and equipment. Under CMS requirements, facilities that offer comprehensive inpatient rehabilitation services must also, at a minimum, provide physician services, physical therapy, and social-psychological services. (See Appendix B for more details on all licensure standards described in this section.)

<sup>&</sup>lt;sup>18</sup> The physical disabilities that may be treated with comprehensive rehabilitation services include stroke, brain injury, polyarthritis, rheumatoid arthritis, amputation, neurological disorders, spinal cord injury, congenital deformity, and major multiple trauma.

**Professional medical association standards for comprehensive rehabilitation include quality measures that focus on outcomes but do not include volume.** With respect to quality measures, professional medical associations provide recommendations on minimum intensity and measurable

outcomes that focus on patient gains from rehabilitation. For example, the Academy of Neurologic Physical Therapy provides numerous scales and ratings for assessing the functional and cognitive gains of stroke, Parkinson's, traumatic brain injury, and multiple sclerosis patients. CMS requires that patients spend a minimum of three hours per day, five days per week or 15 hours per week within a seven consecutive day period in therapy sessions. This level of intensity is associated with positive outcomes, primarily defined as cognitive and physical functional gain. However, neither the relevant professional medical associations nor CMS identify or require minimum volumes for

Professional Medical Associations Establish Best Practices for Comprehensive Rehabilitation

- Patient outcomes
- Quality of staffing
- Facility/staff availability
- Equipment maintenance

comprehensive rehabilitation services. This may be because volume requirements tend to be more applicable to specific procedures, such as a type of surgical procedure, rather than to services that encompass a variety of procedures, as is characteristic of comprehensive rehabilitation services.

Associations provide guidelines and standards related to staffing quality, facility and/or staff availability, and equipment maintenance. For providers of comprehensive inpatient rehabilitation services, professional medical associations make numerous recommendations to ensure staffing quality and service availability. For example, the American Occupational Therapy Association recommends that personnel should pursue continuing medical education to maintain their accreditation. For speech-language therapy and audiology, the American Speech-Language-Hearing Association recommends that speech-language pathology and audiology be licensed separately and that audiologists should attain a doctoral degree. In addition, medical associations such as the Association of Rehabilitation Nurses require that comprehensive inpatient rehabilitation facilities be able to provide services 24 hours per day, seven days per week. Moreover, the American Physical Therapy Association recommends that all equipment be inspected routinely.

While some of AHCA's current comprehensive rehabilitation requirements are commensurate with standards from professional medical associations, differences exist. Professional medical associations provide numerous guidelines for comprehensive rehabilitation personnel. Similarly, AHCA's CON rule for comprehensive rehabilitation services required that the director of a rehabilitation facility be a board-certified or board-eligible physiatrist with at least two years of experience in the management of patients requiring inpatient rehabilitation. However, the agency's CON rules are not as detailed as the recommendations of associations regarding the professional competencies of staff. In addition, AHCA's CON rules differ from the recommendations of professional medical associations with respect to quality outcomes and equipment maintenance.

#### **Neonatal Intensive Care Units**

Neonatal intensive care units are stratified according to the level of care needed for neonates. These facilities refer patients as needed to higher-level centers with the resources and personnel that can address the required complexity of care. Since the 1970's, the American College of Obstetricians and Gynecologists, American Medical Association, American Academy of Pediatrics, and American Academy of Family Physicians have developed guidelines and recommendations for maternal and perinatal hospital care, with a special focus on infant mortality.

These professional medical associations advocate for stratification and regionalization of an integrated maternal and neonatal care system, including effective risk identification, care in a risk-appropriate setting, and maternal and neonatal transport to tertiary care facilities when necessary. The regionalization of perinatal care includes integrating neonatal care based on risk factors with the ultimate goal of optimal outcomes for newborns and mothers. Application of these standards can allow

a basis for comparison of health outcomes, resource use, and health care costs across states; standardized nomenclature for public health; uniform definitions for pediatricians and other health care professionals providing neonatal care; and a foundation for consistent standards of service by entities focused on the improvement of perinatal care. (See Appendix C for more information on licensure standards referenced throughout this section.)

#### The AAP recommends that hospital neonatal care be defined by four levels of care, which differs from AHCA's current standards. NICU levels are defined by factors such as the maximum unit capabilities in terms of neonatal risk

#### Professional Medical Associations Establish Best Practices for NICUs

- Stratified, regionalized care
- Quality of staffing
- Staffing ratios
- Availability of services
- Necessary equipment and technology

factor, minimum functional expectations, and provider credentialing and staffing necessary to maintain each level of neonatal care, but they do not include recommended minimum patient volumes. Both AHCA's CON rules for neonatal care and the AAP's 2012 policy for neonatal levels of care stratify neonatal care according to intensity of skill level required.<sup>19,20</sup> However, AHCA's current licensing standards for NICUs differ from the AAP's definitions and the types of services that can be provided at each level of neonatal care, including the number of levels of care and neonatal condition in terms of weight, gestational age, and wellness or need for complex care. (See Exhibit 3.) Adopting the AAP's standards for neonatal care may have implications for hospital staffing qualifications and protocols for transporting and referring neonates that do not meet the minimum weight, gestational age, or illness criteria.

<sup>&</sup>lt;sup>19</sup> Rule <u>59C-1.042</u>, *F.A.C*.

<sup>&</sup>lt;sup>20</sup> In addition to AHCA's regulatory oversight of neonatal care, the Department of Health's Children's Medical Services provides a full range of obstetrical services for Medicaid recipients with high-risk pregnancies and up to 365 days of neonatal services through its Regional Perinatal Intensive Care Centers (RPICC program). Rule <u>59G-4.264</u>, *F.A.C.* and Rule <u>64C-6.003</u>, *F.A.C.* establish the criteria and standards for RPICC neonatal Level II and Level III beds.

#### Exhibit 3 Both AAP's Policies and AHCA's CON Rules Stratify Neonatal Care by Levels, but There Are Differences

,	
American Academy of Pediatrics' 2012 Neonatal Levels of	Florida Neonatal Care Level Licensing Standards (Embedded in
Care	Florida's Neonatal Care CON Rules, Rule 59C-1.042, <i>F.A.C</i> .)
Neonatal care is stratified by 4 levels	Neonatal care is stratified by 3 levels
Level I—Well-newborn nursery	Level I—Well-baby care services
Level II—Specialty care nursery	Level II—Neonatal intensive care services
Level III—Subspecialty intensive care	Level III—Neonatal intensive care services
Level IV—Regional NICU	
Generally defines neonatal level of care by minimum very low birth weight (1,500 grams) and/or gestational age and stability or	Generally defines neonates that can be served by level on wellness/illness or by extremely low birth weight (1,000 grams)
weilness/liness/need for complex surgical care	Level I — Well-Daby care services
<ul> <li>Level I—Well babies or stabilize and provide care for infants born 35–37 weeks gestation who remain physiologically stable</li> <li>Level II—At least 32 weeks gestation and weighing at least 1,500 grams who have physiologic immaturity or who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis</li> <li>Level III—Comprehensive care for infants born less than 32 weeks gestation and weighing less than 1,500 grams and infants born at all gestational ages and birth weights with critical illness</li> </ul>	<ul> <li>Level II—Restricted to neonates of at least 1,000 grams birth weight</li> <li>Level III—Any neonates with a birth weight of 1,000 grams or less or weighing more than 1,000 grams and requiring one or more of the Level III services, or severely ill regardless of birth weight, require 12 or more hours of nursing care per day</li> </ul>
Level IV—Comprehensive care for infants born less than 32 weeks gestation and weighing less than 1,500 grams and infants born at all gestational ages and birth weights with critical illness or need for surgical repair of complex congenital or acquired conditions capabilities	
capabilities Source: American Academy of Pediatrics and Florida's Agency for Health	Care Administration.

S

Professional medical associations provide additional recommendations for neonatal care best practices, including professional competencies and minimum staffing requirements, staffing ratios, service availability, and necessary equipment and technology. The AAP, ACOG, and professional nursing associations establish best practices for the delivery of care to high-risk neonates.<sup>21</sup> These associations generally agree that neonatal care level of staffing, staff training and certification, and available equipment and technology should be commensurate with the increasing complexity of the needs of neonates at each NICU level. In addition, nursing associations recommend standards for neonatal care nursing staffing, capabilities, and skills. The National Association of Neonatal Nurses and the Association of Women's Health, Obstetric, and Neonatal Nurses recommend that all four levels of neonatal intensive care units be staffed accordingly with a sufficient number and an appropriate mix of qualified registered nurses to attend to the emergent and complex care requirements of critically ill and convalescent infants.<sup>22,23</sup>

Several other states that do not have a CON program reference professional medical association standards for neonatal care. Texas licenses general acute care hospitals but also has a separate designation process for certain services, including neonatal care. Texas generally follows the AAP's recommended levels of care for NICUs and designates the AAP as an approved survey agency for the state's neonatal care units.<sup>24</sup> Pennsylvania's licensing standards for acute care hospitals include criteria specific to neonatal intensive care for hospitals that provide obstetrical and/or neonatal infant

<sup>&</sup>lt;sup>21</sup> The AAP's 2012 policies for neonatal levels of care are incorporated in the AAP and ACOG 2017 Guidelines for Perinatal Care, Eighth Edition.

<sup>&</sup>lt;sup>22</sup> National Association of Neonatal Nurses, RN Staffing in the Neonatal Intensive Care Units, 2014.

<sup>&</sup>lt;sup>23</sup> Association of Women's Health, Obstetric, and Neonatal Nurses, Guidelines for Professional Registered Nursing Staffing for Perinatal Units.

<sup>&</sup>lt;sup>24</sup> In addition to Texas, Georgia and Missouri designate the AAP as an approved survey agency for their state's neonatal care units.

care; the state's criteria follow current guidelines established by ACOG and AAP.<sup>25</sup> Similarly, Utah's licensing standards for acute care hospitals include criteria for perinatal care that address antepartum, labor, delivery, postpartum, and nursery care and reference AAP and ACOG guidelines.<sup>26</sup>

#### Pediatric Cardiac Catheterization

Pediatric cardiac catheterization is a procedure where specialized cardiologists insert a long, thin tube called a catheter into the blood vessels and guide it to the heart using X-ray imaging. This procedure can help diagnose and treat many heart problems in babies born with congenital heart defects or other childhood heart conditions. A pediatric cardiac catheterization procedure is performed in a hospital cardiac catheterization laboratory (CCL). Several professional medical organizations, including the American College of Cardiology Foundation (ACCF) and the Society for Cardiovascular Angiography

Professional Medical Associations Establish Best Practices for Pediatric Cardiac Catheterization

- Quality improvement programs
- Quality of staffing
- Availability of services
- Resource availability
- Equipment capability and maintenance

and Interventions (SCAI), recommend minimum standards for pediatric CCLs. In addition, Florida's Pediatric Cardiac Technical Advisory Panel (PCTAP) has drafted recommendations for pediatric and congenital cardiovascular centers that include pediatric CCL standards for consideration by AHCA.<sup>27</sup> (See Appendix D for more information on licensure standards referenced throughout this section.)

**Professional medical associations generally agree regarding staff qualifications, resources and equipment, maintenance, and quality improvement recommendations for pediatric CCLs.** For example, professional associations recommend that pediatric CCL

directors should be board-certified pediatric cardiologists and have additional expertise in pediatric catheterization and interventional procedures, such as interventional cardiology or electrophysiology. In addition, every procedure should include a minimum of one board-certified or board-eligible pediatric cardiologist and one pediatric nurse with training and experience in pediatric airway management and sedation. Pediatric CCLs should be one of the critical elements of a pediatric cardiovascular center and pediatric cardiac catheterization procedures should be performed in full-service facilities; have the full complement of resources available, including cardiovascular surgery; have equipment capable of providing higher resolution; and require that all systems have a program of rigorous maintenance and troubleshooting. Program quality should include collecting data prospectively to document quality of care and there should be systematic review of all case outcomes and procedural complications at regular catheterization quality assurance conferences.

Florida's PCTAP draft recommendations are consistent with those of other professional medical associations regarding minimum staff qualifications, resource availability, equipment capability, and maintenance. PCTAP recommends that the physician in charge of the pediatric cardiac catheterization procedure be board-certified by the American Board of Pediatrics Sub-Board of Pediatric Cardiology.

<sup>&</sup>lt;sup>25</sup> These guidelines include the AAP/ACOG *Guidelines for Perinatal Care, Eighth Edition*; The Facility Guidelines Institute (FGI)—*Guidelines for Design and Construction of Hospitals*; and FGI—*Guidelines for Design and Construction of Outpatient Facilities*.

<sup>&</sup>lt;sup>26</sup> Utah references an earlier version of AAP-ACOG guidelines for perinatal care, which predates the AAP's 2012 levels. Utah's requirements apply to Level I basic, Level II specialty, and Level III sub-specialty or tertiary care.

<sup>&</sup>lt;sup>27</sup> Section <u>395.1055</u>, *F.S.*, requires AHCA to establish a technical advisory panel to develop procedures and standards for measuring outcomes of pediatric cardiac catheterization programs and pediatric cardiovascular surgery programs. The panel is to recommend to the agency standards for quality of care, personnel, physical plant, equipment, emergency transportation, and data reporting for hospitals that provide pediatric cardiac services. Accordingly, AHCA appointed the PCTAP, which has issued recommended standards for pediatric cardiovascular centers.

In addition, PCTAP recommends that the pediatric CCL be one component of a Pediatric and Congenital Cardiovascular Center and be co-located within a facility completely equipped to accommodate all aspects of the medical and surgical care of the patient. PCTAP also endorses the other professional medical associations' recommendation that equipment be capable of providing higher resolution and that all systems have a program for rigorous maintenance and troubleshooting.

Although there is some disagreement over whether minimum volume requirements or outcome benchmarks are better safeguards for professional competency, two groups of medical professionals agree on volume recommendations. The ACCF and SCAI recommend that pediatric CCLs should have a minimum laboratory volume of more than 100 procedures per year and that individual pediatric cardiac catheter operators have a minimum volume of 50 procedures per year. Although the AAP recommends using specific outcome benchmarks rather than minimum operator or laboratory volumes as a guide to competence, PCTAP had a similar viewpoint as the ACCF and SCAI as to volume requirements and drafted recommendations regarding minimum volume standards for pediatric CCLs and operators. PCTAP recommends a minimum volume 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.<sup>28</sup>

The standards in AHCA's previous CON rules and the recommended standards by professional medical associations and PCTAP generally address the same requirements. AHCA did not receive statutory authority to use the licensure aspect of existing CON rules for pediatric cardiac catheterization until the agency adopts new licensure rules; thus, there are currently no rules specifically governing the creation or expansion of pediatric cardiac catheterization programs. AHCA is working with PCTAP to establish new rules for pediatric cardiac procedures.

However, we compared the former CON rules to those recommended by professional associations and PCTAP to illustrate the degree to which adopting these requirements might result in current providers needing to change their practices. All of the standards establish requirements for quality measures, staffing, availability of operations, and equipment. Similar to AHCA's former CON rules, the AAP and PCTAP recommend that the pediatric catheterization laboratory director should be a board-certified pediatric cardiologist. Professional associations and PCTAP recommend that the pediatric cardiac catheterization laboratory should always function within a larger, full-service pediatric cardiovascular center. Like the previous CON rule, professional associations and PCTAP recommend using biplane-imaging equipment with framing rates of at least 30 frames per second.

<sup>&</sup>lt;sup>28</sup> PCTAP's recommendation did not specify that volume requirements should be annual volumes. However, AHCA drafted rules for PCTAP to consider during its September 20, 2019, meeting that included the PCTAP recommendations but added that volume recommendations needed to be annual, averaged over a two-year period.

### Pediatric Open Heart Surgery

Pediatric open heart surgery refers to operations performed on the heart that require a patient being placed on a heart-lung bypass machine and can be used to repair a variety of congenital or acquired cardiac defects. The AAP, the American College of Surgeons (ACS), and the American Heart Association establish best practices for pediatric open heart surgery.

Professional organizations are in broad agreement on three practices. First, physicians and surgeons responsible for the care of pediatric cardiac patients should be boardcertified or eligible for certification in pediatrics and/or cardiology or have specialized training in cardiology or emergency medicine. This standard applies to nursing Professional Medical Associations Establish Best Practices for Pediatric Open Heart Surgery

- Quality of staffing
- Staffing ratios
- Availability of services
- Equipment
- Target outcomes
- Volume

staff as well, with the overarching recommendation that nurses assisting in the care of pediatric cardiac patients be trained and experienced with pediatric patients. Second, there is broad agreement that personnel serving in a pediatric cardiac center or program be readily available 24 hours a day, seven days a week. Relatedly, the AAP recommends that centers performing pediatric open heart surgery be affiliated with a certified transplant center or offer pediatric cardiac transplants themselves. Third, equipment should be appropriate for pediatric patients, including that used for diagnostic, imaging, and intervening surgical uses in the performance of pediatric open heart surgery. (See Appendix E for more details on licensure standards discussed throughout this section.)

ACS has made recommendations for pediatric surgical centers that include credentials for medical professionals in pediatrics and their particular area of specialty and requirements for equipment. The ACS Children's Surgery Verification Improvement Program recommends that all centers performing pediatric surgeries stratify pediatric surgical care according to the complexity and volume of children with surgical needs, which drive resource needs and level delineation. The ACS recommends that general pediatric surgical care be tiered into three levels, where Level I programs provide the highest level of care for patients under the age of 18, and employ a comprehensive portfolio of medical and surgical subspecialists available 24 hours per day, seven days per week.<sup>29</sup> These medical personnel should not only be board-certified in their particular area of specialty but also in pediatrics. In addition, the ACS recommends pediatric surgical program verification, where facilities, and other capabilities. The ACS also offers pediatric surgical program verification, where facilities and states can have their general pediatric surgical centers verified/certified according to these standards. (See Appendix F for the specific criteria for each ACS level for general pediatric surgery.)

**PCTAP draft recommendations are consistent with those of other professional organizations for staff qualifications and equipment for pediatric open heart surgery, and it made a volume recommendation.** Specifically, PCTAP recommends the continuous availability of board-certified thoracic and cardiovascular surgeons with specialization in pediatrics, along with other sub-specialists (e.g., anesthesiologists, pathologists) who have experience and training with pediatric and/or cardiac care. They also recommend the availability of equipment, including a requirement for rapid referral

<sup>&</sup>lt;sup>29</sup> The ASC also recommends a minimum a volume of 1,000 surgeries per year for Level I centers.

and transportation of critical patients. Also consistent with ACS guidelines, PCTAP recommends that facilities performing pediatric open heart surgery collect data on the number of patients per operation by year and by age group. In addition, in an October 2019 meeting, PCTAP approved making a volume recommendation for pediatric cardiac surgical procedures of 100 annually, averaged over a two-year period.

AHCA's previous CON rules are commensurate with many of the recommendations from professional medical organizations and PCTAP but diverge in some areas. AHCA did not receive statutory authority to use the licensure aspect of existing CON rules for pediatric open heart surgery until the agency adopts new licensure rules. Thus, there are currently no rules specifically governing the creation or expansion of pediatric open heart surgery programs. AHCA is working with PCTAP to establish new rules for pediatric cardiac procedures.

However, we compared the former CON rules to those recommended by professional associations and PCTAP to illustrate the degree to which adopting these requirements might result in current providers needing to change their practices. AHCA's previous CON rules for pediatric open heart surgery are similar to several recommendations from professional organizations and PCTAP. Consistent with most professional medical associations, the previous CON rules do not require a specific surgical volume. Also, consistent with recommendations from PCTAP and multiple professional organizations, the former CON rules require board-certified/credentialed staff, including cardiovascular surgeons, cardiologists, nurses, and anesthesiologists. Finally, the CON rules are consistent with recommendations from professional organizations and PCTAP in requiring pediatric open heart surgeries to be available 24 hours per day, seven days per week. However, professional medical associations such as the American Heart Association recommend that these emergency response teams be able to mobilize within 30 minutes, while the CON rules do not address this. Further, professional medical associations address specific equipment while the CON rules do not, nor do the former CON rules address staffing ratios, while the ACS recommends staffing ratios for all levels of general pediatric surgical programs. In addition, the rules exceed professional medical associations by requiring indigent and charity care in all pediatric open heart surgical centers.

#### **Organ Transplantation**

Two agencies in the U.S. Department of Health and Human Services oversee organ transplant programs: the Centers for Medicare and Medicaid Services oversees hospital transplant programs that receive Medicare reimbursement, and the Health Resources and Services Administration oversees the Organ Procurement and Transplantation Network (OPTN), which manages the nation's organ allocation and transplantation system.<sup>30</sup>

CMS establishes conditions of participation for hospitals that receive Medicare funding and conduct transplants.<sup>31</sup> These rules include requirements for data submission, written patient selection criteria for wait lists, protocols Two Federal Agencies Oversee Organ Transplant Programs

- Centers for Medicare and Medicaid Services oversees hospital transplant programs.
- Health Resources and Services Administration oversees the Organ Procurement and Transplantation Network.

<sup>&</sup>lt;sup>30</sup> We did not identify any professional medical associations that had developed standards for organ transplants. In addition, Pennsylvania is the only non-CON state that we reviewed that had added licensing standards to the federal requirements.

<sup>&</sup>lt;sup>31</sup> Title 42 CFR §<u>482.68 to 482.104</u>.

for organ recovery and receipt, policies for patient and donor management, protection of patient and living donor rights, and quality assessment and performance improvement programs.

OPTN establishes bylaws for transplant centers that include requirements for the training, qualifications, and responsibilities of the primary transplant surgeon and physician; responsibilities of support personnel; and investigation of personnel if directed by the OPTN Membership and Professional Standards Committee (MPSC).<sup>32</sup> The bylaws also address equipment and services availability, contain transplant program performance requirements, and establish criteria for MPSC review of programs that have higher than expected failure rates for graft and patient survival. (See Appendix G for more details on the requirements discussed throughout this section.)

While OPTN establishes volume requirements for some types of organ transplant programs, they measure functional inactivity, not quality. The OPTN bylaws contain provisions for a review of transplant program functional activity and require programs perform at least a minimum number of transplants within specified timeframes. For example, OPTN designates transplant centers as functionally inactive if they have performed fewer than one heart, liver, or kidney transplant in three consecutive months. For lung transplants, OPTN designates a transplant program as functionally inactive when it has conducted less than one transplant every 12 consecutive months. OPTN requires stand-alone pediatric clinics to conduct one transplant every 12 consecutive months to remain functionally active. Although CMS requires transplant programs applying for initial approval to demonstrate that they have performed at least 10 transplants over a 12-month period for heart, liver, and lung transplants, for example, it established a final rule on September 30, 2019, that rescinded this requirement as an ongoing measure used for re-approval of transplant centers. This part of the rule was intended to reduce regulatory burden on transplant centers.

As a measure of performance, OPTN conducts quality oversight of transplant center outcomes, including one-year post transplant mortality rates. OPTN's MPSC conducts reviews of transplant program performance to identify underperforming transplant programs and requires the implementation of quality assessment and performance improvement measures. One measure of transplant program performance is triggered through a review of one-year graft and patient survival rates.<sup>33,34</sup>

CMS also conducts a one-year graft and patient survival rate review for initial approval but rescinded this review for re-approvals in a final rule published on September 30, 2019. Instead, CMS stated that it expects that transplant programs will continue to use their quality assessment and performance improvement programs (QAPI) to monitor quality of care. In addition, CMS stated that the QAPI programs and CMS surveys will be sufficient to ensure transplant programs continue to achieve and maintain high standards of care.<sup>35</sup>

<sup>&</sup>lt;sup>32</sup> OPTN <u>Bylaws</u>, Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs.

<sup>&</sup>lt;sup>33</sup> For example, for programs performing 10 or more transplants in a 2.5 year period, the MPSC will review a transplant program if it has a higher hazard ratio of mortality or graft failure than would be expected for that transplant program. The criteria used to identify programs with a hazard ratio that is higher than expected includes either of the following: the probability is greater than 75% that the hazard ratio is greater than 1.2, or the probability is greater than 10% that the hazard ratio is greater than 2.5.

<sup>&</sup>lt;sup>34</sup> The MPSC uses performance metrics produced by the Scientific Registry of Transplant Recipients, which calculates hazard ratios for each transplant center as a measure of the program's graft failure rate compared with expected graft failure rate based on donor and recipient characteristics. A ratio greater than 1.00 indicates more failures occurred than expected based on the national experience.

<sup>&</sup>lt;sup>35</sup> The CMS surveys evaluate transplant centers for compliance with the Medicare Conditions of Participation. CMS recently gave responsibility for these surveys to state agencies, including AHCA.

### **OPTIONS**

The Agency for Health Care Administration and the Legislature could consider several options when developing tertiary health services licensure standards. There is broad consensus among professional medical associations and academic researchers that volume and quality outcomes for tertiary health services are positively related, but there is little agreement on specific minimum volume threshold requirements. However, these entities do agree that many other factors influence tertiary health service outcome quality. From these sources, we identified consensus-based volume recommendations for pediatric cardiac catheterization and pediatric open heart surgery and licensing standards for comprehensive rehabilitation, NICU, pediatric cardiac catheterization, and pediatric open heart surgery. For organ transplants, there are existing federal requirements for establishing licensing standards. (See Exhibit 4.)

#### Exhibit 4

AHCA and the Legislature Could Consider Several Options When Establishing Tertiary Health Services Licensure Standards

Tertiary Health Service	Options for AHCA's Consideration
Comprehensive Rehabilitation	<ul> <li>Follow standards established by relevant professional medical associations on outcome measurements, quality of staffing, availability of services, and equipment maintenance.</li> </ul>
Neonatal Intensive Care Units	<ul> <li>Follow standards established by relevant professional medical associations on quality of staffing, such as professional competencies and minimum staffing requirements, staffing ratios, availability of services, and equipment and technology.</li> </ul>
	<ul> <li>Revise the designation of neonatal care to follow the American Academy of Pediatrics' 2012 recommendations, which include the designation of four rather than three levels and consider neonatal weight and gestational age criteria and the ability to deliver services for complex congenital and acquired conditions.</li> </ul>
Pediatric Cardiac Catheterization	<ul> <li>Follow standards established by relevant professional medical associations on quality improvement programs, quality of staffing, availability of services, and resources and equipment, including maintenance.</li> </ul>
	• Require minimum volume recommended by relevant professional medical associations, which is a minimum pediatric cardiac catheter operator volume of 50 per year and a minimum laboratory volume of greater than 100 per year. Alternatively, AHCA could require the draft minimum volume requirements recommended by Florida's PCTAP, which is 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.
Pediatric Open heart Surgery	<ul> <li>Follow standards established by relevant professional medical associations on quality of staffing, staffing ratios, availability of services, equipment, and target outcomes.</li> </ul>
	<ul> <li>Require minimum volume recommended by PCTAP, which is 100 pediatric cardiac surgical procedures annually, averaged over a two-year period.</li> </ul>
Organ Transplantation	<ul> <li>Refer to the federal CMS and OPTN requirements when establishing licensing standards.</li> </ul>
Tertiary Health Service	Option for the Legislature's Consideration
Organ Transplantation	<ul> <li>OPTN provides oversight of transplant center quality. If the Legislature is interested in additional quality assurance via a volume requirement, it could consider directing AHCA to assemble a panel of transplant experts that would consist of representatives from all Florida transplant centers to examine clinical research and available data from the United Network for Organ Sharing and the Scientific Registry of Transplant Recipients to develop recommended volume thresholds to ensure quality for each type of organ transplant.</li> </ul>

Source: OPPAGA analysis.

### **APPENDIX A**

### Academic Literature on Volume for the Tertiary Health Services

The volume numbers displayed in Exhibit A-1 are neither outcomes nor are they endorsed requirements. The volume numbers displayed below are classifications of hospital procedure volumes used by researchers to identify "low," "intermediate," or "high" categorizations to simplify the interpretation of results. This list is not exhaustive; rather, these studies represent a sample of research OPPAGA reviewed. This information is provided to illustrate the variation of volume thresholds within the academic literature. Exhibit A-2 provides a bibliography of the research sample.

#### Exhibit A-1

#### Academic Literature Varies When Classifying Volume for Quality of Care Studies

Service	Low	Intermediate	High
Pediatric and Congenital Cardiac Catheterization	92-158/year (O'Byrne et al., 2015)	Three groups: 167-223/year, 228-308/year, and 355-397/year (O'Byrne et al., 2015)	312-756/year (O'Byrne et al., 2015)
	<150/year (Jayaram et al., 2017) <sup>1</sup>	150 to 299/year (Jayaram et al., 2017) <sup>1</sup>	Two groups: 300-499/year and >499/year (Jayaram et al., 2017) <sup>1</sup>
Pediatric Open Heart Surgery	<150/year (Pasquali et al., 2012)	Two groups: 150-250/year and 250-350/year (Pasquali et al., 2012)	>350/year (Pasquali et al., 2012)
Adult Open Heart Surgery	$\leq$ 10/year (Starling et al., 2017)	11-49/year (Starling et al., 2017)	>50/year (Starling et al., 2017)
Adult Heart Transplant	1-5.9/year (Magruder et al., 2016)	6-12.5/year (Magruder et al., 2016)	>12.5/year (Magruder et al., 2016)
	<9/year (Hosenpud, 1994)		≥9/year (Hosenpud, 1994)
	<7/year (Arnaoutakis et al., 2012)	7-15/year (Arnaoutakis et al., 2012)	>15/year (Arnaoutakis et al., 2012)
	<10.5/year (Russo et al., 2010; Pettit et al., 2012)	10.5-47/year (Russo et al., 2010)	>47/year (Russo et al., 2010)
	<14.5/year (Grimm et al., 2015)	14.5-26.5/year (Grimm et al., 2015)	>26.5/year (Grimm et al., 2015)
Pediatric Heart Transplant	<3/year (Rana et al., 2017)	Two groups: Mid/Low: 3-5 and Mid/High: 6-10 (Rana et al., 2017)	>10/year (Rana et al., 2017)
	< 6.5/year (Lui et al., 2015)	6.5-12/year (Lui et al., 2015)	>12.5/year (Lui et al., 2015)
Adult Lung Transplant	1-11.9/year (Magruder et al., 2016)	12-32.9/year (Magruder et al., 2016)	>33/year (Magruder et al., 2016)
	<20/year (Mooney et al., 2016)	20-34/year (Mooney et al., 2016)	>34/year (Mooney et al., 2016)
	<21.8/year (Kilic et al., 2012)	21.8-34.2/year (Kilic et al., 2012)	>34.2/year (Kilic et al., 2012)
Pediatric Lung Transplant	<3/year (Scully et al., 2018)	Two groups: 6-10/year and 3-5/year	>10/year(Scully et al., 2018)
	<4/year (Scully et al., 2017; Khan et al., 2015)		≥4/year (Scully et al., 2017; Khan et al., 2015)
Adult Liver Transplant	≤20/year (Edwards et al., 1999)		>20/year (Edwards et al., 1999)
	1-37/year (Axelrod et al., 2004)	39-66/year (Axelrod et al., 2004)	66-176/year (Axelrod et al., 2004)
	<39/year (Beal et al., 2017)		>39/year (Beal et al., 2017)
	2009: <11-47/year 2010: 13-43/year (Macomber et al., 2012)	2009: 48-75/year, 2010: 44-70/year (Macomber et al., 2012)	2009: >76/year 2010: >71/year (Macomber et al., 2012)
	Median number 31/year (Ozhathil et al., 2011)	Median number 64/year (Ozhathil et al., 2011)	Median number 102/year (Ozhathil et al., 2011)

Service	Low	Intermediate	High
Pediatric Liver Transplant	<5/year (Rana et al., 2015 <u>)</u>	Two groups: Mid/Low: 5-9 and Mid/High: 10-15 (Rana et al., 2015)	>15/year (Rana et al., 2015)
Adult Kidney Transplant	1-31/year (Barbas et al., 2018)	32-74/year (Barbas et al., 2018)	>75/year (Barbas et al., 2018)
	Two groups: Very low: 1-45/year; low: 46-75/per year (Axelrod et al., 2004)	76-124/per year (Axelrod et al., 2004)	125-278/year (Axelrod et al., 2004)
	<66/year (Sonnenberg et al., 2019)		>196/year (Sonnenberg et al., 2019)
Adult Pancreas Transplant	Simultaneous pancreas-kidney: 1-3/year Pancreas alone: 1-6/year (Alhamad et al., 2017)	Simultaneous pancreas-kidney: 4-10/year Pancreas alone: 7-13/year (Alhamad et al., 2017)	Simultaneous pancreas-kidney: 11-33/year Pancreas alone: 14-34/year (Alhamad et al., 2017)

<sup>1</sup> This study analyzed all congenital cardiac catheterizations for pediatric and adult congenital heart disease. Source: Academic journal articles. See bibliography in Exhibit A-2 for full citations.

#### Exhibit A-2 Bibliography of Academic Literature on Tertiary Health Service Volume

Alhamad, T., Malone, A.F., Brennan, D. C., Stratta, R. J., Chang, S., Wellen, J. R., Horwedel, T. A., and Lentine, K. L. "Transplant center volume and the risk of pancreas allograft failure," *Transplantation* 101, 11 (2017): 2757.

Arnaoutakis, G. J., George, T. J., Allen, J. G., Russell, S. D., Shah, A. S., Conte, J. V., and Weiss, E. S. "Institutional volume and the effect of recipient risk on short-term mortality after orthotopic heart transplant," *The Journal of Thoracic and Cardiovascular Surgery* 143, 1 (2012): 157-167.

Axelrod, D. A., Guidinger, M. K., McCullough, K. P., Leichtman, A. B., Punch, J. D., and Merion, R. M. "Association of center volume with outcome after liver and kidney transplantation," *American Journal of Transplantation* 4 (2004): 920-927.

Barbas, A. S., Dib, M. J., Rege, A. S., Vikraman, D. S., Sudan, D. L., Knechtle, S. J., and Scarborough, J. E. "The volume-outcome relationship in deceased donor kidney transplantation and implications for regionalization," *Annals of Surgery* 267, 6 (2018): 1169-1172.

Beal, E. W., Black, S. M., Mumtaz, K., Hayes Jr., D., EL-Hinnawi, A., Washburn, K., and Tumin, D. "High center volume does not mitigate risk associated with using high donor risk organs in liver transplantation," *Digestive Diseases and Sciences* (2017).

Burki, S., and Fraser Jr., C. D. "Larger centers may produce better outcomes: Is regionalization in congenital heart surgery a superior model?," *Seminars in Thoracic and Cardiovascular Surgery: Pediatric Cardiac Surgery Annual* 19 (2016): 10-13.

Chung, J. H., Phibbs, C. S., Boscardin, W. J., Kominski, G. F., Ortega, A. N., and Needleman, J. "The effect of neonatal intensive care level and hospital volume on mortality of very low birth weight infants," *Medical Care* 48, 7 (2010): 635-644.

Edwards, E. B., Roberts, J. P., McBride, M. A., Schulak, J. A., and Hunsicker, L. "The effect of the volume of procedures at transplantation centers on mortality after liver transplantation," *New England Journal of Medicine* 341, 27 (1999): 2049-2053.

Grimm, J. C., Kilic, A., Shah, A. S., Magruder, J. T., Valero III, V., Dungan, S. P., Russell, S. D., Tedford, R. J., Whitman, G. J.R., and Sciortino, C. M. "The influence of institutional volume on the incidence of complications and their effect on mortality after heart transplantation," *The Journal of Heart and Lung Transplantation* 34, 11 (2015): 1390-1397.

Hayes Jr., D., Sweet, S. C., Benden, C., Kopp, B.T., Goldfarb, S. B., Visner, G. A., Mallory, G. B., Tobias, J. D., and Tumin, D. "Transplant center volume and outcomes in lung transplantation for cystic fibrosis," Transplant International 30 (2017): 371–377.

Hosenpud, J. D., Breen, T. J., Edwards, E. B., Daily, O. P., and Hunsicker, L. G. "The effect of transplant center volume on cardiac transplant outcome: A report of the United Network for Organ Sharing Scientific Registry," *JAMA* 271, 23 (1994): 1844-1849.

Jayaram, N., Spertus, J. A., O'Byrne, M. L., Chan, P. S., Kennedy, K. F., Bergersen, L., and Glatz, A. C. "Relationship between hospital procedure volume and complications following congenital cardiac catheterization: A report from the IMPACT® registry," *American Heart Journal* 183 (2017): 118–128.

Jensen, E. A., and Lorch, S. A. "Effects of a birth hospital's neonatal intensive care unit level and annual volume of very low-birthweight infant deliveries on morbidity and mortality," *JAMA Pediatrics* 169, 8 (2015): 1-9.

Kansy, A., zu Eulenburg, C., Sarris, G., Jacobs, J. P., Fragata, J., Tobota, Z., Ebels, T., and Maruszewski, B. "Higher programmatic volume in neonatal heart surgery is associated with lower early mortality," *The Annals of Thoracic Surgery* 105 (2018): 1436-1440.

Khan, M. S., Zhang, W., Taylor, R. A., McKenzie, E. D., Mallory, G. B., Schecter, M. G., Morales, D. L.S., Heinle, J. S., and Adachi, I. "Survival in pediatric lung transplantation: The effect of center volume and expertise," *The Journal of Heart and Lung Transplantation* 34, 8 (2015): 1073-1081.

Kilic, A., George, T. J., Beaty, C. A., Merlo, C. A., Conte, J. V., and Shah, A. S. "The effect of center volume on the incidence of postoperative complications and their impact on survival after lung transplantation," *The Journal of Thoracic and Cardiovascular Surgery* 144 (2012): 1502-1509.

Kroelinger, C. D., Okoroh, E. M., Goodman, D. A., Lasswell, S. M., and Barfield, W. D. "Comparison of state risk-appropriate neonatal care policies with the 2012 AAP policy statement," *Journal of Perinatology* 38, 4 (2018): 411–420.

Lui, C., Grimm, J. C., Magruder, J. T., Dungan, S. P., Spinner, J. A., Do, N., Nelson, K. L., Cameron D. E., Vricella, L. A., and Jacobs, M. L. "The effect of institutional volume on complications and their impact on mortality after pediatric heart transplantation," *The Annals of Thoracic Surgery* 100 (2015): 1423-1431.

Macomber, C. W., Shaw, J. J., Santry, H., Saidi, R. F., Jabbour, N., Tseng, J. F., Bozorgzadeh, A., and Shah, S.A. "Centre volume and resources consumption in liver transplantation," *HPB* 14 (2012): 554-559.

Magruder, J. T., Shah, A. S., Crawford, T. C., Grimm, J. C., Kim, B., Orens, J.B., Bush, E. L., Higgins, R. S., and Merlo, C. A. "Simulated regionalization of heart and lung transplantation in the United States," *American Journal of Transplantation* 17 (2017): 485-495.

Modi, R., Tumin, D., Kruger, A. J., Beal, E. W., Hayes, Jr., D., Hanje, J., Michaels, A. J., Washburn, K., Conteh, L. F., Black, S. M., and Mumtaz, K. "Effect of transplant center volume on post-transplant survival in patients listed for simultaneous liver and kidney transplantation," *World Journal of Hepatology* 10, 1 (2018): 134-141.

Mooney, J. J., Weill, D., Boyd, J. H., Nicholls, M. R., Bhattacharya, J., and Dhillon, G. S. "Effect of transplant center volume on cost and readmissions in Medicare lung transplant recipients," *Annals of the American Thoracic Society* **13**, 7 (2016): 1034-1041.

Nguyen, Y., Wallace, D. J., Yordanov, Y., Trinquart, L., Blomkvist, J., Angus, D. C., Kahn, J. M., Ravaud, P., and Guidet, B. "The volume-outcome relationship in critical care: A systematic review and meta-analysis," *Chest* 148, 1 (2015): 79-92.

O'Byrne, M. L., Glatz, A. C., Shinohara, R. T., Jayaram, N., Gillespie, M. J., Dori, Y., Rome, J. J., and Kawut, S. "Effect of center catheterization volume on risk of catastrophic adverse event after cardiac catheterization in children," *American Heart Journal* 169, 6 (2015): 823-832.

Ozhathil, D. K., Li, Y., Smith, J. K., Tseng, J. F., Saidi, R.F., Bozorgzadeh, A., and Shah, S. A. "Effect of centre volume and high donor risk index on liver allograft survival," *HPB* 13 (2011): 447-453.

Pasquali, S. K., Li, J.S., Burstein, D. S., Sheng, S., O'Brien, S. M., Jacobs, M. L., Jaquiss, R. D.B., Peterson, E. D., Gaynor, J. W., and Jacobs, J. P. "Association of center volume with mortality and complications in pediatric heart surgery," *Pediatrics* 129, 2 (2012): e370-e376.

Pettit, S. J., Jhund, P. S., Hawkins, N. M., Gardner, R. S., Haj-Yahia, S., McMurray, J. J.V., and Petrie, M. C. "How small is too small? A systematic review of center volume and outcome after cardiac transplantation," *Circulation: Cardiovascular Quality and Outcomes* 5 (2012): 783-790.

Phibbs, C. S., Baker, L. C., Caughey, A. B., Danielsen, B., Schmitt, S. K., and Phibbs, R. H. "Level and volume of neonatal intensive care and mortality in very-low-birth-weight infants," *The New England Journal of Medicine* 356 (2007): 2165-2175.

Profit, J., Gould, J. B., Bennett, M., Goldstein, B. A., Draper, D., Phibbs, C. S., and Lee, H. C. "The association of level of care with NICU quality," *Pediatrics* 137, 3 (2016): e20144210.

Rana, A., Pallister, Z., Halazun, K., Cotton, R., Guiteau, J., Nalty, C., O'Mahony, C., and Goss, J. "Pediatric liver transplant center volume and the likelihood of transplantation," *Pediatrics* 136, 1 (2015): e99-e107.

Rana, A., Fraser, C. D., Scully, B. B., Heinle, J. S., McKenzie, E. D., Dreyer, W. J., Keuht, M., Lui, H., Brewer, E. D., Rosengart, T. K., O'Mahony, C.A., and Goss, J. A. "Inferior outcomes on the waiting list in low-volume pediatric heart transplant centers," *American Journal of Transplantation* 17 (2017): 1515-1524.

Rochow, N., Landau-Crangle, E., Lee, S., Schünemann, H., and Fusch, C. "Quality indicators but not admission volumes of neonatal intensive care units are effective in reducing mortality rates of preterm infants," *PLoS ONE* 11(8): 1-12.e

Rogowski, J., Horbar, J. D., Staiger, D. O., Kenny, M., Carpenter, J., and Geppert, J. "Indirect vs. direct hospital quality indicators for very-low-birth-weight infants," *JAMA* 291, 2 (2004): 202-209.

Russo, M. J., Iribarne, A., Easterwood, R., Ibrahimiye, A. N., Davies, R., Hong, K. N., Ascheim, D. D., Gelijns, A. C., and Naka, Y. "Post-heart transplant survival is inferior at low-volume centers across all risk strata," *Circulation* 122, suppl\_1 (2010): S85-S91.

Scully, B. B., Goss, M., Liu, H., Keuht, M. L., Adachi, I., McKenzie, E. D., Fraser, C. D., Melicoff, E., Mallory, G. B., Heinle, J. S., and Rana, A. "Waiting list outcomes in pediatric lung transplantation: Poor results for children listed in adult transplant programs," *The Journal of Heart and Lung Transplantation* 36, 11 (2017): 1201-1208.

Scully, B. B., Heinle, J. S., Kueht, M.L., McKenzie, E. D., Mallory, G. B., Melicoff, E., and Rana, A. "Poor outcomes on the waiting list for pediatric lung retransplant patients listed in low volume centers," *The Journal of Heart and Lung Transplantation* 37, 4S (2018): 135.

Sonnenberg, E. M., Cohen, J. B., Hsu, J. Y., Potluri, V.S., Levine, M. H., Abt, P.L., and Reese, P.P. "Association of kidney transplant center volume with 3-year clinical outcomes," *American Journal of Kidney Diseases* (2019).

Starling, R. C., and Xanthopoulos, A. "Are outcomes related to left ventricular assist device center volume?: Too complex to answer," *JACC: Heart Failure* 5,10 (2017): 700-702.

Wang, H., Dong, Y., and Sun, B. "Admission volume is associated with mortality of neonatal respiratory failure in emerging neonatal intensive care units," *The Journal of Maternal-Fetal & Neonatal Medicine* 32, 13 (2019): 2233-2240.

Wehby, G., Ullrich, F., and Xie, Y. "Very low birth weight hospital volume and mortality—an instrumental variables approach," *Med Care* 50, 8 (2012): 714-721.

Source: OPPAGA review of academic journal articles.

### **APPENDIX B**

### **Comprehensive Rehabilitation**

-	
Background	Comprehensive Medical Rehabilitation Inpatient Services is a collection of services geared toward assisting patients who are physically disabled. These physical disabilities include, but are not limited to, stroke, brain injury, polyarthritis, rheumatoid arthritis, amputation, neurological disorders, spinal cord injury, congenital deformity, and major multiple trauma. Services include physical therapy, occupational therapy, speech-language therapy, and therapy for those with prosthetics. Comprehensive Medical Rehabilitation Inpatient Services is designated a tertiary health service by s. 408.032, <i>Florida Statutes 2018.</i>
Current Florida Requirements (embedded in certificate of need rules until replaced by licensing standards)	AHCA is authorized to use standards embedded in the comprehensive inpatient rehabilitation certificate of need (CON) rules (Rule <u>59C-1.039</u> , <i>Florida Administrative Code</i> ) that Ch. <u>2019-136</u> , <i>Laws of Florida</i> , repealed until the agency promulgates licensing rules to replace the CON standards. Rule <u>59C-1.039</u> , <i>Florida Administrative Code</i> defines Comprehensive Medical Rehabilitation Inpatient Services as an organized program of integrated intensive care services provided by a coordinated multidisciplinary team to patients with severe physical disabilities, such as stroke; spinal cord injury; congenital deformity; amputation; major multiple trauma; fracture of femur; brain injury; polyarthritis, including rheumatoid arthritis; neurological disorders, including multiple sclerosis; motor neuron diseases; polyneuropathy; muscular dystrophy; Parkinson's disease; and burns. Florida requires that facilities providing comprehensive rehabilitation must participate in Medicare and Medicaid programs. The Director of Rehabilitation must be a board-certified or board-eligible physiatrist with at least two years of experience in the medical management of inpatients requiring rehabilitation services. Centers providing comprehensive medical rehabilitation nursing, physical therapy, occupation therapy, speech pathology and audiology, social services, psychological services, and orthotic and prosthetic services.
Federal Requirements	The Centers for Medicare and Medicaid Services establishes standards for hospitals for the administration of comprehensive rehabilitation care (listed below).
<ul> <li>ARN: Association o</li> <li>ARN: Association o</li> <li>AOTA: American Oc</li> <li>AOTA: American Oc</li> <li>AOTA: American Oc</li> <li>AOTA: American Oc</li> <li>ASHA: American Sp Pathologists, and Au</li> <li>APTA: American Ph</li> <li>APTA: Academy of <i>Rehabilitation</i> (ANPT</li> <li>ANPT: Academy of <i>Outpatient Rehabilita</i></li> <li>ANPT: Academy of Parkinson's)</li> <li>CARF: Commission Programs)<sup>2</sup></li> </ul>	ATANDARDS FROM PROFESSIONAL ORGANIZATIONS AND ACCREDITORS <sup>1</sup> f Rehabilitation Nurses <i>Post-Acute Rehabilitation Levels of Care–Inpatient Care</i> (ARN Levels) f Rehabilitation Nurses Rehabilitation Nurse Manager (ARN Rehab Nurse Manager) ccupational Therapy Association <i>Model State Legislation</i> (AOTA Model) ccupational Therapy Association <i>Model of Continuing Competence Requirements</i> (AOTA Comp. Model) beech-Language-Hearing Association <i>Model Bill for State Licensure of Audiologists, Speech-Language</i> <i>udiology and Speech-Language Pathology Assistants</i> 2014 (ASHA Model Leg.) hysical Therapy Association <i>Criteria for Standard of Practice for Physical Therapy</i> 2014 (APTA CSP) hysical Therapy Association <i>Delivery of Value-Based Physical Therapist Services</i> 2015 (APTA VBPT) hysical Therapy Association <i>Direct Access to Physical Therapy Services</i> 2018 (APTA Access) Neurologic Physical Therapy— <i>TBI Edge Outcome Measures for In and Outpatient Rehabilitation</i> 2013 injury) (ANPT TBI) Neurologic Physical Therapy— <i>MS EDGE Outcome Measures for Inpatient and Outpatient</i> T Stroke) Neurologic Physical Therapy— <i>MS EDGE Outcome Measures for Multiple Sclerosis (MS) In and</i> <i>ation</i> 2012 (or multiple sclerosis) (ANPT MS) Neurologic Physical Therapy—Recommendations for Patients with Parkinson's Disease (ANPT on Accreditation of Rehabilitation Facilities Medical Rehabilitation Program Descriptions 2019 (CARF
requirements for teaching hosp	itals and for residents and fellows. For treatments and procedures falling under the purview of comprehensive

rehabilitation, requirements depend on the specialty of the fellow. Residents assigned to an acute inpatient rehabilitation service should be responsible for a minimum of six physical medicine and rehabilitation patients and should care for an average daily patient load of eight patients over the 12-month inpatient experience. For those treating patients with brain injury, fellows are expected to devote at least three months of their clinical experience to the care of hospitalized patients and three months to non-hospitalized patients. Fellows specializing in spinal cord medicine should have a minimum of three months of inpatient and three months of outpatient rehabilitation experience and provide care for at least eight hospitalized patients during an inpatient rotation.

<sup>2</sup> The Commission on Accreditation of Rehabilitation Facilities is an accreditation organization for disability rehabilitation, treatment for addiction and substance abuse, home and community based services, retirement living, or other health and human services providers.

	QUALITY MEASURES
Minimum Volume	<ul> <li>N/A</li> </ul>
Outcome Measures	<ul> <li>ANPT TBI: Highly recommend Coma-Recovery Scale and Moss Attention Rating Scale for traumatic brain injury (TBI) patients.</li> </ul>
	<ul> <li>ANPT Stroke: All adults with neurological disorders should be evaluated by the following core measures:</li> <li>6 minute walk test, 10 meter walk test, Berg Balance Test, Functional Gait Assessment, Activities-Specific Balance Confidence Scale, and 5 Time Sit to Stand Test.</li> </ul>
	<ul> <li>ANPT Stroke: Highly recommend Fugl-Meyer Assessment, Functional Independence Measure, Postural Assessment Scale for Stroke Patients, Stroke Impact Scale, and Stroke Rehabilitation Assessment for Movement</li> </ul>
	<ul> <li>ANPT MS: Highly recommend 12-item MS Walking Scale, 6-Minute Walk Test, 9-Hole Peg Test, Berg Balance Scale, MS Impact Scale, MS Quality of Life, Times 25 Foot Walk, and Time Up &amp; Go with Cognitive and Manual.</li> </ul>
	<ul> <li>ANPT Parkinson's: Highly recommend MDS-UPDRS revision-part 3, MDS-UPDRS-part 1, Montreal Cognitive Assessment, 6 minute walk, 10 meter walk MINI, BESTest, MDS-UPDRS-part 2, Functional Gait Assessment, Sit to Stand 5 times, 9 hole peg test, and PDQ-8 or PDQ-39.</li> </ul>
Other	<ul> <li>N/A</li> </ul>
Caveats	■ N/A
	QUALITY OF STAFFING
Professional Competencies,	Program Director(s):
Certification, Specialization	<ul> <li>ARN Nurse Manager: Nurse managers should have experience in clinical rehab nursing.</li> <li>ARN Nurse Manager: Nurse managers are preferred to have a minimum of a backbard darger in pursing.</li> </ul>
	<ul> <li>ARN Nurse Manager: Nurse managers are preferred to have a minimum of a bachelor's degree in nursing.</li> <li>ARN Nurse Manager: Nurse managers should have certification in rehab nursing or obtain certification as soon as possible.</li> </ul>
	• ARN Nurse Manager: Nurse manager supports the interdisciplinary team model within the continuum of care.
	Physical and Occupational Therapy:
	AOTA Comp. Model: Occupational therapists must maintain their licenses via competency activities,
	continuing education, academic coursework, independent learning, mentorship, fieldwork supervision/capstone monitoring, professional writing, research, grant-writing, and post-professional programs for a tatal of 24 context hours during the two wear research pariod.
	<ul> <li>APTA CSP: Physical therapist of record is the therapist who assumes responsibility for patient/client</li> </ul>
	management and is accountable for the coordination, continuation, and progression of the plan of care.
	Neurological (Stroke, Brain, Spinal Cord, Parkinson's, MS):
	application and the site survey all portions of the program that the organization provides.
	<ul> <li>CARF Programs: Programs seeking accreditation as a spinal injury specialty program must include in the application and the site survey all portions of the program that the organization provides.</li> </ul>
	Speech-Language Therapy:
	<ul> <li>ASHA Model Leg.: Licensure should be granted in either audiology or speech-language pathology.</li> <li>ASHA Model Leg.: Audiologists should have a doctoral degree from an accredited program</li> </ul>
	<ul> <li>ASHA Model Leg.: Audiologists should have 1,820 hours of supervised clinical practicum.</li> </ul>
	<ul> <li>ASHA Model Leg.: Speech-language pathologists should possess a master's or doctoral degree from an accordited institution</li> </ul>
	<ul> <li>AOTA Model: An occupational therapist licensed by the state board to oversee all aspects of therapy service delivery</li> </ul>
	<ul> <li>AOTA Comp. Model: Re-licensure after a minimum of 24 contact hours during a two-year period.</li> </ul>
	<ul> <li>All Therapy Types:</li> <li>ARN Levels: Rehabilitation nurses should be used to facilitate the discharge transition process.</li> </ul>
Staffing to Patient Ratios, By Profession	<ul> <li>N/A</li> </ul>
Other	<ul> <li>N/A</li> </ul>

	AVAILABILITY
Available Hours of Operation	• CARF Levels Programs: Inpatient rehabilitation program is available 24 hours/day.
	<ul> <li>ARN Levels: 24 hours licensed nursing and rehabilitation care.</li> </ul>
Other	• N/A
	EQUIPMENT
Availability of Appropriate Equipment/ Technology/ Ancillary Services	<ul> <li>N/A</li> </ul>
Maintenance	<ul> <li>APTA CSP: All equipment is inspected routinely.</li> </ul>
Other	<ul> <li>N/A</li> </ul>
APPLICABI Title 42, Code of I State Operations N CMS Inpatient Ref Medicare Benefit F	LE STANDARDS FROM THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) Federal Regulations, §485.58 Manual, Chapter 2 Nabilitation Facility (IRF) Provider Training Policy Manual, Chapter 15
	QUALITY MEASURES
Minimum Volume	<ul> <li>CMS does not provide a minimum volume requirement in the form of minimum patients. Instead, CMS outlines a minimum intensity.</li> <li>CMS IRF Provider Training: Minimum of 3 hours/day, 5 days/week, or 15 hours/week for a 7 consecutive day period.</li> </ul>
Outcome Measures	<ul> <li>N/A</li> </ul>
Other	<ul> <li>State Operations Manual: Facilities must be accredited by the Joint Commission, the Commission on Accreditation of Rehabilitation Facilities, the Council on Accreditation of Services for Families and Children (COA), or by any other accrediting organization with comparable standards that is recognized by the state.</li> </ul>
Caveats	• N/A
	QUALITY OF STAFFING
Professional Competencies, Certification, Specialization	<ul> <li>Program Director(s)</li> <li>42 CFR §485.58: Facility physician available to supervise medical and non-medical staff.</li> <li>CMS IRF Provider Training: Multidisciplinary team available must include a registered nurse (RN) with specialized training or experience with rehabilitation.</li> <li>Physical and Occupational Therapy:</li> <li>Medicare Benefit Policy Manual: Qualified occupational therapist is licensed within the state, a graduate of an accredited program, and eligible for, or has board certification by the National Board for Certification in Occupational Therapy.</li> <li>Medicare Benefit Policy Manual: Physical therapist is licensed within the state where practicing and a graduate of a physical therapy education program with curriculum accreditation provided by the Commission on Accreditation in Physical Therapy Education (CAPTE) or the American Physical Therapy Association (APTA).</li> <li>CMS IRF Provider Training: Certified occupational and physical therapy assistants may provide therapy services under the appropriate supervision of a licensed therapist.</li> <li>Trauma (Brain, Spinal Cord, Stroke):</li> <li>Medicare Benefit Policy Manual: Occupational therapy shall be provided by a qualified occupational therapist</li> </ul>
	<ul> <li>in order to treat, improve, or restore functions that have been impaired by illness or injury or, where function has been permanently lost or reduced by illness or injury, to improve the individual's ability to perform those tasks required for independent functioning.</li> <li>Speech-Language Therapy:         <ul> <li>Medicare Benefit Policy Manual: Therapist must have education and experience requirements for a Certificate of Clinical Competence in speech-language pathology granted by the American Speech-Language-Hearing Association.</li> </ul> </li> <li>All Therapy Types:         <ul> <li>CMS IRF Provider Training: Technicians and aides are limited to performing administrative and support functions and may not be directly involved in the provision of therapy services to the beneficiary.</li> </ul> </li> </ul>

Staffing to Patient Ratios, By Profession	42 CFR §485.58: One qualified professional representing each service must be available either on premises	
Othor	<ul> <li>N/A</li> </ul>	
	AVAILABILITY	
Available Hours of Operation	<ul> <li>42 CFR §485.58: At least one qualified professional must be on the premises during the facility's operating hours</li> </ul>	
	<ul> <li>CMS IRF Provider Training: Regardless of weekends or holidays, inpatient rehabilitation facilities are expected</li> </ul>	
	to comply with all the coverage requirements.	
Other	<ul> <li>42 CFR §<u>485.58</u>: Must provide, at minimum, physician's services, physical therapy services, and social/psychological services.</li> </ul>	
	EQUIPMENT	
Availability of Appropriate	<ul> <li>42 CFR §485.58: Facility must have necessary equipment to implement plan of treatment and sufficient space to provide care.</li> </ul>	
Services		
Maintenance	<ul> <li>Ν/Δ</li> </ul>	
Othor	- N/A	
LICENSING 3	STANDARDS FROM SELECTED UTHER STATES THAT DU NUT HAVE A CON PROCESS	
<ul> <li>Colorado (CO)</li> </ul>		
<ul> <li>New Hampshire (NH</li> </ul>	ł)	
<ul> <li>Pennsylvania (PA)</li> </ul>		
<ul> <li>Texas (TX)</li> </ul>		
<ul> <li>Utah (UT)</li> </ul>		
Utah (UT)	QUALITY MEASURES	
Utah (UT)  Minimum Volume	QUALITY MEASURES	
Utah (UT)  Minimum Volume Outcome Measures	QUALITY MEASURES           • N/A           • N/A	
Utah (UT)  Minimum Volume Outcome Measures Other	QUALITY MEASURES           • N/A           • N/A           • N/A	
Utah (UT)  Minimum Volume Outcome Measures Other Caveats	QUALITY MEASURES           • N/A           • N/A           • N/A	
Utah (UT)  Minimum Volume Outcome Measures Other Caveats	QUALITY MEASURES           • N/A           • N/A           • N/A           • N/A           • N/A           • QUALITY OF STAFFING	
Utah (UT)  Minimum Volume Outcome Measures Other Caveats Professional Competencies,	QUALITY MEASURES   N/A  N/A  N/A  QUALITY OF STAFFING  Program Director(s):	
Utah (UT)  Minimum Volume Outcome Measures Other Caveats  Professional Competencies, Certification, Specialization	QUALITY MEASURES         • N/A         • OLALITY OF STAFFING         Program Director(s):         • CA: Directors should be a physician and a registered nurse with training and experience in rehabilitation.	
Utah (UT)  Minimum Volume Outcome Measures Other Caveats  Professional Competencies, Certification, Specialization	QUALITY MEASURES     N/A     N/A     N/A     N/A     N/A     OUALITY OF STAFFING     Program Director(s):     CA: Directors should be a physician and a registered nurse with training and experience in rehabilitation.     CO: Chief of staff shall have training and expertise in rehabilitative medicine.     NH: Medical director should be a Dector of Medicine MD licensed in the state of NH board-certified by the	
Utah (UT)  Minimum Volume Outcome Measures Other Caveats  Professional Competencies, Certification, Specialization	QUALITY MEASURES     N/A     N/A     N/A     N/A     N/A     OUALITY OF STAFFING     QUALITY OF STAFFING     OUALITY OF STAFFING     OUALITY OF STAFFING     OUALITY OF STAFFING     N/A     OUALITY OF STAFFING     N/A	
Utah (UT)  Minimum Volume Outcome Measures Other Caveats  Professional Competencies, Certification, Specialization	QUALITY MEASURES     N/A     N/A     N/A     N/A     N/A     N/A     OUALITY OF STAFFING     DUALITY OF STAFFING     Program Director(s):     CA: Directors should be a physician and a registered nurse with training and experience in rehabilitation.     CO: Chief of staff shall have training and expertise in rehabilitative medicine.     NH: Medical director should be a Doctor of Medicine MD licensed in the state of NH, board-certified by the American Board of Physical Medicine and Rehabilitation or the American Society of Neurorehabilitation, have two years of training and experience, and be available for at least 20 hours per week.	
Utah (UT)  Minimum Volume Outcome Measures Other Caveats  Professional Competencies, Certification, Specialization	<ul> <li>QUALITY MEASURES</li> <li>N/A</li> <li>N/A</li> <li>N/A</li> <li>N/A</li> <li>QUALITY OF STAFFING</li> <li>Program Director(s):         <ul> <li>CA: Directors should be a physician and a registered nurse with training and experience in rehabilitation.</li> <li>CO: Chief of staff shall have training and expertise in rehabilitative medicine.</li> <li>NH: Medical director should be a Doctor of Medicine MD licensed in the state of NH, board-certified by the American Board of Physical Medicine and Rehabilitation or the American Society of Neurorehabilitation, have two years of training and experience, and be available for at least 20 hours per week.</li> <li>PA: Director should be a physiatrist who is a member of the medical staff.</li> </ul> </li> </ul>	
Utah (UT)  Minimum Volume Outcome Measures Other Caveats  Professional Competencies, Certification, Specialization	OUALITY MEASURES     N/A     N/A     N/A     N/A     N/A     N/A     OUALITY OF STAFFING     Program Director(s):     CA: Directors should be a physician and a registered nurse with training and experience in rehabilitation.     CO: Chief of staff shall have training and expertise in rehabilitative medicine.     NH: Medical director should be a Doctor of Medicine MD licensed in the state of NH, board-certified by the American Board of Physical Medicine and Rehabilitation or the American Society of Neurorehabilitation, have two years of training and experience, and be available for at least 20 hours per week.     PA: Director should be a physiatrist who is a member of the medical staff.     TX: A hospital providing comprehensive rehabilitation shall have a medical director or clinical director who experience of administrate the requiring and experience of acmerchanging regulation shall have a medical director or clinical director who experience and edministrate the requiring a dispersion of a physicing comprehensive rehabilitation shall have a medical director or clinical director who experience and edministrate the requiring a dispersion or the administrate the administrate the requiring the providing comprehensive rehabilitation shall have a medical director or clinical director who	
Utah (UT)  Minimum Volume Outcome Measures Other Caveats  Professional Competencies, Certification, Specialization	QUALITY MEASURES     N/A     N/A     N/A     N/A     N/A     N/A     N/A     OUALITY OF STAFFING     OUALITY     OUALITY	
Utah (UT)  Minimum Volume Outcome Measures Other Caveats  Professional Competencies, Certification, Specialization	<ul> <li>N/A</li> <li>N/A</li> <li>N/A</li> <li>N/A</li> <li>N/A</li> <li>N/A</li> <li>N/A</li> <li>Outling of staff shall have training and experise in rehabilitative medicine.</li> <li>Chief of staff shall have training and expertise in rehabilitative medicine.</li> <li>NH: Medical director should be a Doctor of Medicine MD licensed in the state of NH, board-certified by the American Board of Physical Medicine and Rehabilitation or the American Society of Neurorehabilitation, have two years of training and experience, and be available for at least 20 hours per week.</li> <li>PA: Director should be a physician who is a member of the medical staff.</li> <li>TX: A hospital providing comprehensive rehabilitation shall have a medical director or clinical director or shall be a physician who is board-certified or eligible for board certification in physical medicine and rehabilitation, orthopedics, neurology, neurosurgery, internal medicine, or rheumatology as</li> </ul>	
Utah (UT)  Minimum Volume Outcome Measures Other Caveats  Professional Competencies, Certification, Specialization	QUALITY MEASURES     N/A     N/A     N/A     N/A     N/A     N/A     N/A     N/A     OUALITY OF STAFFING     Program Director(s):     CA: Directors should be a physician and a registered nurse with training and experience in rehabilitation.     CO: Chief of staff shall have training and expertise in rehabilitative medicine.     NH: Medical director should be a Doctor of Medicine MD licensed in the state of NH, board-certified by the American Board of Physical Medicine and Rehabilitation or the American Society of Neurorehabilitation, have two years of training and experience, and be available for at least 20 hours per week.     PA: Director should be a physician who is a member of the medical staff.     TX: A hospital providing comprehensive rehabilitation shall have a medical director or clinical director or shall be a physician who is board-certified or eligible for board certification in physical medicine and rehabilitation, orthopedics, neurology, neurosurgery, internal medicine, or rheumatology as appropriate for the rehabilitation program and qualified by training or at least two years' training and	
Utah (UT)  Minimum Volume Outcome Measures Other Caveats  Professional Competencies, Certification, Specialization	QUALITY MEASURES         • N/A         • OUALITY OF STAFFING         Program Director(s):         • CA: Directors should be a physician and a registered nurse with training and experience in rehabilitation.         • CO: Chief of staff shall have training and expertise in rehabilitative medicine.         • NH: Medical director should be a Doctor of Medicine MD licensed in the state of NH, board-certified by the American Board of Physical Medicine and Rehabilitation or the American Society of Neurorehabilitation, have two years of training and experience, and be available for at least 20 hours per week.         • PA: Director should be a physiatrist who is a member of the medical staff.         • TX: A hospital providing comprehensive rehabilitation shall have a medical director or clinical director shall be a physician who is board-certified or eligible for board certification in physical medicine and rehabilitation, orthopedics, neurology, neurosurgery, internal medicine, or rheumatology as appropriate for the rehabilitation program and qualified by training or at least two years' training and experience to serve as medical or clinical director.         • Thy: Duraled thereare to filte must be under the direction of a physical theremit	
Utah (UT)  Minimum Volume Outcome Measures Other Caveats  Professional Competencies, Certification, Specialization	OUALITY MEASURES     N/A     N/A	
Utah (UT)  Minimum Volume Outcome Measures Other Caveats  Professional Competencies, Certification, Specialization	<ul> <li>N/A</li> <li>N/A</li> <li>N/A</li> <li>N/A</li> <li>N/A</li> <li>N/A</li> <li>N/A</li> <li>N/A</li> <li>N/A</li> <li>Outeration of the second second</li></ul>	

<sup>&</sup>lt;sup>3</sup> We identified 15 states that do not have a certificate of need process for the tertiary health services. However, two of the states, Arizona and Minnesota, either had a CON for some other related services or had a process that was not called a CON but would have similar effects. Seven of the states were not comparable to Florida due to factors such as having a small number of teaching hospitals; a significantly different breakdown of citizens on Medicaid, Medicare, or uninsured; a smaller population size; and/or a higher portion of the state that is rural. These seven states were Idaho, Kansas, New Mexico, North Dakota, South Dakota, Wisconsin, and Wyoming. For the remaining six states, we conducted an in-depth review to identify and evaluate any licensing standards for the services considered tertiary in Florida. These six states were California, Colorado, New Hampshire, Pennsylvania, Texas, and Utah.

	CO: Occupational therapy shall be under the direction of a board-certified (American Board of Physical
	Medicine and Kehabilitation) physician.
	of State Boards of Physical Therapy (ESBPT) in order to be eligible for licensure as a physical therapist
	<ul> <li>TX: Physical therapists must be licensed by the Executive Council of Physical and Occupational Therapy</li> </ul>
	Examiners.
	<ul> <li>TX: Occupational therapists must be licensed by the Executive Council of Physical and Occupational Therapy Examiners.</li> </ul>
	Speech-Language Therapy:
	<ul> <li>CO: Speech therapy services shall be provided by persons qualified by training, experience, and ability.</li> <li>TX: Speech-language pathology (speech therapy) services must be provided by a licensed speech-language pathologist (SLP) or a licensed speech-language pathologist assistant (SLPA) under the supervision of an SLP who is licensed by the State Board of Examiners for Speech-Language Pathology and Audiology.</li> </ul>
	All Therapy Types:
	<ul> <li>NH: Director of nursing services should be a NH-licensed RN with a bachelor's degree and three years of experience in the provision of comprehensive rehabilitation.</li> </ul>
	<ul> <li>PA: Restorative nurses shall be supervised by an RN trained and experienced in rehabilitation and restorative nursing.</li> </ul>
	<ul> <li>CA: Inpatient rehabilitation facilities should have the following personnel: audiologist, orthotist, prosthetist, vocational rehab counselor, recreational therapist, psychiatrist, psychologist, registered nurse with public health nursing certificate. learning disability specialist, and social worker.</li> </ul>
	<ul> <li>NH: Occupational therapist, physical therapist, speech-language therapist, respiratory therapist, psychologist, orthoptist/prosthetist_rehabilitation purse_ and other pursing staff</li> </ul>
	<ul> <li>UT: All therapy services shall be directed by a qualified licensed provider for that particular need.</li> </ul>
	<ul> <li>TX: Those hospitals providing comprehensive medical rehabilitation services shall use a coordinated interdisciplinary team that is directed by a physician and that works in collaboration to develop and implement the patient's treatment plan.</li> </ul>
Staffing to Patient Ratios, By Profession	TX: Staffing ratios should be sufficient for the number of patients served.
Other	■ N/A
	AVAILABILITY
Available Hours of Operation	<ul> <li>TX: Personnel providing emergency care shall be staffed for 24-hour coverage and accessible to all patients receiving services.</li> </ul>
Other	• TX: Services shall be in a hospital under the medical supervision of a physician who is on duty and available or on call 24 hours each day.
	EQUIPMENT
Availability of Appropriate	• TX: The hospital shall have the necessary equipment and sufficient space to implement the treatment plan to
Equipment/Ancillary	all for adequate care.
Services	<ul> <li>IX: Hospitals that provide comprehensive medical rehabilitation services shall have emergency equipment, supplies medications, and designated percented.</li> </ul>
Maintananaa	- N/A
maintenance	
Other	• N/A

Source: OPPAGA review of journal articles; state and federal statutes/laws and rules; and standards from professional organizations, accreditors, and other states.

### APPENDIX C Neonatal Intensive Care Unit (NICU)

Background	<ul> <li>Neonatal care is the care provided to newborn babies in the hospital. Since the 1970s, professional organizations have stratified and regionalized maternal and perinatal care to improve outcomes for high-risk neonates, born either preterm or with serious medical or surgical conditions, by referring patients to higher-level centers with the resources and personnel to address the required complexity of care needed. As such, hospital neonatal care is categorized according to the intensity and specialization of are that can be provided in the hospital's neonatal intensive care unit (NICU). While the classification of neonatal care has varied over the years, in 2012, the American Academy of Pediatrics updated its policy on its recommendations for neonatal care level classifications to reflect the overall evidence for risk-appropriate care.<sup>1</sup> This includes standards for the minimal level of units' capabilities in terms of neonatal risk factors, minimal functional expectations, and provider type and skills and competences necessary to maintain each level of care. The 2012 updated neonatal care level classification consists of four levels of neonatal care, with each higher level of care capable of performing the functions of the lower. Generally, these levels are designed to serve the following infants:</li> <li>Level I—Specialty care nursery is for infants born at 32 weeks gestation or later, who weigh 1,500 grams or more or are physiologically immature, or who are moderately ill with problems that are expected to resolve quickly and are not anticipated to neonatal infants with less than 32 weeks gestation and weighing less than 1,500 grams or for all critically ill infants. This level provides a full range of respiratory support, which may include conventional and/or high frequency ventilation and inhaled Nitric oxide; prompt and readily available access to a full range of pediatric medical subspecialities, pediatric surgical specialitis, and eduative agreement; and advanced imaging with interpretat</li></ul>
<b>Current Florida Requirements</b> (embedded in certificate of need rules until replaced by licensing standards)	<ul> <li>AHCA is authorized to use standards embedded in the neonatal intensive care services certificate of need (CON) rules (Rule <u>59C-1.042</u>, <i>F.A.C.</i>) that Ch. <u>2019-136</u>, <i>Laws of Florida</i>, repealed, until the agency promulgates licensing rules to replace the CON standards. Rule <u>59C-1.042</u>, <i>F.A.C.</i>, defines neonatal care according to the intensity and specialization of the care that can be provided in the hospital's neonatal care unit. The Agency distinguishes three intensity levels of neonatal care, intravenous feedings, and gavage to neonates and does not include ventilator assistance except for resuscitation and stabilization. The hospital must have a triage procedure to assess the need for transfer of obstetrical patients to facilities with Level II or Level III Neonatal Intensive Care Services prior to their delivery where there is an obstetrical indication that resuscitation will be required for the neonates.</li> <li>Level II Neonatal Intensive Care is restricted to neonates of 1,000 grams birth weight and over and can provide ventilator services and at least six hours of nursing care per day. Ventilation may be provided for neonates of less than 1,000 grams birth weight only while waiting to transport the baby to a facility with Level III Neonatal Intensive Care Services. Level II neonatal intensive care must be directed by a neonatologist or a group of neonatologists who are either board-certified or board-eligible in neonatal-perinatal medicine, are active staff of the hospital with unlimited privileges, and provide 24-hour coverage.</li> <li>Level III Neonatal Intensive Care can provide continuous cardiopulmonary support services, 12 or more hours of nursing care per day, complex neonatal surgery, neonatal cardiovascular surgery, pediatric neurology and neurosurgery, and pediatric cardiac catheterization. If the unit does not reactive staff of the hospital with unlimited privileges of a pediatric surgeon, or pediatric cardiac catheterization and cardiovascular surgery, the facility shall enter</li></ul>

<sup>1</sup> The American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG) 2017 Guidelines for Perinatal Care, Eighth Edition, includes AAP's 2012 NICU levels.

<sup>&</sup>lt;sup>2</sup> In addition to the AAP *Policy Statement Levels of Neonatal Care*, in 2013, the *Consensus Committee on Recommended Design Standards for Advanced Neonatal Care, Eighth Edition*, updated its recommended minimum standards for physical design for NICU Level III. This design standard includes unit configuration, location within the hospital, minimum space, clearance, and privacy requirements. This includes that the NICU be a distinct area within the health-care facility, with controlled access and a controlled environment in close and controlled proximity to the area of the hospital where births occur and traffic to other services shall not pass through the unit. The updated edition contains recommended changes for patient room size and feeding preparation areas and a number of refinements of previously recommended standards regarding family space, hand hygiene, lighting, and other aspects of the newborn intensive care unit design.

The CON rule for neonatal care services also includes the following minimum physician and nursing credentials and staffing requirements for neonatal intensive care units (NICUs):

- Level III NICUs must maintain a board-certified obstetrician who is qualified by training, experience, or special competence certification in maternal-fetal medicine (maternal-fetal medical specialist) on active staff of the hospital with unlimited staff privileges and have a pediatric cardiologist, who is either board-certified or boardeligible in pediatric cardiology, available for consultation at all times.
- Both Level II and Level III NICUs must
  - be directed by a neonatologist or a group of neonatologists who are on active staff of the hospital with unlimited privileges, provide 24 hours coverage, and are either board-certified or board-eligible in neonatal-perinatal medicine;
  - have at least one certified respiratory care practitioner therapist with expertise in the care of neonates available at all times, with at least one respiratory therapist technician for every four infants receiving assisted ventilation; and

o have nursing staff that must

- be supervised by a registered professional head nurse (RN) with experience and training in neonatal intensive care nursing;
- be RNs for at least one-half of the nursing staff assigned to each work shift in Level II and Level III NICUs;
- be trained to administer cardio-respiratory monitoring, assist in ventilation, administer intravenous (IV) fluids, provide pre- and post-operative care of newborns requiring surgery, manage neonates being transported, and provide emergency treatment of conditions such as apnea, seizures, and respiratory distress; and
- have a nurse-to-neonate ratio of at least 1:4 in Level II NICU and 1:2 in Level III NICU.

In addition to AHCA's regulatory oversight of neonatal care, the Department of Health's (DOH) Children's Medical Services provides a full range of obstetrical services for Medicaid recipients with high-risk pregnancies and up to 365 days of neonatal services through its **Regional Perinatal Intensive Care Centers (RPICC program)**. Financially eligible neonates and infants may be admitted into the RPICC program if the infant meets at least one of the following medical criteria: neonates that weigh under 1,500 grams or neonates that weigh more than 1,500 grams and have either birth asphyxia or five minute Apgar of six or less; an oxygen dependent respiratory disease; the need for supplemental oxygen for more than 24 hours; or a diagnosis of a specific medical illness. RPICCs provide services in DOH-designated hospitals through the two interrelated components of neonatal intensive care Level II beds.

**RPICC Neonatal Intensive Care Level II** beds must be capable of delivering special care to newborns, including oxygen therapy, supplemental parenteral alimentation, and constant electronic monitoring of vital signs. The minimum nursing staff ratio is one nurse to four patients.

**RPICC Neonatal Intensive Care Level III** beds must be capable of delivering total intensive care to newborns, including total respiratory support, supplemental parenteral alimentation, constant electronic monitoring of vital signs, and long term arterial catheterization. The minimum nursing staff ratio is one nurse to two patients, at all times, for the critical care of unstable neonates.

The rule (<u>64C-6</u>, *F.A.C.*) for RPICCs was last updated in May 1996 but addresses minimum requirements for staff and equipment, including the professional staffing requirements for the CMS consultant neonatologist, pediatric cardiologist, head nurse and nursing staff, and respiratory therapy technicians. It also includes requirements for equipment.

Federal Requirements We did not identify any federal requirements specifically for neonatal intensive care. The Centers for Medicare and Medicaid Services establishes standards for hospitals in general that receive Medicare funding.

#### STANDARDS FROM PROFESSIONAL ORGANIZATIONS AND ACCREDITORS<sup>3</sup>

- Guidelines for Professional Registered Nursing Staffing for Perinatal Units, Association of Women's Health, Obstetric and Neonatal Nurses, 2010 (AWHONN)
- Levels of Neonatal Care Policy Statement, American Academy of Pediatrics, 2012 (AAP)
- RN Staffing in the Neonatal Intensive Care Units, National Association of Neonatal Nurses, 2014 (NANN)
- Guidelines for Perinatal Care Eighth Edition, American Academy of Pediatrics and the American College of Obstetricians and Gynecologists, 2017 (AAP/ACOG)<sup>4,5</sup>

#### QUALITY MEASURES

Minimum Volume	<ul> <li>AAP/ACOG: Not identified specifically. However, designation of Level III care should be based on clinical experience as demonstrated by large patient volume, increasing complexity of care, and availability of pediatric medical subspecialists and pediatric surgical specialists.</li> </ul>
Outcome Measures	<ul> <li>AAP/ACOG:         <ul> <li>Prevention of preterm births</li> <li>Improve the outcomes of high-risk infants born either preterm or with serious medical or surgical conditions<sup>6</sup></li> </ul> </li> <li>Healthy People 2010 goal that 90% of deliveries of very low birth weight (VLBW &lt;1,500 g) infants occur at Level III facilities</li> </ul>
Other	• N/A
Caveats	• N/A
	QUALITY OF STAFFING
Professional Competencies, Certification, Specialization	<ul> <li>Level I:         <ul> <li>AAP/ACOG: Minimum staffing and type:                 <ul></ul></li></ul></li></ul>
	<ul> <li>Pediatric medical subspecialists<sup>7</sup></li> <li>Pediatric anesthesiologists<sup>7</sup></li> <li>Pediatric surgeons<sup>7</sup></li> <li>Pediatric ophthalmologists<sup>7</sup></li> </ul> Level IV: <ul> <li>AAP/ACOG: Minimum staffing and type:</li> <li>Level I, Level II, and Level III physicians and staff</li> </ul>

outpatient experience for each fellow; and ensure each program comply with the ACGME program requirements for the respective subspecialty, which may exceed the minimum ACGME requirements for neonatal-perinatal medicine. NICU subspecialists may include neonatologists, pediatric surgery, and pediatric cardiothoracic surgery. The ACGME requirements for some specialties like pediatric surgery and pediatric cardiology include minimum volume requirements for the teaching hospital and for residents and fellows. <sup>4</sup> *Guidelines for Perinatal Care* was developed through the cooperative efforts of the AAP's Committee on Fetus and Newborn and the ACGG's Committee on

<sup>&</sup>lt;sup>4</sup> Guidelines for Perinatal Care was developed through the cooperative efforts of the AAP's Committee on Fetus and Newborn and the ACOG's Committee on Obstetric Practice.

<sup>&</sup>lt;sup>5</sup> The AAP and ACOG's *Guidelines for Perinatal Care* is periodically updated. The eighth edition was released in September 2017.

<sup>&</sup>lt;sup>6</sup> The AAP and ACOG recommend that NICU Level III and Level IV collect and evaluate data. NICU Level III should collect data to assess outcomes within the facility and compare with other levels. NICU Level IV should collect data on long-term outcomes to evaluate both the effectiveness of delivery of perinatal health care services and the safety and efficacy of new therapies.

<sup>&</sup>lt;sup>7</sup> Includes all providers with relevant experience, training, and demonstrated competence.

Staffing to Patient Ratios, By	Level I (newborn or well care nursery):		
Profession	<ul> <li>AWHONN.<sup>8</sup> Healthy newborns—1:5-6 nurse-to-patient ratio</li> </ul>		
	Level II. ■ AWHONN <sup>.</sup>		
	<ul> <li>Higher level-of-care newborns—1:2 or 1:1 nurse-to-patient ratio, depending on acuity</li> </ul>		
	<ul> <li>Continuing-care newborns—1:3-4 nurse-to-patient ratio</li> </ul>		
	<ul> <li>Intermediate-care newborns—1:2-3 nurse-to-patient ratio</li> </ul>		
	<ul> <li>NANN.<sup>9</sup> Intermediate-care patients—2:6 (or fewer) nurse (neonatal experienced RNs)-to-patient ratio</li> </ul>		
	Level III:		
	<ul> <li>AWHUNN:</li> <li>Intensive care newborns 1:1.2 nurse to nation ratio</li> </ul>		
	<ul> <li>Multisvstem-support care newborn—1:1 nurse-to-patient ratio</li> </ul>		
	<ul> <li>Unstable complex-critical care newborns—1 or more:1 nurse-to-patient ratio</li> </ul>		
	• At least 2:6 or 4 nurse-to-patient ratio when there are fewer than 6 intermediate care newborns or 4		
	intensive care neonatal care newborns in the special care nursery or neonatal intensive care unit		
	• NANN: Intermediate-care patients—2:6 (or tewer) nurse (neonatal experienced RNS)-to-patient ratio		
	Level IV: ■ AWHONN <sup>.</sup>		
	<ul> <li>Intensive-care newborns—1:1- 2 nurse-to-patient ratio</li> </ul>		
	<ul> <li>Multisystem-support care newborn—1:1 nurse-to-patient ratio</li> </ul>		
	<ul> <li>Unstable complex-critical care newborns—1 or more:1 nurse-to-patient ratio</li> </ul>		
	<ul> <li>At least 2:6 or 4 nurse-to-patient when there are fewer than 6 intermediate care newborns or 4 intensive care neonatal care newborns in the special care nursery or neonatal intensive care unit</li> </ul>		
	<ul> <li>NANN: Intermediate-care patients—2:6 (or fewer) nurse (neonatal experienced BNs)-to-patient ratio</li> </ul>		
Other			
Culor	<ul> <li>AAP/ACOG: Facilities should have pediatric expertise, social services, and pastoral care.</li> </ul>		
	Level IV:		
	<ul> <li>AAP/ACOG:</li> </ul>		
	<ul> <li>Level IV units include the capabilities of Level III with additional capabilities and considerable experience in the care of the most complex and critically ill newborn infante.</li> </ul>		
	<ul> <li>Coordinate the development of specialized services and professional continuing education to maintain</li> </ul>		
	competency.		
	AVAILABILITY		
Available Hours of Operation	<ul> <li>N/A</li> </ul>		
Other	Level II:		
	<ul> <li>AAP/ACOG: Continuously available physicians, specialized nurses, respiratory therapists, radiology techniciana, laboratory techniciana</li> </ul>		
	■ AAP/ACOG:		
	o Continuously available neonatologists, neonatal nurses, respiratory therapists.		
	<ul> <li>A broad range of pediatric medical subspecialists and pediatric surgical specialists should be readily</li> </ul>		
	accessible on site of by preantinged consultative agreements, including via telemedicine of phone consultation		
	<ul> <li>Pediatric surgical specialists and pediatric anesthesiologists should be on site or at a closely related</li> </ul>		
	institution to perform major surgery.		
	<ul> <li>Access to pediatric ophthalmologic services with an organized program for the monitoring, treatment, and follow up of rationanthy of promotivity.</li> </ul>		
	anu ionow-up oi reunopauny oi prematunty. I evel IV·		
	<ul> <li>AAP/ACOG:</li> </ul>		
	<ul> <li>A full-time, board-certified neonatologist NICU director.</li> </ul>		
	• Pediatric medical and pediatric surgical specialty consultants continuously available 24 hours a day.		

<sup>8</sup> AWHONN did not classify staffing-to-patient ratios by AAP's 2012 recommended guidelines. Instead, they classified staffing according to the type of patient care needs. OPPAGA categorized AWHONN staffing-to-patient care needs into AAP's 2012 descriptions of staffing requirements and minimum levels of care needed to be provided at each neonatal care level.

<sup>9</sup> NANN did not qualify specific ratios by individual NICU. Instead, they recommended that the specific types of patients and clinical situations should dictate specific staffing ratios and that NICU Levels II, III, and IV include at least two registered nurses with neonatal expertise and training for fewer than six intermediate-care neonatal patients or four or fewer intensive care patients.

	EQUIPMENT
Availability of Appropriate Equipment/ Technology/ Ancillary Services	<ul> <li>Level II:</li> <li>AAP/ACOG: <ul> <li>Minimum equipment and technology are based on the overall evidence for risk-appropriate care capabilities for each NICU level of care.</li> <li>Ventilation on an interim basis until the infant's condition either soon improves or the infant can be transferred to a higher-level facility.</li> <li>Mechanical ventilation can be provided for a brief duration (less than 24 hours).</li> <li>Portable x-ray machine and blood gas analyzer.</li> <li>Access to pediatric ophthalmologic services with an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity.</li> </ul> </li> <li>Level III: <ul> <li>AAP:</li> <li>Advanced recordination cumport and physiologic monitoring equipment, laboratory and imaging facilities</li> </ul> </li> </ul>
	<ul> <li>Advanced respiratory support and physiologic monitoring equipment, laboratory and imaging facilities, nutrition, and pharmacy support.</li> <li>Ongoing assisted ventilation for 24 hours or more, which may include conventional ventilation, high frequency ventilation, and inhaled nitric oxide.</li> <li>Computed Tomography (CT), magnetic resonance imaging (MRI), and echocardiography advanced imaging with interpretation on an urgent basis.</li> </ul>
	<ul> <li>AAP/ACOG:         <ul> <li>Possess all the capabilities of Level III with additional capabilities and considerable experience in the care of the most complex and critically ill newborn infants.</li> <li>Include the capability for surgical repair of complex conditions (e.g., congenital cardiac malformations that require cardiopulmonary bypass with or without extracorporeal membrane oxygenation).</li> </ul> </li> </ul>
Maintenance	<ul> <li>N/A</li> </ul>
Other	<ul> <li>Level III:         <ul> <li>AAP/ACOG:                 <ul></ul></li></ul></li></ul>
LICENSING ST California (CA) Colorado (CO) New Hampshire (NH) Pennsylvania (PA) Texas (TX) Utah (UT)	ANDARDS FROM SELECTED OTHER STATES THAT DO NOT HAVE A CON PROCESS <sup>10</sup>
Overview	<b>CO and NH</b> licensing standards for acute care hospitals include criteria for pediatric care, which may generally cover neonatal care but do not include criteria for neonatal care specifically. <b>CA</b> licensing standards for acute care hospitals include a provision for intensive care newborn nursery services but do not distinguish these services by level of care. Intensive care newborn nursery is defined as providing comprehensive care for all life-threatening or disability-producing situations; consultation service to referring perinatal units; infant transport services between perinatal units and the intensive care newborn nursery; a transport team consisting of at least a physician and registered nurse or respiratory care practitioner; continuing education for staff of the intensive care newborn nursery as well as referring perinatal units; and reviewing and evaluating service programs of perinatal units. Like Florida' RPICC program, California's Department of Health Care Services (DHCS), California Children's Services (CCS) program has standards for neonatal intensive care units (NICUs). The system specifies three levels of NICUs: Intermediate, Community, and Regional NICUs.

<sup>10</sup> OPPAGA identified 15 states that do not have a certificate of need (CON) process for the tertiary health services. However, two of the states (Arizona and Minnesota) either had a CON for some other related services or had a process that was not called a CON but would have similar effects. Seven of the states were not comparable to Florida due to factors such as having a small number of teaching hospitals; a significantly different breakdown of citizens on Medicaid, Medicare, or uninsured; a smaller population size; and/or a higher portion of the state that is rural. These seven states were Idaho, Kansas, New Mexico, North Dakota, South Dakota, Wisconsin, and Wyoming. For the remaining six states, we conducted an in-depth review to identify and evaluate any licensing standards for the services considered tertiary in Florida. These six state were California, Colorado, New Hampshire, Pennsylvania, Texas, and Utah.

PA licensing standards for acute care hospitals include criteria specific to neonatal intensive care for hospitals that provide obstetrical, neonatal infant care, or both. The criteria include that maternity and neonatal services shall be separate and apart from other hospital services and especially from potential sources of infection. Access to each neonatal care unit shall be controlled to ensure security and safety of all infants. The criteria follow current auidelines where applicable for hospital and neonatal care unit design, including:

- Guidelines for Perinatal Care Eighth Edition, American Academy of Pediatrics and the American College of Obstetricians and Gynecologists (AAP/ACOG)
- The Facility Guidelines Institute—Guidelines for Design and Construction of Hospitals
- The Facility Guidelines Institute—Guidelines for Design and Construction of Outpatient Facilities

PA recognizes three levels of neonatal care units:

- (1) Level I: Normal Neonatal
- (2) Level II: Neonatal Intermediate/Intensive Care
- (3) Level III: Neonatal Intensive Care

TX licenses general acute care hospitals but also has a separate designation process for certain services, including neonatal care. Texas's four neonatal care levels generally follow the AAP's 2012-updated NICU levels classification, and the AAP is an approved survey agency for the state NICUs.<sup>11</sup>

Level I provides care for mothers and their infants generally of >=35 weeks gestational age who have routine, transient perinatal problems.

Level II provides care for mothers and their infants of generally >=32 weeks gestational age and birth weight >=1,500 grams who have physiologic immaturity or who have problems that are expected to resolve rapidly and are not anticipated to require subspecialty services on an urgent basis. This level also provides care. including assisted endotracheal ventilation for less than 24 hours or nasal continuous positive airway pressure (NCPAP) until the infant's condition improves, or appropriate transfer to a higher-level designated facility. If the facility performs neonatal surgery, the facility shall provide the same level of care that the neonate would receive at a higher-level designated facility and shall complete an in depth critical review of the care provided through the QAPI Program.

Level III provides care for mothers and comprehensive care of their infants of all gestational ages with mild to critical illnesses or requiring sustained life support, consultation to a full range of pediatric medical subspecialists and pediatric surgical specialists, and the capability to perform major pediatric surgery on-site or at another appropriate designated facility. Level III has skilled medical staff and personnel with documented training, competencies, and continuing education specific for the patient population served; facilitates transports: and provides outreach education to lower-level designated facilities.

Level IV provides care for the mothers and comprehensive care of their infants of all gestational ages with the most complex and critically ill neonates/infants with any medical problems, and/or requiring sustained life support.

UT licensing standards for acute care hospitals include criteria for perinatal care that include antepartum, labor, delivery, postpartum, and nursery care. The Utah standards reference an earlier version of AAP/ACOG Guidelines for Perinatal Care that pre-dates the AAP's 2012 guidelines defining four levels of NICU care.<sup>12</sup> As such, Utah's requirements apply to three levels of care. Utah also requires its three levels of care to be in accordance with the Guidelines for Design and Construction of Heath Care Facilities, 2010 Edition, and the Guidelines for Perinatal Care, Sixth Edition.

Level I (Basic) is for full-term or well-baby nursery with 24 inches between bassinets. Level II (Specialty) is a continuous care nursery with four feet between bassinets. Level III (Sub-specialty) is a newborn intensive care nursery with four feet between bassinets.

QUALITY MEASURES		
Minimum Volume • TX: A m	ninimum volume is not required.	
Outcome Measures • N/A		
Other • TX evalu their des	ates whether the neonatal care unit was able to care for the required gestational ages required by signated neonatal care level and if the facilities discharged those babies home.	
Caveats • N/A		

OUNLITY MEASURES

<sup>11</sup> In addition to Texas, other states, including Georgia and Missouri, base their NICU standards on AAP's neonatal care policy statements. Missouri statutes specifically name AAP as an organization that can verify neonatal level of care, and AAP is currently exploring a formal partnership with Georgia to conduct NICU surveys as well.

<sup>12</sup> AAP-ACOG's *Guidelines for Perinatal Care, Sixth Edition* was established in 2010.

		QUALITY OF STAFFING
Professional Competencies, Certification, Specialization	Directo CA PA me TX:	<b>r(s)</b> : One American Board certified, or eligible for certification, pediatrics physician. : For all NICUs, one American Board of Pediatrics certified medical staff member or an equivalent board ember.
	0	Level I—One currently practicing pediatrician, family medicine physician, or physician specializing in obstetrics and gynecology with experience in the care of neonates/infants that demonstrates completion of Neonatal Resuscitation Program (NRP) and has completed annual continuing medical education specific to neonatal care.
	0	Level II—One board-eligible/certified neonatologist, with experience in the care of neonates/infants, who demonstrates a successful completion of the Neonatal Resuscitation Program. Alternatively, one pediatrician who has continuously provided neonatal care for the last consecutive two years; has experience and training in the care of neonates/infants including assisted endotracheal ventilation and NCPAP management; maintains a consultative relationship with a board-eligible/certified neonatologist; demonstrates effective administrative skills and oversight of the QAPI Program; demonstrates a current status on successful completion of the NRP; and has completed continuing medical education annually specific to the care of neonates. Level III and IV—Board-eligible or certified neonatologist who has a current status of successfully completing the Neonatal Resuscitation Program.
	<ul> <li>UT me by</li> </ul>	: If the hospital provides pediatric services, those services shall be under the direction of a member of the direction staff who is experienced in pediatrics and whose functions and scope of responsibility are defined the medical staff.
	Surgeo	ns/Physicians –
	<ul> <li>CA</li> </ul>	: Not specified by NICU Level—
	0	A pediatrician
	0	An American Board of Anestnesiology certilied of eligible for certilication physician A neonatal experienced curgeon
	0	A pediatric cardiologist
	<ul> <li>PA</li> </ul>	
	0	All Levels—A physician must be available at all times who is certified by the American Board of Pediatrics (or an equivalent), attained pre-board certification status, or successfully completed an approved residency in pediatrics.
	0	Levels II and III—A pediatrician designated by the director of the neonatal services shall be on call 24 hours a day. Private physicians or specialists may care for their patients in neonatal intensive care units. However, the final authority for policy in neonatal intensive care units shall reside with the director of neonatal services.
	<ul> <li>TX:</li> </ul>	
	0	Level I—Primary physician with special competence in the care of neonates, whose credentials have been reviewed by the Neonatal Medical Director (NMD) and who demonstrates successful completion of the American Heart Association/AAP resuscitation of all infants NRP and has completed annual continuing education specific to the care of neonates.
	0	Level II—One physician with special competence in the care of neonates, whose credentials have been reviewed by the NMD and is on call, and who has successfully completed the NRP and annual continuing education specific to the care of neonates.
	0	Level III—At least one of the following shall be on-site and available at all times: pediatric hospitalists, neonatologists, or neonatal nurse practitioners or neonatal physician assistants who have demonstrated competence in management of severely ill neonates/infants and whose credentials have been reviewed by the NMD and has a current status of successful completion of the NRP. Must also have completed continuing education annually, specific to the care of neonates.
	0	<ul> <li>Level III and IV—Have</li> <li>at least one person immediately available on-site with the skills to perform a complete neonatal resuscitation, including endotracheal intubation, establishment of vascular access, and administration of medications, and</li> </ul>
		<ul> <li>a comprehensive range of pediatric medical subspecialists and pediatric surgical subspecialists available to arrive on-site for face-to-face consultation and care, with the capability to perform major pediatric surgery including the surgical repair of complex conditions.</li> </ul>
	0	Level IV—Board-certified or board-eligible neonatologists whose credentials have been reviewed by the

 Level IV—Board-certified or board-eligible neonatologists whose credentials have been reviewed by the NMD and is on call; who is current on successful completion of the NRP; who has completed continuing education annually, specific to the care of neonates; and who is on-site and immediately available at the neonate/infant bedside as requested. • Level IV—Pediatric anesthesiologists shall directly provide anesthesia care to the neonate.

UT: Personnel working with pediatric patients shall have specific training and experience relating to the care
of pediatric patients. Orientation and in-service training for pediatric care staff shall include pediatric-specific
training on drugs and toxicology, intravenous therapy, pediatric emergency procedures, infant and child
nutrition, the emotional needs and behavioral management of hospitalized children, child abuse and neglect,
and other topics according to the needs of the pediatric patients.

#### Nursing Staff:

- CA: One registered nurse with training and experience in intensive care of the newborn.
- PA:
  - NICUs are required to meet current APP/ACOG *Perinatal Guidelines* Levels II and III and staffing requirements and must be in accordance with the *Guidelines*.
  - PA: NICU All Levels —One registered professional nurse, especially trained and experienced in the care
    of normal and high-risk infants, shall be responsible for the neonatal care unit at all times when the unit
    is occupied.
- TX:
  - NICU Level I—One advanced practice nurse and/or physician assistant with special competence in the care of neonates, whose credentials have been reviewed by the NMD, who demonstrates successful completion of the American Heart Association/AAP resuscitation of all infants NRP, and who has completed annual continuing education specific to the care of neonates.
  - NICU Levels II, III, and IV—One advanced practice nurse and/or physician assistant with special competence in the care of neonates, whose credentials have been reviewed by the NMD and is on call, and who has successfully completed the NRP and annual continuing education specific to the care of neonates.
- UT:
  - A pediatrics-qualified registered nurse must supervise nursing care and must supervise the documentation of the implementation of pediatric patient care on an interdisciplinary plan of care.

Personnel working with pediatric patients shall have specific training and experience relating to the care of pediatric patients. Orientation and in-service training for pediatric care staff shall include pediatric specific training on drugs and toxicology, intravenous therapy, pediatric emergency procedures, infant and child nutrition, the emotional needs and behavioral management of hospitalized children, child abuse and neglect, and other topics according to the needs of the pediatric patients.

#### Additional Medical Personnel:

- CA:
  - $\circ$   $\,$  One respiratory care practitioner trained in newborn respiratory care.
  - A transport team consisting of at least a physician and registered nurse or respiratory care practitioner.
- PA: Levels II and III—Ancillary personnel employed to meet the needs of infants shall have appropriate,
- specified skills and training.
- TX:
  - Level II—
    - Personnel at the bedside within 30 minutes of an urgent request.
    - Appropriately trained personnel shall be available on-site to provide ongoing care and to respond to emergencies when an infant is maintained on endotracheal ventilation.
    - Staff capable of interpreting neonatal and perinatal x-rays and ultrasound studies available at all times.
    - A respiratory therapist, with experience and specialized training in the respiratory support of neonates/infants, whose credentials have been reviewed by the neonatal medical director.
  - o Levels III and IV-
    - For facilities that have their own transport program, the Transport Medical Director (TMD) or Co-Director shall be a physician who is a board-eligible/certified neonatologist or pediatrician with expertise and experience in neonatal/infant transport.
    - A dietitian or nutritionist who has special training in perinatal and neonatal nutrition and can plan diets that meet the special needs of neonates/infants.
    - Speech language pathologist, an occupational therapist, or a physical therapist with neonatal/infant experience shall be available to evaluate and manage feeding and/or swallowing disorders.
    - A respiratory therapist, with experience and specialized training in the respiratory support of neonates/infants, whose credentials have been reviewed by the NMD, shall be immediately available on-site.
    - A certified lactation consultant.
  - o Level III—Specialist with expertise in retinopathy evaluation for prematurity.
  - Level IV—On-site pediatric ophthalmologist to ensure the timely evaluation and treatment of retinopathy
    of prematurity.

	<ul> <li>Levels II, III, and IV—An occupational or physical therapist with neonatal expertise shall be available to most the needed of the perputation control</li> </ul>
	meet the needs of the population served.
	<ul> <li>If the hospital provides a pediatric unit, it shall have an interdisciplinary committee responsible for policy development and review of practice within the unit. This committee must include representatives from administration, the medical and nursing staff, and rehabilitative support staff.</li> </ul>
	<ul> <li>Personnel working with pediatric patients shall have specific training and experience relating to the care of pediatric patients. Orientation and in-service training for pediatric care staff shall include pediatric specific training on drugs and toxicology, intravenous therapy, pediatric emergency procedures, infant</li> </ul>
	and child nutrition, the emotional needs and behavioral management of hospitalized children, child abuse and neglect, and other topics according to the needs of the pediatric patients.
Staffing to Patient Ratios, By Profession	<ul> <li>CA: 1:2 or fewer nurse-to-patient ratio. A registered nurse trained in intensive care of newborns shall be on duty on each shift.</li> </ul>
Other	• N/A
	AVAILABILITY
Available Hours of Operation	<ul> <li>N/A</li> </ul>
Other	<ul> <li>PA: Levels II and III—Units shall be staffed on every shift by at least one registered professional nurse who has special training, experience, and interest in infants requiring special care and who is assigned no other responsibilities.</li> </ul>
	TX: Level II—
	<ul> <li>Personnel on-site at all times when a neonate/infant is maintained on endotracheal ventilation.</li> <li>At each birth, at least one provider who demonstrates current status of successful completion of the neonatal resuscitation program whose primary responsibility is the management of the neonate and initiating resuscitation.</li> </ul>
	<ul> <li>At least one person must be immediately available on-site with the skills to perform a complete neonatal resuscitation, including endotracheal.</li> </ul>
	TX: Level III and IV—     TX: Level high a standard by at least one provider who demonstrates surrent status of successful
	<ul> <li>Each birth shall be attended by at least one provider who demonstrates current status of successful completion of the NRP whose primary responsibility is the management of the neonate and initiating resuscitation. At least one person must be immediately available on-site with the skills to perform a complete neonatal resuscitation, including endotracheal intubation, establishment of vascular access, and administration of medications.</li> </ul>
	<ul> <li>Each high-risk delivery shall have in attendance at least two providers who demonstrate current status of successful completion of the NRP whose only responsibility is the management of the neonate.</li> </ul>
	EQUIPMENT
Availability of Appropriate Equipment/Ancillary Services	<ul> <li>CA:</li> <li>Resuscitation equipment to include at least glass trap suction device with catheter or a device which</li> </ul>
	serves this function; pharyngeal airways, assorted sizes; laryngoscope, including a blade for premature infants; endotracheal catheters, assorted sizes with malleable stylets; arterial catheters, assorted sizes; and ventilatory assistance bag and infant mask.
	<ul> <li>DC defibrillator (within the hospital), cardiac monitor, blood gas analyzer (within the hospital).</li> </ul>
	<ul> <li>Umbilical blood vessel catheterization tray, portable incubator with power pack to provide continuous temperature control and monitoring, and ventilatory equipment designed for the care of newborn infants.</li> </ul>
	<ul> <li>PA:</li> <li>Laboratory carvices shall be available on a 24 hour a day. 7 day a week basis for at a minimum</li> </ul>
	hemoglobin; hematocrit; Coombs test; blood type; Rh type; urinalysis; bacteriologic cultures; spinal fluid analysis; and microchemical determinations for bilirubin, blood glucose, sodium, potassium, chloride and total protein.
	<ul> <li>Radiological equipment and services shall be available on a 24-hour-a-day, seven-day-a-week basis.</li> </ul>
	<ul> <li>TX: Level II—</li> <li>Madical important provides a shall be in compliance with Taylor requirements, will incompare to a site of the second state of</li></ul>
	Medical imaging—Radiology services shall be in compliance with Texas requirements; will incorporate the "As Low as Reasonably Achievable" principle when obtaining imaging in neonatal and maternal patients; and shall have personnel appropriately trained in the use of x-ray equipment on-site and available at all times.
	<ul> <li>A full range of NRP equipment and supplies shall be immediately available for trained staff to perform resuscitation and stabilization on any neonate/infant.</li> </ul>
	<ul> <li>TX: Level III and IV—Medical imaging—Radiology services shall be in compliance with Texas requirements; will incorporate the "As Low as Reasonably Achievable" principle when obtaining imaging in neonatal and maternal patients: and</li> </ul>
	<ul> <li>personnel appropriately trained in the use of x-ray equipment shall be on-site and available at all times;</li> </ul>

	<ul> <li>personnel appropriately trained in ultrasound, computed tomography, magnetic resonance imaging, echocardiography, and/or cranial ultrasound equipment shall be on-site within one hour of an urgent request; fluoroscopy shall be available;</li> <li>interpretation of neonatal and perinatal diagnostic imaging studies by radiologists with pediatric expertise at all times; and</li> <li>pediatric echocardiography with pediatric cardiology interpretation and consultation within one hour of an urgent request.</li> <li>A full range of resuscitative equipment, supplies, and medications shall be immediately available for trained staff to perform complete resuscitation and stabilization on each neonate/infant.</li> <li>UT: Hospitals admitting pediatric patients shall have equipment and supplies in accordance with the bospital's scope of nediatric services</li> </ul>
Maintenance	<ul> <li>N/A</li> </ul>
Other	<ul> <li>N/A</li> </ul>

Source: OPPAGA review of journal articles; state and federal statutes, laws, and rules; and standards from professional organizations, accreditors, and other non-CON states.

### APPENDIX D

### Pediatric Cardiac Catheterization

Background	Cardiac catheterization is a procedure where specialized cardiologists insert a long, thin tube called a catheter into the blood vessels and guide it to the heart using X-ray imaging. Pediatric cardiac catheterization can help diagnose and treat many heart problems in babies born with congenital heart defects or other childhood heart conditions. A cardiac catheterization procedure is performed in a hospital cardiac catheterization laboratory (CCL). As of 2012, three-fourths of all pediatric catheterizations were for therapeutic, and not simply diagnostic, reasons. A substantial number of unique procedures performed to address pediatric congenital heart disease, such as atrial septostomy, are not applicable to adults. <sup>1</sup> Florida statute does not consider adult cardiac catheterization a tertiary service, but s. 408.032, <i>Florida Statutes 2018</i> , designates <u>pediatric</u> cardiac catheterization as a tertiary health service.	
Former Florida Requirements	Chapter <u>2019-136</u> , <i>Laws of Florida</i> , repealed certificate of need (CON) for pediatric cardiac catheterizations and did not include an authorization for the agency to keep standards embedded in its CON rule (Rule 59C-1032, <i>F.A.C.</i> , in place until the agency promulgates licensing rules to replace the CON standards. AHCA has been working with the Pediatric Cardiac Technical Advisory Committee (PCTAP), created pursuant to s. 395.1055, <i>F.S.</i> , to draft new licensing rules for pediatric cardiac procedures. <sup>2</sup>	
	The former pediatric cardiac catheterization rule, Rule <u>59C-1.032</u> , <i>F.A.C.</i> , required that pediatric cardiac catheterization programs be capable of providing immediate endocardiac catheter pace-making in cases of cardiac arrest and pressure recording to monitor and evaluate valvular disease or heart failure. Further, the rules required that a range of non-invasive cardiac or circularity diagnostic services be available within the facility itself. These included hematology studies or coagulation studies, electrocardiography, chest x-ray, blood gas studies, and clinical pathology studies and blood chemistry analysis. The rules also required that pediatric cardiac catheterization programs have the capability of providing rapid mobilization of the study team within 30 minutes for emergency procedures 24 hours a day, 7 days a week.	
	Further, the rules required that the pediatric CCL program have a department or unit which is organized, directed, staffed, and integrated with other units and departments of the hospital in a manner designed to assure the provision of quality of care, and that, at a minimum, the team involved in pediatric cardiac catheterization consists of a physician, one nurse, and one or more technicians. The rules also included minimum standards for pediatric CCL staffing. For example, the rules required the program to have a director who is board-eligible or board-certified by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics or the American Osteopathic Association in the area of pediatric cardiology. Support staff were required to be highly skilled in conventional radiographic techniques and angiographic principles and knowledgeable in every aspect of catheterization and angiographic instrumentation, with a thorough knowledge of the anatomy and physiology of the circulatory system, among other areas. The pediatric CCL was also required to have minimum ancillary equipment and capabilities, including a special procedure x-ray room that has X-ray equipment with the capability in cineangiocardiography; an electrocardiograph; a blood gas analyzer; and a biplane angiography, with framing rates of 30-60 frames per second (fps) and injection rates of up to 40 mL/s.	
Federal Requirements	We did not identify any federal requirements specifically for pediatric cardiac catheterization. The Centers for Medicare and Medicaid Services establishes standards for hospitals in general that receive Medicare funding.	
	STANDARDS FROM PROFESSIONAL ORGANIZATIONS AND ACCREDITORS <sup>3</sup>	
<ul> <li>Guidelines for Pedia</li> <li>2012 American Coll</li> </ul>	ITIC UARDIOVASCULAR UERTERS, AMERICAN ACADEMY OF PEDIATRICS, 2002 (AAP)	
Consensus Docume	ent on Cardiac Catheterization Laboratory Standards Update, American College of Cardiology Foundation	
Task Force on Expert Consensus Documents Developed in Collaboration with the Society of Thoracic Surgeons and Societ for Vascular Medicine, 2012 <sup>1,4</sup> (ACCE/SCAI/STS/SVM)		
<ul> <li>Best Practices in the Cardiac Catheterization Laboratory: Society for Cardiovascular Angiography and Interventions, SCAI</li> </ul>		
Expert Consensus S	Statement, 2016 (SCAI)	
<sup>1</sup> Bashore TM, Balter S, Barac A, Byrr JWM, Oliver-McNeil SM, Popma JJ, T <i>Consensus Document on Cardiac Ca</i>	ne JG, Cavendish JJ, Chambers CE, Hermiller JB Jr, Kinlay S, Landzberg JS, Laskey WK, McKay CR, Miller JM, Moliterno DJ, Moore "ommaso CL. 2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert theterization Laboratory Standards Update. Journal for the American College of Cardiology 2012; 59:2221–305.	

<sup>2</sup> Section 395.1055, *F.S.*, requires the Agency for Health Care Administration to establish a technical advisory panel to develop procedures and standards for measuring outcomes of pediatric cardiac catheterization programs and pediatric cardiovascular surgery programs. The panel is to recommend to the agency standards for quality of care, personnel, physical plant, equipment, emergency transportation, and data reporting for hospitals that provide pediatric cardiac services. Accordingly, AHCA appointed the Pediatric Cardiac Technical Advisory Panel, which has issued recommended standards for pediatric cardiovascular centers.

<sup>3</sup> The Accreditation Council for Graduate Medical Education (ACGME) Program Requirements for Graduate Medical Education in Pediatric Surgery 2018 provides minimum standards, including experience and minimum volume levels, for teaching hospitals and for residents and fellows. Each pediatric cardiac catheterization lab accredited facility must perform a minimum of 400 interventional procedures per year and each secondary laboratory must perform a minimum of 200 interventional procedures per year. Each fellow must perform and interpret a minimum of 300 pediatric echocardiography studies and, during three years of training, each fellow should participate in a minimum of 100 catheterizations and 10 pediatric intracardiac electro-physiologic studies.

<sup>4</sup> ACCF/SCAI/STS/SVM stated that a cardiac catheterization laboratory and its functions will continue to evolve and grow over the next decade as newer devices and treatment options emerge and that the cardiac catheterization laboratory of 2012 differed significantly from that of a decade before. The consensus committee anticipated that the cardiac catheterization laboratory would undergo a similar evolution within 10 years from the time of its report.

QUALITY MEASURES			
Minimum Volume	ACCF/SCAI/STS/SVM: Suggests a minimum pediatric cardiac catheter operator volume of 50 per year and a minimum laboratory volume of >100 per year. AAP: Suggests using specific outcome benchmarks rather than minimum operator or laboratory volumes as a guide to competence.		
Outcome Measures	N/A		
Other	AAP: Data should be gathered prospectively to document quality of care. There should be systematic review of all case outcomes and procedural complications at regular catheterization quality assurance conferences. ACCF/SCAI/STS/SVM: Continuous quality assessments and quality improvement program, including a committee with a chair and staff coordinator, a database, and a means of data collection, with a goal to eliminate outliers, reduce variation, and enhance performance. ACCF/SCAI/STS/SVM: Quality Improvement Program with Data Reporting and Analysis—Strongly recommends that labs participate in national registries, such as the American College of Cardiology's National Cardiovascular Data Registry (NCDR), to ensure data are systematically collected and available in a predefined format to allow for future analyses. In this manner, all laboratories can benchmark their performance and make appropriate corrections. ACCF/SCAI/STS/SVM: For most children, an overnight stay following the procedure is medically prudent. Each laboratory should establish a written policy on who might be expected to be discharged immediately following the procedure.		
Caveats	N/A		
	QUALITY OF STAFFING		
Professional Competencies, Certification, Specialization	<ul> <li>actor</li> <li>AAP and ACCF/SCAI/STS/SVM: Suggests that all pediatric catheterizations should have a director responsible for all aspects of the laboratory operation.</li> <li>AAP: The pediatric catheterization laboratory should be directed by a board-certified pediatric cardiologist who has additional fellowship training (or qualifying experience) in pediatric catheterization and interventional procedures.</li> <li>ACCF/SCAI/STS/SVM: A laboratory director is a prerequisite for all CCLs. The director should be a pediatric cardiologist and may have special interests such as in interventional cardiology or electrophysiology. The director should be an attending physician who is board-certified and thoroughly trained in cardiac radiographic imaging and radiation protection, proficient in performing procedures specific to the laboratory, and supportive to the needs of the operating physicians. Ideally, the director should be an avenced practice professional (APP) (e.g., physician assistant or nurse practitioner), either a registered cardiovascular technologist or nurse, with a minimum of five years' CCL experience, who also has administrative expertise to participate in institutional and CCL decision-making.</li> <li><b>er Physicians</b></li> <li>SCAI: All cardiac catheterization physicians maintain procedure-specific credentialing and privileging by their institution, typically requiring American Board of Internal Medicine (ABIM), American Osteopathic Association (AOA), or evolving certification models, such as that from the National Board of Physicians and Surgeons (NBPAS). Each lab should have a procedures the completion of ongoing professional practice evaluation for newly hired operators performing a procedure in case of a perceived problem.</li> <li>ACCF/SCAI/STS/SVM: Attending physicians should be board-certified in gediatric expressional practice evaluation for newly hired operators performing a procedure in case of a perceived problem.</li> </ul>		
Staffing to Patient Ratios, By Profession	AAP: Every cardiac catheterization procedure should include a minimum of one board-certified (or board- eligible) pediatric cardiologist and one pediatric nurse with training and experience in pediatric airway		
Other			
Available Hours of Oppration	ACCE/SCAI/STS/SVM: Pediatric CCLs should function as one of the critical elements within a pediatric		
	cardiovascular center. All facilities that perform cardiac catheterization on children must be full-service facilities.		
Other	N/A		

EQUIPMENT			
Availability of Appropriate Equipment/Ancillary Services	<ul> <li>AAP: Recommends that a pediatric catheterization laboratory have biplane imaging equipment with a moveable C-arm, immediate replay capabilities (preferably digital), a physiologic recorder, a blood gas analyzer, a pulse oximeter, an infant warming device, pacing catheters and an external pacemaker, a defibrillator and an emergency cart, and a comprehensive inventory of pediatric catheters, devices, and expendables.</li> <li>AAP: Recommends an appropriate intensive care unit (ICU) available to care for patients before and after cardiac catheterization, and interventional procedures require the availability of in-hospital pediatric cardiac surgery backup.</li> <li>ACCF/SCAI/STS/SVM: All facilities that perform pediatric cardiac catheterization         <ul> <li>must have the full complement of resources available, including cardiovascular surgery, though pediatric laboratories may be dedicated facilities or shared with an adult program, and</li> <li>should be accessible to extracorporeal membrane oxygenation (ECMO), in addition to routine resuscitation equipment.</li> </ul> </li> <li>ACCF/SCAI/STS/SVM: Biplane x-ray capabilities should be standard, though certain procedures can be done with single-plane systems satisfactorily.</li> </ul>		
Maintenance	<ul> <li>ACCF/SCAI/STS/SVM:</li> <li>Right and left heart hemodynamics and angiography are routine procedures and require high-resolution equipment to ensure the diagnosis. The framing rates depend on the patient's heart rate, and 30 fps is often required to capture all the necessary information. Due to the high heart rates, contrast must be injected at a higher rate (i.e., over one to two seconds).</li> <li>The modern diagnostic and interventional catheterization laboratory uses many sophisticated radiological, electronic, and computer-based systems, each of which requires a program of rigorous maintenance and troubleshooting.</li> <li>The x-ray imaging system, a crucial component of every laboratory, must be carefully assessed at frequent intervals to detect early signs of deterioration in performance.</li> </ul>		
Other	• N/A		
APPLICABLE STAN	DARDS RECOMMENDED BY THE PEDIATRIC CARDIAC TECHNICAL ADVISORY PANEL (PCTAP)		
	QUALITY MEASURES		
Minimum Volume	<ul> <li>Minimum CCL volume standards shall be 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. Cases are defined to include children with congenital and acquired heart disease under 21 years old and adults 21 years or older with congenital heart disease.</li> </ul>		
Outcome Measure	• N/A		
Other	• N/A		
Caveats	<ul> <li>N/A</li> </ul>		
	QUALITY OF STAFFING		
Professional Competencies, Certification, Specialization	<ul> <li>The cardiac catheterization laboratory is one of the required components of the Pediatric and Congenital Cardiovascular Center (PCCC). The Pediatric CCL must be co-located within a facility completely equipped to accommodate all aspects of the medical and surgical care of the patient. The Pediatric CCL is required to have</li> <li>a physician in charge of the cardiac catheterization procedures that is board-certified by the American Board of Pediatrics, Sub-Board of Pediatric Cardiology<sup>5</sup>, and</li> <li>in addition to the physician performing the procedure, in interventional cardiac catheterizations, an anesthesiologist and a thoracic surgeon, each with advanced training in the cardiovascular aspects of their specialty, who must be immediately available within the facility or in close proximity for consultation, assistance, emergency and elective surgical procedures and peri-operative care.</li> <li>Each cardiac catheterization lab must have</li> <li>a full-time registered nurse, with special training in cardiovascular techniques and in the care of children, precatheterization evaluation and instruction of the patient and family, care of the patient post-catheterization, and discharge teaching for the patient and family;</li> <li>a Registered Cardiovascular Technologist (RCVT) certified by the Cardiovascular Credentialing Institute and State of Florida licensed, under the Clinical Laboratory law, with special training in CCL techniques:</li> </ul>		

<sup>5</sup> Pediatric cardiologists trained in other countries or for any reason not eligible for certification by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics, who have completed an additional 12-month fellowship in interventional pediatric cardiology, may be credentialed as a Department of Health physician by the Surgeon General/Secretary of the Department of Health or designee as a special situation after a review and in-depth evaluation by the PCTAP, which recommended such approval.

	<ul> <li>a trained cardiovascular recorder who has no other responsibilities during procedures; and</li> </ul>
	<ul> <li>Immediate access to personnel trained in equipment repair and maintenance.</li> <li>With adaptive training, and part active training, and part active training, and part active training, and part active training.</li> </ul>
	<ul> <li>with adequate training, one person may initiative jobs (pre-caneterization evaluation and post caneterization trained nursing staff, cardiovascular catheterization lab trained technologist, dedicated trained cardiovascular</li> </ul>
	recorder, and personnel trained in equipment repair and maintenance) in order to permit 24-hour coverage of
	essential team functions.
Other	• N/A
	AVAILABILITY
Available Hours of Operation	• N/A
Other	• N/A
	EQUIPMENT
Availability of Appropriate	<ul> <li>Radiological, electronic, and computer-based systems are integral components of the equipment in a</li> </ul>
Equipment/Ancillary	catheterization laboratory. For pediatric patients specifically, biplane angiography with higher resolution and
Services	hijection rates are required. The pediatic CCL must be also be able to perform procedures in a patient supported by extracorporeal membrane oxygenation
	<ul> <li>The pediatric CCL must be co-located within a facility completely equipped to accommodate all aspects of the</li> </ul>
	medical and surgical care of the patient. It must have the following equipment and software capabilities:
	<ul> <li>Cardiac magnetic resonance imaging (MRI) scanners shall be ACR accredited with equipment performance</li> </ul>
	monitoring in accordance with state, recercine requirements. $\sim$ Cardiac MRI scanners shall have field strength of $> 1.5$ Tesla and be equipped with localized multichannel
	radiofrequency surface coil and ECG gating. ECG gating capabilities shall include prospective triggering,
	retrospective gating, and triggered retrogating.
	<ul> <li>An MRI-compatible power injector is required for performing myocardial perfusion MR imaging or any MR</li> </ul>
	anglographic methods.
	precession, phase-contrast flow quantification, fast multi-slice myocardial perfusion imaging, and late
	contrast-enhanced myocardial imaging. Parallel imaging and half-Fourier capabilities are desirable to permit
	shortened breath-hold requirements.
	<ul> <li>Commercial FDA-approved software for processing data (calculation of ejection fractions, reformatting applications) and the subject of the APPL system of the APPL system of the APPL system of the sys</li></ul>
	anylographic data) shall be available either as part of the wirk system of on a separate workstation. Post- processing shall be performed or supervised by the cardiac MRI physician
	<ul> <li>Appropriate emergency equipment and medications must be immediately available to treat adverse reactions</li> </ul>
	associated with administered medications.
Maintenance	<ul> <li>PCTAP endorses the ACCF/SCAI/STS/SVM recommendation that all systems require a program of rigorous</li> </ul>
	maintenance and troubleshooting, including maintaining biplane angiography, higher frame rates (30-60 fps), and
	nigher injection rates (up to 40 mL/s), which are required to help define abnormal initia-calulac anatomy. The catheterization laboratory must be able to perform procedures in a patient supported by extracorporeal membrane
	oxygenation.
	<ul> <li>Electrical safety and radiation protection shall be followed in accordance with the manufacturer's</li> </ul>
	recommendations and applicable state and federal regulations.
	<ul> <li>The equipment and medications shall be monitored for inventory and drug expiration dates on a regular basis. The equipment medications and other emergency support must be appropriate for the range of ages and sizes in the</li> </ul>
	patient population.
Other	• N/A
LICENSING	STANDARDS FROM SELECTED OTHER STATES THAT DO NOT HAVE A CON PROCESS <sup>6</sup>
<ul> <li>California (CA)</li> </ul>	
<ul> <li>Colorado (CO)</li> </ul>	
<ul> <li>New Hampshire (NH</li> </ul>	1)
<ul> <li>Pennsylvania (PA)</li> </ul>	
<ul> <li>Texas (TX)</li> </ul>	
<ul> <li>Utah (UT)</li> </ul>	

<sup>6</sup> We identified 15 states that do not have a certificate of need process for the tertiary health services. However, two of the states, Arizona and Minnesota, either had a CON for some other related services or had a process that was not called a CON but would have similar effects. Seven of the states were not comparable to Florida due to factors such as having a small number of teaching hospitals; a significantly different breakdown of citizens on Medicaid, Medicare, or uninsured; a smaller population size; and/ or a higher portion of the state that is rural. These seven states were Idaho, Kansas, New Mexico, North Dakota, South Dakota, Wisconsin, and Wyoming. For the remaining six state, we conducted an in-depth review to identify and evaluate any licensing standards for the services considered tertiary in Florida. These six state were California, Colorado, New Hampshire, Pennsylvania, Texas, and Utah.

Overview	<ul> <li>CO, TX, and UT: Do not address pediatric cardiac catheterization as a specific licensed service or impose additional requirements under the general acute care licensing requirements.</li> <li>CA: Includes pertinent provisions in its regulations for supplemental services within its licensing for general acute care hospitals. These supplemental services include pediatric cardiac surgery services, which are a part of an acute care hospital capable of performing cardiac catheterizations.</li> <li>NH: Provides specialty licenses for cardiac catheterization that include pediatric; however, the state is in the process of promulgating rules that have not been finalized.</li> <li>PA: Requires pediatric cardiac catheterization only be performed in an acute care facility that has inpatient medical and surgical services onsite, a coronary care unit onsite with 24-hour per day monitoring capability, and a peripheral vascular surgical program available. PA provides supplemental criteria for pediatric heart surgery that includes cardiac catheterization.</li> </ul>
	QUALITY MEASURES
Minimum Volume	<ul> <li>CA: Establishes volume standards for general cardiovascular procedures, including cardiac catheterization. The volume standards are not exclusive to pediatric cardiac catheterization.<sup>7</sup></li> <li>NH: According to NH licensing staff, future licensing standards may include minimum standards for volume, but rules have not yet been developed.</li> </ul>
Outcome Measures	• N/A
Other	<ul> <li>N/A</li> </ul>
Caveats	• N/A
	QUALITY OF STAFFING
Professional Competencies, Certification, Specialization	<ul> <li>Director(s):</li> <li>CA: A physician shall have overall responsibility for the cardiac catheterization laboratory service. This physician shall be certified or eligible for certification in cardiology by either the American Board of Internal Medicine or the American Board of Pediatrics or have equivalent experience and training.</li> <li>PA: All staff responsible for care of the pediatric patient shall have experience and training in pediatrics, including both physiological and psychosocial needs of the patient. The director of the cardiac catheterization service shall be board-certified in cardiology or pediatric cardiology, as appropriate.</li> <li>Surgeons/Physicians:</li> <li>CA: One American Board of Radiology certified or eligible-for-certification physician with special training or experience in cardiovascular radiology shall be available to the cardiovascular surgery service staff.</li> <li>PA: Shall be staffed by at least two physicians that are to perform angiographies. These physicians shall be either board-certified or shall have attained pre-board certification status in cardiovascular diseases with specialized training in invasive procedures.</li> <li>Nursing Staff:</li> <li>CA: Registered nurses or cardiovascular technicians trained in the use of all instruments and equipment and supervised by a physician.</li> <li>PA: At least one registered nurse assigned to provide nursing care for patients in the cardiac catheterization area at all times. The nurse shall have intensive care or coronary care experience and knowledge of cardiovascular medications and experience with cardiac catheterization patients. In pediatric units, this nurse shall also have experience in pediatric cardiac surgery units.</li> <li>Additional Medical Personnel:</li> <li>CA: A biomedical engineer shall be available for consultation as required. An electronic technician shall be available where required.</li> <li>PA: Catheterization laboratory nursing personnel shall be assigned to duties consistent with their trainin</li></ul>
Staffing to Patient Ratios, By Profession	<ul> <li>CA: Two persons (registered nurses or cardiovascular technicians) shall assist during the performance of all cardiac catheterization procedures, be trained in the use of all instruments and equipment, and be supervised by a physician.</li> <li>PA: Shall have         <ul> <li>nursing and other health care personnel and a means for assessing the nursing and other personnel needs of the patients and determining adequate staffing to meet those needs;</li> <li>staffing patterns that are adequate to the nursing goals, standards of practice, and the needs of the patients;</li> <li>an adequate number of licensed and unlicensed assistive personnel to assure that staffing levels meet the total nursing needs of the patient; and</li> <li>nursing and catheterization laboratory health care personnel assigned to duties consistent with their training, experience, and scope of practice, where applicable.</li> </ul> </li> </ul>
Other	<ul> <li>N/A</li> </ul>

<sup>7</sup> California's volume standard for general cardiovascular procedures is 260 cardiac catheterizations and 150 cardiovascular procedures requiring extracorporeal bypass. However, this volume requirement is not exclusive to pediatric cardiac procedures.

AVAILABILITY				
Available Hours of Operation	N/	N/A		
Other	•	N/A		
		EQUIPMENT		
Availability of Appropriate Equipment	•	<ul> <li>PA: Pediatric heart surgery programs must include diagnostic laboratory with radiographic and cardiac catheterization equipment generally similar to that for adults. Bi-plane cineangiography shall be readily available 24 hours per day, and laboratories (both catheterization and general chemical) shall be equipped for small volume samples catheterization.</li> <li>PA: The equipment used for pediatric cardiac catheterizations is appropriate to meet the needs of the pediatric patient. Bi-plane cineangiography shall be readily available 24 hours per day, and laboratories (both catheterization and general chemical) shall be equipped for small volume samples</li> <li>CA: Not specifically identified for pediatric cardiac catheterization, but CCL equipment and supplies must include, but not be limited to,</li> <li>X-ray machine;</li> <li>image intensifier;</li> <li>pulse generator;</li> <li>camera;</li> <li>spot film device;</li> <li>videotape viewing equipment of fluoroscopic procedures;</li> <li>magnetic tape recording and playback equipment;</li> <li>monitoring and recording equipment;</li> <li>pressure transducers;</li> <li>equipment for determining cardiac output;</li> <li>equipment for determining cardiac output;</li> <li>equipment for determining oxygen saturation, hemoglobin, blood gas analysis, and pH;</li> <li>appropriate cardiac catheters and accessory equipment; and</li> </ul>		
Maintenance	•	N/A		
Other	-	N/A		

Source: OPPAGA review of journal articles; state and federal statutes/laws and rules; and standards from professional organizations, accreditors, PCTAP, and other states.

### **APPENDIX E**

### Pediatric Open Heart Surgery

Background	Pediatric open heart surgery refers to operations performed on the heart that require a patient being placed on a heart- lung bypass machine. This often may require surgeons to stop the heart with a solution called "cardioplegia," which is a cold, high-potassium solution, allowing the heart to be opened and repaired in a bloodless, still environment. Open heart surgery can be used to repair a variety of cardiac defects, such as atrial septal defects, ventricular septal defects, atrioventricular (AV) canals, transposition of the great arteries, and tetralogy of Fallot. Pediatric open heart surgery was designated a tertiary health service by s. 408.032, <i>Florida Statutes</i> 2018.
Former Florida Requirements	Chapter 2019-136, <i>Laws of Florida</i> , repealed the certificate of need (CON) for pediatric open heart surgery programs and did not include an authorization for the agency to keep standards embedded in its CON rules (Rule <u>59C-1.033</u> , <i>Florida Administrative Code</i> ) in place until it promulgates licensing rules to replace the CON standards. AHCA has been working with the Pediatric Cardiac Technical Advisory Committee, created pursuant to s. <u>395.1055</u> , <i>Florida Statutes</i> , to draft new licensing rules for pediatric cardiac procedures. <sup>1</sup> The former pediatric open heart surgery CON rule, Rule <u>59C-1.033</u> , <i>Florida Administrative Code</i> , required that centers have the capability to provide a full range of open heart surgery operations, including repair or replacement of heart valves, repair of congenital heart defects, cardiac revascularization, repair of congenital heart defects, repair or construction of intrathoracic vessels, and the treatment of cardiac trauma. Further, the rules required that the following trained personnel be available to perform in these capacities during open heart surgery: board-certified or board-eligible anesthesiologist trained in open heart surgery, a registered nurse (RN) or certified operating room technician trained to serve in open heart-surgery operations and perform circulating duties, and a perfusionist to perform extracorporeal perfusion, or a physician or specially trained nurse, technician, or physician assistant under the supervision of the operating surgeon to operate the heart-lung machine. In addition, the rule required at least one board-certified or board-eligible pediatric cardiac surgeon on the staff of a hospital with a pediatric open heart surgery program. Centers were required to be available for elective open heart operations 8 hours per day, 5 days per week, and available 24 hours per day, 7 days per week for rapid mobilization of surgical and medical support teams. Programs were also required to serve patients needing open heart surgery regardless of ability to pay
Federal Requirements	We did not identify any federal requirements specifically for pediatric open heart surgery. The Centers for Medicare and Medicaid Services establishes standards for hospitals in general that receive Medicare funding.
<ul> <li>STANDARDS FROM PROFESSIONAL ORGANIZATIONS AND ACCREDITORS<sup>2</sup></li> <li>American Academy of Pediatrics Section on Cardiology and Cardiac Surgery <i>Guidelines for Pediatric Cardiovascular Centers</i> 2002 (AAP)</li> <li>American College of Surgeons <i>Optimal Resources for Children's Surgical Care v.1</i> 2015 (ACS)<sup>3</sup></li> <li>Joint Commission and American Heart Association <i>Standards Revisions for Comprehensive Cardiac Centers</i> 2018 (JC-AHA)</li> </ul>	
	QUALITY MEASURES
Minimum Volume	ACS: 1,000 patients annually for all pediatric surgeries (not exclusive to open heart surgeries).
Outcome Measures	<ul> <li>AAP: Mortality rate of less than 1% for procedures that treat conditions such as atrial septal defect, ventricular septal defect, or coarctation of the aorta.</li> </ul>
	<ul> <li>AAP: Mortality rate of less than 5% for tetralogy of Fallot, complete atrioventricular canal defect, and transposition of the great arteries.</li> </ul>
Other	• N/A
Caveats	• N/A
<sup>1</sup> Section 395.1055, F.S., requires the	ne Agency for Health Care Administration to establish a technical advisory panel to develop procedures and standards

<sup>1</sup> Section 395.1055, F.S., requires the Agency for Health Care Administration to establish a technical advisory panel to develop procedures and standards for measuring outcomes of pediatric cardiac catheterization programs and pediatric cardiovascular surgery programs. The panel is to recommend to the agency standards for quality of care, personnel, physical plant, equipment, emergency transportation, and data reporting for hospitals that provide pediatric cardiac services. Accordingly, AHCA established the Pediatric Cardiac Technical Advisory Panel (PCTAP), which has issued recommended standards for pediatric cardiovascular centers. Based on the recommendations of the advisory panel, AHCA is required to adopt rules for pediatric cardiac programs which, at a minimum, include standards for pediatric cardiac catheterization services and pediatric cardiovascular surgery, including quality of care, personnel, physical plant, equipment, emergency transportation, and appropriate operating hours and timeframes for mobilization for emergency procedures; outcome standards consistent with nationally established levels of performance; and specific steps to be taken by AHCA and licensed facilities when the facilities do not meet the outcome standards within a specific time.

<sup>2</sup> The Accreditation Council of Graduate Medical Education (ACGME) *Program Requirements for Graduate Medical Education in Pediatric Surgery* and the *Program Requirements for Pediatric Cardiac Care* 2018 provide minimum standards, including experience and minimum volume levels, for teaching hospitals and for residents and fellows.

<sup>3</sup> The American College of Surgeons provides extensive guidelines for levels of pediatric surgical care. These requirements are provided for all pediatric surgeries and are part of a larger ACS verification program. These standards, along with a detailed explanation of the ACS pediatric surgical center levels, can be found on the organization's <u>website</u>.

QUALITY OF STAFFING		
Professional Competencies, Certification, Specialization	<ul> <li>Program Director(s):</li> <li>JC-AHA: Cardiac center executive; quality improvement specialist/data manager; physicians who have specialized training in cardiology and are privileged in cardiology, specialized training in cardiology and are privileged in interventional cardiology, specialized training in cardiology and are privileged in emergency medicine; cardiothoracic surgeon; and registered nurse with clinical experience and training in cardiovascular care to serve as executive leadership team.</li> <li>JC-AHA: Designated physician leader accountable for the entire center.</li> <li>Surgeons/Physicians: <ul> <li>AAP: At least one board-certified or board-eligible pediatric cardiologist.</li> <li>AAP: Congenital heart surgeon with at least two years of pediatric cardiac fellowship and additional years working as a junior staff surgeon in a pediatric and congenital heart program.</li> <li>ACS: At least one pediatric surgeon (depending on level) certified or eligible for certification by the Pediatric Surgery Board of the American Board of Surgery or equivalent body.</li> <li>ACS: At least two pediatric surgeons certified or eligible for certification by the Pediatric Surgery Board of the American Board of Surgery or equivalent body.</li> </ul> </li> </ul>	
	<ul> <li>American Board of Surgery or equivalent body; pediatric emergency physician for Level I facilities.</li> <li>JC-AHA: Physicians who have specialized training in cardiology and are privileged in cardiology, specialized training in cardiology and are privileged in interventional cardiology, specialized training in cardiology and are privileged in emergency medicine.</li> <li>JC-AHA: Qualified cardiothoracic surgeons who have specialized training and are privileged in cardiothoracic surgery.</li> <li>JC-AHA: Physicians must have expertise in cardiac critical care, coronary interventions, advanced heart failure care, cardiac imaging, arrhythmia management, and cardiothoracic surgery.</li> <li>JC-AHA: Nurses providing acute cardiac patient care must have obtained a minimum of eight hours of education per year on cardiovascular disease and participate in continuing professional development.</li> <li>Additional Medical Personnel:</li> <li>ACS: At least one pediatric anesthesiologist certified or eligible for certification by the American Board of Anesthesiology, or equivalent body, in Level II and Level III facilities.</li> <li>ACS: Two pediatric anesthesiologists certified or eligible for certification by the American Board of Anesthesiology, or equivalent body, in Level I and Level III facilities.</li> <li>ACS: Pediatric radiologist with certification by the American Board of Anesthesiology, or equivalent body, in Level I facilities.</li> </ul>	
Staffing to Patient Ratios, By Profession	<ul> <li>experience, and 10 or more pediatric Category I CME credit hours annually.</li> <li>ACS Level I: Includes two pediatric surgeons, two pediatric anesthesiologists, pediatric critical care physicians, pediatric nursing, respiratory therapy, pharmacy staff, two pediatric radiologists, comprehensive panel of pediatric medical and surgical specialists, emergency pediatric physician, and pediatric rapid response team (see Appendix F for more detail).</li> <li>ACS Level II: Includes one pediatric surgeon, one pediatric anesthesiologist, pediatric critical care physicians, neonatologists, pediatric ophthalmologists, respiratory therapists, one pediatric radiologist, emergency medical personnel, rapid response team, and surgical sub-specialists (see Appendix F for more detail).</li> <li>ACS Level III: Includes general surgeons and general anesthesiologists with pediatric expertise, pediatric rapid response team, pediatric emergency medical personnel, and radiologist with pediatric expertise (see Appendix F for more detail).</li> </ul>	
Maximum Work Hours	• N/A	
Other	• N/A	
	AVAILABILITY	
Available Hours of Operation	<ul> <li>JC-AHA: Personnel available onsite within 30 minutes, 24/7 and 45 minutes for one or more additional cardiologists.</li> <li>JC-AHA: Qualified and credentialed physicians available 24/7.</li> </ul>	
Other	• AAP: Affiliation with a certified transplant center, or offer pediatric cardiac transplants themselves.	

EQUIPMENT		
Availability of Appropriate Equipment/Ancillary Services	<ul> <li>ACS Level I and Level II: Pediatric-appropriate equipment present.</li> <li>ACS Level III: Pediatric-appropriate equipment available.</li> <li>AAP: One or more operating rooms designated for pediatric cardiology.</li> <li>JC-AHA: Emergency cardiovascular diagnostic, imaging, and interventional surgical services.</li> <li>AAP: Pediatric intensive care units should be equipped to provide respiratory support, with mechanical ventilators, complete hemodynamic and cardiac rhythm monitoring and recording, cardiac pacing, open- and close-chest resuscitation and operating, extracorporeal membrane oxygenation (ECMO), and ventricular assist devices (VADs).</li> </ul>	
Maintenance Other	<ul> <li>N/A</li> <li>N/A</li> </ul>	
APPLICABLE STAN	DARDS RECOMMENDED BY THE PEDIATRIC CARDIAC TECHNICAL ADVISORY PANEL (PCTAP)	
	QUALITY MEASURES	
Minimum Volume	<ul> <li>100 pediatric cardiac surgical procedures annually averaged over two years.</li> </ul>	
Outcome Measure	• N/A	
Caveats	• N/A	
Other	<ul> <li>Must collect data on number of patients/operations by year.</li> <li>Must collect data on number of patients/operations by age group.</li> </ul>	
	QUALITY OF STAFFING	
Professional Competencies, Certification, Specialization Staffing to Patient Ratios, by Profession	<ul> <li>Director(s): <ul> <li>Physician in charge of a Pediatric Cardiology Clinic must be board-certified by the Sub-board of Pediatric Cardiology of the American Board of Pediatrics.</li> </ul> </li> <li>Surgeons/Physicians: <ul> <li>Department of Health credentialed thoracic and cardiovascular surgeon with specialization in pediatrics (board-certified–American Board of Thoracic Surgery).</li> </ul> </li> <li>Nursing: <ul> <li>Specialty trained nurses.</li> </ul> </li> <li>Additional Medical Personnel: <ul> <li>Sub-specialists available for consultation on patients with heart disease.</li> <li>Anesthesiologists trained and experienced with open and closed heart pediatric anesthesia.</li> <li>Radiologist trained in cardiopulmonary disease.</li> </ul> </li> <li>Respiratory therapist with training and experience in short- and long-term ventilatory support in infants and children.</li> <li>Pathologist with skills and training in cardiovascular pathology.</li> </ul>	
Other	• N/A	
	AVAILABILITY	
Available Hours of Operation	<ul> <li>General pediatric coverage with sub-specialty capability 24 hours/day, 7 days/week.</li> <li>24-hour physician coverage.</li> <li>Laboratory and radiology technicians available 24 hours/day, 7 days/week.</li> <li>Continuous availability of a team capable of performing intra-operative Transesophageal Echoes (TEE) to aid in post-surgical assessment of operative procedures.</li> </ul>	
Other	<ul> <li>Pediatric patient rooms with provision for a parent, relative, or guardian to stay overnight.</li> </ul>	
EQUIPMENT		
Availability of Appropriate Equipment/Ancillary Services	<ul> <li>Effective system of rapid referral and transportation, including life support equipment for transport.</li> <li>Availability of Extra Corporeal Membrane Oxygenation.</li> </ul>	
Maintenance	• IV/A	
Uther	<ul> <li>N/A</li> </ul>	

#### LICENSING STANDARDS FROM SELECTED OTHER STATES THAT DO NOT HAVE A CON PROCESS⁴

- California (CA)
- Colorado (CO)
- New Hampshire (NH)
- Pennsylvania (PA)
- Texas (TX)
- Utah (UT)

Most states we reviewed have both general pediatric surgical requirements as well as open heart surgery requirements. New Hampshire provides specialty licenses for cardiac open heart surgery that include pediatric; however, the state is in the process of promulgating rules that have not been finalized, and thus, they are not included in this analysis.

#### **QUALITY MEASURES<sup>5</sup>**

Minimum Volume	<ul> <li>CA: Establishes a volume standard for general cardiovascular surgery that is not exclusive to pediatric open heart surgery.<sup>6</sup></li> </ul>
Outcome Measure	• N/A
Caveats	• N/A
Other	• N/A
	QUALITY OF STAFFING
Professional Competencies, Certification, Specialization	• N/A
Staffing to Patient Ratios, by Profession	<ul> <li>CA: 3 surgeons/surgical team for all cardiovascular operations requiring extracorporeal bypass.</li> <li>CA: 1:2 (or less) nurse to patient ratio for critical care; 1:4 (or less) for pediatrics.</li> </ul>
Other	CA: 8 or more pediatric (age 13 or younger) beds requires a pediatric nursing unit.
	CO: Facility shall have separate pediatric care units when the number of pediatric beds is or exceeds 14 beds.
	AVAILABILITY
Available Hours of Operation	<ul> <li>PA: Board-certified or board-eligible thoracic and pediatric surgeons, a cardiac catheterization team with interventional ability, and anesthesiologists available 24/7.</li> <li>CA: Specialty physicians in pediatrics shall be available 24 hours per day.</li> </ul>
Other	<ul> <li>PA: Rapid mobilization of cardiac surgical team.</li> <li>CA: Cardiovascular surgical services available at all times for emergencies.</li> </ul>
	EQUIPMENT
Availability of Appropriate Equipment/Ancillary Services	<ul> <li>CA: Monitoring and recording equipment for electrocardiograms, pressure, coronary blood flow, cardiac output, patient temperature, blood gas analyzer, heart-lung machine with oxygenator, device for rapid cooling and heating of the patient, direct current (DC) defibrillator, magnetic tape recording equipment, suction outlets, piped in air and oxygen and tanks of gas including mixtures of oxygen and carbon dioxide.</li> <li>PA: Pediatric-appropriate equipment.</li> <li>PA: Must have surgical equipment appropriate for newborns, infants, and children.</li> <li>PA: Diagnostic and therapeutic services, radiography and catheterization equipment similar to that for adults</li> </ul>
	<ul> <li>Dragnostic and therapeutic services, ratiography and catheterization equipment similar to that for adults, bi-plane cineangiography (24/7), and labs.</li> <li>UT: Operating rooms have a call-in system, cardiac monitor, ventilation support system, defibrillator, aspirator, and resuscitation equipment.</li> </ul>
Maintenance	• N/A
Other	CA, CO: Play area for patients.

<sup>4</sup> We identified 15 states that do not have a certificate of need (CON) process for the tertiary health services. However, two of the states, Arizona and Minnesota, either had a CON for some other related services or had a process that was not called a CON but would have similar effects. Seven of the states were not comparable to Florida due to factors such as having a small number of teaching hospitals; a significantly different breakdown of citizens on Medicaid, Medicare, or uninsured; a smaller population size; and/or a higher portion of the state that is rural. These seven states were Idaho, Kansas, New Mexico, North Dakota, South Dakota, Wisconsin, and Wyoming. For the remaining six states, we conducted an in-depth review to identify and evaluate any licensing standards for the services considered tertiary in Florida. These six states were California, Colorado, New Hampshire, Pennsylvania, Texas, and Utah.

<sup>5</sup> Texas, California, and Colorado all have requirements that pediatric surgery facilities and cardiac beds be located separately from adult facilities. Also, California specifies that children under the age of three must be located separately from older pediatric patients.

<sup>6</sup> California's volume standard for general cardiovascular surgery is 260 cardiac catheterizations per year and 150 cardiovascular procedures per year requiring extracorporeal bypass. However, this is not a standard exclusive to pediatric open heart surgery.

Source: OPPAGA review of journal articles; state and federal statutes/laws and rules; and standards from professional organizations, accreditors, PCTAP, and other states.

### **APPENDIX F**

### American College of Surgeons' Volume, Staffing, and Equipment Recommendations for General Pediatric Surgery

#### Exhibit F-1

The American College of Surgeons' Volume, Staffing, and Equipment Recommendations for Children's Surgical Care Vary by Level of General Pediatric Surgery

Level	Volume	Staffing	Equipment
Level I	<ul> <li>1,000 surgeries/year on patients under the age of 18</li> </ul>	<ul> <li>Comprehensive portfolio of medical and surgical subspecialists available 24/7 to service major congenital anomalies and complex diseases</li> <li>Two or more pediatric surgeons on staff – available within 60 minutes, 24/7; must serve as the primary surgeon for all children age five and under<sup>1</sup></li> <li>Two or more pediatric anesthesiologists on staff to serve as the primary anesthesiologists for all children age two and younger<sup>2</sup></li> <li>All surgical specialists require institutional credentials for privileges for operative procedures to be performed specifically in children</li> <li>Collaborative care neonatologists and staffing and services consistent with a Level IV Neonatal Intensive Care Unit (NICU) (American Academy of Pediatrics)</li> <li>Nursing, respiratory therapy, pharmacy, and other support staff must have training and expertise in pediatrics</li> <li>Two or more pediatric radiologists on the medical staff able to provide service within 60 minutes, 24/7<sup>3</sup></li> <li>Attending pediatric emergency physician on-site 24/7<sup>4</sup></li> <li>Comprehensive panel of pediatric medical and surgical specialists ready for consultation<sup>5</sup></li> <li>Pediatric rapid response and/or resuscitation team is required</li> </ul>	<ul> <li>Age and size appropriate, or equipment and support for the patient populations served</li> <li>Pediatric-specific equipment for the scope of service to include airway managements, vascular access, thermal control, surgical instruments, intraoperative imaging capabilities, equipment for endoscopic evaluation (airway and gastrointestinal endoscopy), and minimally invasive surgery</li> <li>Age-appropriate resuscitation fluids, medications, and pharmacy support must be available to support the operative services provided</li> </ul>

<sup>1</sup> Pediatric surgeon is defined as an individual certified or eligible for certification in pediatric surgery by the Pediatric Surgery Board and the American Board of Surgery or equivalent body.

<sup>2</sup> Pediatric anesthesiologist is defined as an individual certified or eligible for certification in pediatric anesthesiology by the American Board of Anesthesiology or equivalent body.

<sup>3</sup> Pediatric radiologist is defined as an individual certified by the American Board of Radiology or equivalent, in addition to being board certified or eligible for certification in pediatric radiology by the American Board of Radiology or equivalent body.

<sup>4</sup> Pediatric emergency physician is an individual who is board certified or eligible to be certified in either pediatrics or emergency medicine and who has completed an ACGME-approved or equivalent pediatric emergency medicine fellowship training program.

<sup>5</sup> Pediatric medical and surgical specialists are defined as individuals who are certified or eligible for certification by the appropriate board of the American Board of Medical Specialties (ABMS) or equivalent; who have obtained, or are eligible for, the pediatric certificate of added qualification or equivalent when offered, or who have obtained ACGME pediatric postgraduate fellowship training (or equivalent) when a certificate of added qualification is not offered in the discipline; and who are specifically credentialed to provide children's specialty care in the discipline.

Level	Volume	Staffing	Equipment
Level II	<ul> <li>Volume not specified</li> <li>If located in a population-dense area, should complement the clinical activity of a Level I facility</li> <li>If located in a less population-dense area without a Level I institution close by, meant to serve as the lead children's facility</li> </ul>	<ul> <li>One or more pediatric surgeons available on a consultant basis within 60 minutes, 24/7; must provide relevant care for children age five and younger</li> <li>One or more pediatric anesthesiologists on staff and available within 60 minutes, 24/7; must be the primary anesthesiologist for children age two and younger and should serve as primary for children age five and younger</li> <li>Must be able to provide access to a wide range of pediatric subspecialists and neonatologists</li> <li>Pediatric critical care physicians, respiratory therapists, nurses, and others with demonstrable pediatric training and experience</li> <li>One or more pediatric radiologists on staff<sup>6</sup></li> <li>Emergency medical care provided by pediatric medicine physicians or emergency medicine physicians with pediatric expertise<sup>7</sup></li> <li>Pediatric rapid response and/or resuscitation team to support the scope of service is required to be in place 24/7 to respond to any site in the facility. Doing so requires the 24/7 physical presence of a pediatric provider to include current Pediatric Advanced Life Support (PALS) certification in the leadership role.</li> </ul>	<ul> <li>Age and size appropriate, or equipment and support for the patient populations served</li> <li>Pediatric-specific equipment for the scope of service to include airway managements, vascular access, thermal control, surgical instruments, intraoperative imaging capabilities, equipment for endoscopic evaluation (airway and gastrointestinal endoscopy), and minimally invasive surgery</li> <li>Age-appropriate resuscitation fluids, medications, and pharmacy support must be available to support the operative services provided</li> </ul>
Level III	<ul> <li>Volume not specified, but meant to serve children over the age of 6 months who do not have comorbidities</li> </ul>	<ul> <li>General surgeons and anesthesiologists with pediatric expertise on staff and available within 60 minutes, 24/7<sup>8</sup></li> <li>Must have a pediatric rapid response and/or resuscitation team with experience and training with the presence of a pediatric provider to include current PALS certification to support the scope of service in place 24/7 to respond to any site in the facility.</li> <li>Emergency medical coverage by physicians with pediatric-specific experience and training</li> <li>A radiologist with pediatric expertise must be available to provide care within 60 minutes, 24/7</li> </ul>	<ul> <li>Age and size appropriate, or equipment and support for the patient populations served</li> <li>Pediatric-specific equipment for the scope of service to include airway managements, vascular access, thermal control, surgical instruments, intraoperative imaging capabilities, equipment for endoscopic evaluation (airway and gastrointestinal endoscopy), and minimally invasive surgery</li> <li>Age-appropriate resuscitation fluids, medications, and pharmacy support must be available to support the operative services provided</li> </ul>

<sup>&</sup>lt;sup>6</sup> Can be supplemented by a radiologist with pediatric expertise, defined as a radiologist with certification by the American Board of Radiology or equivalent, demonstrable pediatric experience to support the scope of actual practice, and 10 or more pediatric Category 1 continuing medical education (CME) credit hours annually.

Source: OPPAGA review of the American College of Surgeons, Optimal Resources for Children's Surgical Care v.1, Children's Surgery Verification Quality Improvement Program; American College of Surgeons, Children's Surgery Verification website.

<sup>&</sup>lt;sup>7</sup> Defined as an individual certified by the American Board of Emergency Medicine, the American Board of Pediatrics, or equivalent and who has demonstrable pediatric experience and training to support the actual scope of emergency medicine practice, as well as 10 hours of pediatric Category 1 CME annually.

<sup>&</sup>lt;sup>8</sup> A general surgeon with pediatric expertise is one who is certified or eligible for certification by the American Board of Surgery or equivalent in general surgery, who must demonstrate ongoing clinical engagement and expertise in children's surgery as evidenced by the performance of 25 or more procedures annually in patients younger than 18 years, as well as completion of 10 or more pediatric Category 1 CME credit hours annually. An anesthesiologist with pediatric expertise is one who is certified or eligible for certification by the American Board of Anesthesiology or equivalent; who demonstrates continuous experience with children younger than 24 months, defined as 25 patients per anesthesiologist per year; and who demonstrates ongoing pediatric clinical engagement with patients younger than 18 years and will complete 10 or more pediatric Category 1 CME credit hours annually.

## APPENDIX G

### Organ Transplantation

Background	Organ transplantation is the process of surgically transferring a donated organ into a patient with organ failure. Deceased donors provide kidneys, pancreas, liver, lungs, heart, and intestines. Living donors can provide a kidney; a lung; or a portion of the liver, intestine, or pancreas. Organ transplantation is often the only treatment for end-state organ failure, such as liver and heart failure. Kidney transplantation, the most frequent transplantation, is also the most cost-effective treatment of end stage renal disease. Section 408.032, <i>Florida Statutes 2018</i> , designates organ transplantation as a tertiary health service.
Requirements (embedded in certificate of need rules until replaced by licensing standards)	<ul> <li>Artu-A is auriorized to use standards embedded in the transplant certificate of need (UUN) rules (296-1.044, <i>Honda</i> Administrative Code), establishes rules for all transplantation programs and includes specific requirements for heart, liver, kidney, and bone marrow transplantation programs.</li> <li>All transplant programs shall have staff and other resources necessary to care for the patient's chronic illness prior to transplantation, during transplantation, and in the post-operative period; a written agreement with an organ acquisition center for organ procurement for cadaveric transplantation programs, and an age-appropriate (adult or pediatric) intensive care unit which includes facilities for prolonged reverse isolation when required. Additional requirements address evaluation and decision-making regarding the suitability of a transplant candidate; written protocols for patient care for each type of organ transplantation program, detailed therapeutic and evaluative procedures for the acute and long-term management of each transplant program program patient, equipment, an onsite tissue-typing laboratory; pathology services; blood banking facilities; staff education and training; and education regarding aftercare for the patient, family, and the patient's primary care physician. Staffing requirements include a byoard-certified or board-eligible adult cardiologist, or, in the case of a pediatric heart transplantation program, a board-certified or board-eligible pediatric cardiologist; an anesthesiologist experienced in both open heart surgery and heart transplantation; and -ebedroom isolation room in an age-appropriate intensive care unit. In addition, the standards contain the following minimum volume requirements:</li> <ul> <li>24 transplants performed in each existing heart transplantation provider in the applicable service area; 12 transplants performed vy eave within two years of certificate of need approval;</li> <li>500 duplicated cardiac catheterization patient caseload;</li></ul></ul>

	<ul> <li>Allogeneic and autologous bone marrow transplantation programs have specific requirements for pediatric allogeneic and autologous bone marrow transplantation programs, adult allogeneic bone marrow transplantation programs, and adult autologous bone marrow transplantation programs. In addition to specific requirements for staff, units for post-transplant hospitalization, and radiation therapy, all three programs are limited to teaching and research hospitals and an established research-oriented oncology program. In addition, the standards contain the following minimum volume requirements:         <ul> <li>10 pediatric allogeneic and autologous bone marrow transplants; if both are performed, 10 of each shall be projected;</li> <li>10 adult allogeneic bone marrow transplants shall be projected; and</li> <li>10 adult autologous bone marrow transplants shall be projected.</li> </ul> </li> </ul>
Federal Requirements	The federal Centers for Medicare and Medicaid Services (CMS) and the Organ Procurement and Transplantation Network (OPTN) have established requirements for the operation of organ transplant programs. In ss. <u>482.72 to 482.104</u> , <i>Code of Federal Regulations</i> , CMS establishes Conditions of Participation for hospitals that receive Medicare funding and conduct transplants. These rules include requirements for initial approval by CMS, including data submission; the minimum number of transplants performed over a 12-month period and of patient and graft survival rates; written patient selection criteria for wait lists and protocols for organ recovery and receipt; policies for patient and donor management; and protection of patient and living donor rights. <sup>1</sup> The rules also require transplant hospitals to be members of OPTN. OPTN establishes <u>bylaws for transplant centers</u> that include requirements for OPTN approval as a designated transplant program for at least one organ. The bylaws also include requirements for facilities and resources; the transplant program director; the primary transplant surgeon and physician; support personnel; and investigation of personnel if directed by the OPTN Membership and Professional Standards Committee (MPSC). In addition, the OPTN bylaws contain provisions for a review of transplant program functional activity and require programs to remain functionally active by performing at least a minimum number of transplants within specified timeframes. The bylaws also contain transplant program performance requirements and establish criteria for MPSC review of programs that have higher than expected failure rates for graft and patient survival. Select required minimum standards from CMS and OPTN are outlined below.

### REQUIRED FEDERAL STANDARDS FROM THE U.S. CENTERS FOR MEDICARE AND MEDICAID SERVICES AND ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK<sup>2</sup>

QUALITY MEASURES	
Minimum Volume	<ul> <li>Heart: <ul> <li>CMS: 10 (for initial approval)</li> <li>OPTN: Functionally inactive status is &lt;1 in three consecutive months</li> </ul> </li> <li>Liver: <ul> <li>CMS: 10 (for initial approval)</li> <li>OPTN: Functionally inactive status is &lt;1 in three consecutive months</li> </ul> </li> <li>Kidney: <ul> <li>CMS: 3 (prior to request for initial approval)</li> <li>OPTN: Functionally inactive status is &lt;1 in three consecutive months</li> </ul> </li> <li>Pancreas: <ul> <li>CMS: No requirement</li> <li>OPTN: Functionally inactive status is both &lt;2 in 12 consecutive months and either a median waiting time of the program's kidney-pancreas and pancreas or pancreas candidates that is above the 67<sup>th</sup> percentile of the national waiting list or the program had no kidney-pancreas or pancreas candidates registered at the program Lung: <ul> <li>CMS: 10 for lung (for initial approval); no requirement for heart/lung</li> <li>OPTN: Functionally inactive status is &lt;1 in six consecutive months</li> </ul> </li> <li>CMS: No requirement</li> <li>CMS: 10 for lung (for initial approval); no requirement for heart/lung</li> <li>OPTN: Functionally inactive status is &lt;1 in six consecutive months</li> </ul></li></ul>

<sup>1</sup> In addition to meeting the transplant program's Conditions of Participation, the hospital that houses the transplant center must also comply with the hospital Conditions of Participation (specified in <u>42 CFR § 482.1 to 482.57)</u>.

<sup>&</sup>lt;sup>2</sup> The Accreditation Council of Graduate Medical Education (ACGME) *Program Requirements for Graduate Medical Education* 2018 provides minimum standards, including minimum volume levels, for teaching hospitals and for residents and fellows.

Outcome Measures	All Transplants:
	<ul> <li>CMS (for initial approval): Comparison of each transplant center's observed number of patient deaths and graft failures one-year post-transplant to the center's expected number of patient deaths and graft failures one- year post-transplant using data contained in the most recent Scientific Registry of Transplant Recipients (SRTR) center-specific report. CMS will not consider a center's patient and graft survival rates to be acceptable if</li> </ul>
	<ul> <li>a center's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate and graft survival rate; and</li> <li>all three of the following thresholds are crossed over:</li> <li>The one-sided p-value is less than 0.05:</li> </ul>
	<ul> <li>The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than three; and</li> <li>The number of observed events divided by the number of expected events is greater than 1.85</li> </ul>
	<ul> <li>OPTN: The Membership and Professional Standards Committee will conduct reviews of transplant program performance to identify underperforming transplant programs and require the implementation of quality assessment and performance improvement measures. One measure of transplant program performance is triggered through a review of the one-year graft and patient survival rates.</li> </ul>
	For programs performing 10 or more transplants in a 2.5-year period, the MPSC will review a transplant program if it has a higher hazard ratio of mortality or graft failure than would be expected for that transplant program. The criteria used to identify programs with a hazard ratio that is higher than expected will include either of the following:
	<ul> <li>The probability is greater than 75% that the hazard ratio is greater than 1.2; or</li> <li>The probability is greater than 10% that the hazard ratio is greater than 2.5.</li> </ul>
	For programs performing nine or fewer transplants in a 2.5-year period, the MPSC will review a transplant program if the program has one or more events in a 2.5-year cohort.
Other	<ul> <li>CMS (for initial approval): A center that performs 50% or more of its transplants in a 12-month period on adult patients must be approved to perform adult transplants in order to be approved to perform pediatric transplants.</li> <li>CMS (for initial approval): A center that performs 50% or more of its transplants in a 12-month period on pediatric patients must be approved to perform pediatric transplants in order to be approved to perform adult transplants.</li> </ul>
	<ul> <li>CMS (for initial approval): A center that performs 50% or more of its transplants on pediatric patients in a 12-month period is not required to meet the clinical experience requirements prior to its request for approval as a pediatric transplant center.</li> </ul>
Caveats	<ul> <li>CMS (for initial approval): A heart/lung transplant center, an intestine transplant center, and a pancreas transplant center are not required to comply with the outcome requirements.</li> </ul>
	<ul> <li>On September 30, 2019, CMS published a final rule rescinding volume requirements and review of post- transplant mortality rates for re-approval of transplant centers.</li> </ul>
QUALITY OF STAFFING	
Professional Competencies, Certification, Specialization	<ul> <li>OPTN: All transplant hospitals and transplant programs must have a transplant program director who is a physician or surgeon and a member of the hospital staff, a qualified primary surgeon, and a primary physician for each organ type.</li> </ul>
	Primary Surgeon and Primary Physician:
	<ul> <li>OPTN: The primary surgeon and primary physician for each organ type must have the following qualifications:</li> <li>The surgeon or physician must have a Doctor of Medicine (M.D), Doctor of Osteopathic Medicine (D.O.), or equivalent degree from another country, with a current license to practice medicine in the hospital's state or invisiding to the surgeon of th</li></ul>
	<ul> <li>The surgeon or physician must be accepted onto the hospital's medical staff and be on site at this hospital;</li> <li>The surgeon or physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education and that the physician is currently a member in good standing of the hospital's medical staff; and</li> <li>The surgeon or physician must be board-certified; the particular certifications vary by organ type.<sup>3</sup></li> </ul>

<sup>3</sup> The bylaws allow for exceptions to current certification if the primary surgeon or physician is ineligible for American Board certification, provide a plan for continuing education that is comparable to American Board maintenance of certification, and provide to OPTN contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital.

- OPTN: The primary surgeon or primary physician must provide an assessment of all of the surgeons and physicians who are involved in the transplant program.
- OPTN: The OPTN bylaws provide details on training pathways for primary surgeons and primary physicians for each organ type.
  - Primary surgeon training pathways:
    - **Kidney, liver, and pancreas:** Complete a formal, two-year surgical transplant fellowship, a clinical experience pathway, or an alternative pathway for predominantly pediatric programs
    - Heart and lung: Must complete at least one of the following:
      - > The formal cardiothoracic surgery residency pathway;
      - > The 12-month transplant fellowship pathway;
      - > The transplant program clinical experience pathway; or
      - > The alternative pathway for predominantly pediatric programs.
  - **Primary physician** training pathways:
    - Kidney and liver: Must complete at least one of the following:
      - $\succ$  The transplant fellowship pathway;
      - The clinical experience pathway;
      - $\succ$  The three-year pediatric fellowship pathway;
      - > The 12-month pediatric transplant fellowship pathway;
      - > The combined pediatric training and experience pathway;
      - > The alternative pathway for predominantly pediatric programs; or
      - > The conditional approval pathway, if the primary transplant physician changes at an approved transplant program.
    - Pancreas, heart and lung: Must complete at least one of the following:
      - $\succ$  The 12-month transplant fellowship pathway;
      - $\succ$  The clinical experience pathway:
      - > The alternative pathway for predominantly pediatric programs; or
      - > The conditional approval pathway, if the primary transplant physician changes at an approved pancreas transplant program.
  - For detailed descriptions of the primary surgeon and primary physician pathways for specific organs, see the following appendices of the OPTN bylaws:
    - Appendix E: Membership and Personnel Requirements for Kidney Transplant Programs
    - Appendix F: Membership and Personnel Requirements for Liver Transplant Programs
    - <u>Appendix G: Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant</u>
       <u>Programs</u>
    - Appendix H: Membership and Personnel Requirements for Heart Transplant Programs
    - Appendix I: Membership and Personnel Requirements for Lung Transplant Programs

#### Other Personnel:

- OPTN: Outlines duties of other key personnel, including the clinical transplant coordinator, financial coordinator, clinical transplant pharmacist, collaboration with medical expert support (anesthesiology; hepatology; histocompatibility and immunogenetics; immunology; infectious disease; nephrology, including dialysis capability; pathology; pediatrics; physical therapy and rehabilitation medicine; and pulmonary medicine, including respiratory therapy support and radiology), professional mental health, and social support staff.
   OPTN: Establishes some specific requirements for certain types of transplant programs, such as kidney and liver
  - OPTN: Establishes some specific requirements for certain types of transplant programs, such as kidney and liver transplant centers that offer a live donor option are required to have an independent living donor advocate and liver transplant centers are required to designate a director of anesthesia for liver transplant surgery.

Staffing to Patient Ratios, By Profession	■ N/A	
Other	<ul> <li>N/A</li> </ul>	
AVAILABILITY		
Available Hours Of Operation	<ul> <li>OPTN: Transplant programs must have transplant surgeons and transplant physicians available 365 days a year, 24 hours a day, 7 days a week to provide program coverage, unless a written explanation is provided that justifies the current level of coverage to the satisfaction of the MPSC.</li> <li>OPTN: A transplant surgeon must be readily available in a timely manner to facilitate organ acceptance, procurement, and transplantation.</li> <li>OPTN: A transplant surgeon or transplant physician may not be on call simultaneously for two transplant programs more than 30 miles apart unless the MPSC has reviewed and approved the circumstances.</li> </ul>	

Other	<ul> <li>OPTN: The program director, in conjunction with the primary surgeon and primary physician, must submit a detailed Program Coverage Plan to the OPTN contractor. The plan must describe how transplant surgeons and physicians who have been credentialed by the transplant hospital to provide transplant services to the program provide continuous medical and surgical coverage.</li> <li>OPTN: Transplant programs must provide patients with a written summary of the Program Coverage Plan when they are placed on the waiting list and when there are any substantial changes in the program or its personnel.</li> <li>OPTN: Unless the MPSC provides an exemption for specific reasons, the primary surgeon or primary physician cannot be designated as the primary surgeon or primary physician at more than one transplant hospital unless there are additional transplant surgeons or transplant physicians at each of those facilities.</li> </ul>
	EQUIPMENT
Availability Of Appropriate Equipment/Ancillary Services	<ul> <li>OPTN: Transplant hospitals must allocate sufficient operating and recovery room resources, intensive care resources, surgical beds, and personnel to the transplant program.</li> <li>OPTN: Transplant centers must have letters of agreement or contracts with an organ procurement organization (OPO) and a written agreement with an OPTN-approved histocompatibility laboratory to perform the tissue typing of recipients and donors. The histocompatibility laboratory must meet the standards for testing as described in <i>Appendix C: Membership Requirements for Histocompatibility Laboratories</i>.</li> <li>OPTN: Transplant programs must have access to large quantities of blood and provide proof of extensive blood bank support.</li> <li>OPTN: Transplant programs must have immediate access to microbiology, clinical chemistry, histocompatibility testing, and radiology services, as well as the necessary resources to monitor immunosuppressive medications.</li> </ul>
Maintenance	<ul> <li>N/A</li> </ul>
Other	• N/A
LICENSING California (CA) Colorado (CO) New Hampshire (NH Pennsylvania (PA) Texas (TX) Utah (UT) Although we reviewed docum found standards relating to tr	STANDARDS FROM SELECTED OTHER STATES THAT DO NOT HAVE A CON PROCESS <sup>4</sup> +) nents and interviewed state personnel for these six states, Pennsylvania was the only state for which we ansplant centers.
	QUALITY MEASURES
Minimum Volume	<ul> <li>PA: Each transplantation program shall perform an adequate number of procedures to maximize quality.</li> </ul>
Outcome Measures	■ N/A
Other	• N/A
Caveats	• N/A
	QUALITY OF STAFFING
Professional Competencies, Certification, Specialization	<ul> <li>PA: Each transplantation center shall have onsite, on a full-time basis, at least one transplantation coordinator certified by the American Board of Transplant Coordinators within two years of obtaining this position.</li> <li>PA: Lung and heart/lung transplantation programs shall have on staff and available a cardiologist and a pulmonologist who are either certified by or who have attained pre-board certification status with the respective appropriate American Board or equivalent Board. Either of these specialists may also serve as the transplant physician.</li> </ul>

<sup>&</sup>lt;sup>4</sup> We identified 15 states that do not have a certificate of need process for the tertiary health services. However, two of the states, Arizona and Minnesota, either had a CON for some other related services or had a process that was not called a CON but would have similar effects. Seven of the states were not comparable to Florida due to factors such as having a small number of teaching hospitals; a significantly different breakdown of citizens on Medicaid, Medicare, or uninsured; a smaller population size; and/or a higher portion of the state that is rural. These seven states were Idaho, Kansas, New Mexico, North Dakota, South Dakota, Wisconsin, and Wyoming. For the remaining six states, we conducted an in-depth review to identify and evaluate any licensing standards for the services considered tertiary in Florida. These six states were California, Colorado, New Hampshire, Pennsylvania, Texas, and Utah.

	•	<ul> <li>PA: Liver transplantation programs shall have on staff and available a gastroenterologist who is either certified by or who has attained pre-board certification status with the American Board of Gastroenterology or an equivalent Board. The gastroenterologist shall have at least two years of experience in hepatology. The gastroenterologist may also serve as the transplant physician. The pathologist shall be specifically trained in liver pathologist may also serve as the transplant physician. The pathology comprised of at least one endocrinologist currently certified by the American Board of Endocrinology or an equivalent Board. If the endocrinologist serves as the transplant physician, then the endocrinologist shall have at least one year of training or two years of experience in the care of transplant patients.</li> <li>PA: Kidney transplantation programs shall have a division of urology comprised of at least one urologist who is either certified by or who has attained pre-board certification status with the American Board of Urology or an equivalent Board. The urologist shall be available to act as a consultant when appropriate for the preoperative, operative, and postoperative surgical evaluation and management of transplant patients and living donors. A kidney transplantation program shall patricipate in and be certified by the Federal End Stage Renal Disease (ESRD) (Medicare) program and as an ESRD center.</li> <li>PA: Those transplantation centers that are exclusively pediatric shall have on staff and available the following specialits who shall be either certified by or how attained pre-board certification status with the appropriate subspecialty board of the American Board of Pediatric pulmonologist, and a pediatric cardiac surgeon; pediatric patients shall have on staff and available the following specialists who shall be either certified by or both, as follows: an anesthesiologist, and a pediatric cardiac surgeon; pediatric patients shall have on staff and available the following p</li></ul>
		sufficient complement to meet nursing care goals, standards of nursing practice, and nursing care needs of pediatric patients; and an occupational therapist who is registered with the American Occupational Therapy
		Association and who has one year of experience in treating pediatric patients. PA: <b>A pediatric program that provides kidney transplantation services to pediatric patients</b> shall have on staff
		and available a urologist who is either certified by or who has attained pre-board certification status with the American Board of Urology or an equivalent Board and who has two years of experience providing urology services to pediatric patients.
Staffing to Patient Ratios, By Profession	•	N/A
Other	•	N/A
		AVAILABILITY
Available Hours of Operation		N/A
Other	•	N/A
		EQUIPMENT
Availability Of Appropriate Equipment/Ancillary Services	•	<ul> <li>PA: For lung and heart/lung transplantation programs, the hospital shall have a cardiac catheterization service that meets all the regulatory requirements for this service. The cardiac catheterization laboratory shall be available to perform these procedures on an emergency basis.</li> <li>PA: Transplantation centers that provide transplantation programs to pediatric patients shall have appropriate equipment available to provide the following services to pediatric patients:</li> <li>Dialysis,</li> <li>Anesthesia,</li> <li>Intensive care, and</li> <li>Operating room.</li> </ul>

Maintenance	•	N/A
Other	•	<ul> <li>PA: For lung and heart/lung transplantation programs, the hospital shall have an open heart surgery program and shall meet all the regulatory requirements for this service.</li> <li>PA: For pancreas transplantation programs in which combined kidney/pancreas transplants or sequential kidney and pancreas or sequential pancreas and kidney transplants are performed, there shall be an active kidney transplantation program.</li> <li>PA: A kidney transplantation program must have, in addition to dialysis facilities for acute hemodialysis, a kidney transplantation program capable of providing peritoneal dialysis.</li> <li>PA: For a pediatric transplantation program, the hospital must have cardiac catheterization and open heart</li> </ul>
		surgical services that meet all of the regulatory requirements for pediatric patients.

Source: OPPAGA review of journal articles; state and federal statutes/laws and rules; and standards from professional organizations, accreditors, and other states.

This page intentionally left blank



OPPAGA provides performance and accountability information about Florida government in several ways.

- <u>Reports</u> deliver program evaluation and policy analysis to assist the Legislature in overseeing government operations, developing policy choices, and making Florida government more efficient and effective.
- Government Program Summaries (GPS), an online encyclopedia, <u>www.oppaga.state.fl.us/government</u>, provides descriptive, evaluative, and performance information on more than 200 Florida state government programs.
- <u>PolicyNotes</u>, an electronic newsletter, delivers brief announcements of research reports, conferences, and other resources of interest for Florida's policy research and program evaluation community.
- Visit OPPAGA's website at <u>www.oppaga.state.fl.us</u>.

OPPAGA supports the Florida Legislature by providing data, evaluative research, and objective analyses that assist legislative budget and policy deliberations. This project was conducted in accordance with applicable evaluation standards. Copies of this report in print or alternate accessible format may be obtained by telephone (850/488-0021), by FAX (850/487-3804), in person, or by mail (OPPAGA Report Production, Claude Pepper Building, Room 312, 111 W. Madison St., Tallahassee, FL 32399-1475).

**OPPAGA website:** <u>www.oppaga.state.fl.us</u> Project supervised by Becky Vickers (850/717-0515)

Project conducted by Teresa Cornacchione, Daphne Holden, and Kim Shafer Laila Racevskis, Staff Director, Health and Human Services Policy Area (850/717-0524) R. Philip Twogood, Coordinator