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The 2020 Florida Statutes

[Title XXIX](#)[PUBLIC HEALTH](#)[Chapter 395](#)[HOSPITAL LICENSING AND REGULATION](#)[View Entire Chapter](#)

395.1055 Rules and enforcement.—

(1) The agency shall adopt rules pursuant to ss. [120.536\(1\)](#) and [120.54](#) to implement the provisions of this part, which shall include reasonable and fair minimum standards for ensuring that:

(a) Sufficient numbers and qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care and safety.

(b) Infection control, housekeeping, sanitary conditions, and medical record procedures that will adequately protect patient care and safety are established and implemented.

(c) A comprehensive emergency management plan is prepared and updated annually. Such standards must be included in the rules adopted by the agency after consulting with the Division of Emergency Management. At a minimum, the rules must provide for plan components that address emergency evacuation transportation; adequate sheltering arrangements; postdisaster activities, including emergency power, food, and water; postdisaster transportation; supplies; staffing; emergency equipment; individual identification of residents and transfer of records, and responding to family inquiries. The comprehensive emergency management plan is subject to review and approval by the local emergency management agency. During its review, the local emergency management agency shall ensure that the following agencies, at a minimum, are given the opportunity to review the plan: the Department of Elderly Affairs, the Department of Health, the Agency for Health Care Administration, and the Division of Emergency Management. Also, appropriate volunteer organizations must be given the opportunity to review the plan. The local emergency management agency shall complete its review within 60 days and either approve the plan or advise the facility of necessary revisions.

(d) Licensed facilities are established, organized, and operated consistent with established standards and rules.

(e) Licensed facility beds conform to minimum space, equipment, and furnishings standards as specified by the department.

¹(f) All hospitals submit such data as necessary to conduct certificate-of-need reviews required under part I of chapter 408. Such data shall include, but shall not be limited to, patient origin data, hospital utilization data, type of service reporting, and facility staffing data. The agency may not collect data that identifies or could disclose the identity of individual patients. The agency shall utilize existing uniform statewide data sources when available and shall minimize reporting costs to hospitals.

(g) Each hospital has a quality improvement program designed according to standards established by their current accrediting organization. This program will enhance quality of care and emphasize quality patient outcomes, corrective action for problems, governing board review, and reporting to the agency of standardized data elements necessary to analyze quality of care outcomes. The agency shall use existing data, when available, and shall not duplicate the efforts of other state agencies in order to obtain such data.

(h) Licensed facilities make available on their Internet websites, and in a hard copy format upon request, a description of and a link to the patient charge and performance outcome data collected from licensed facilities pursuant to s. [408.061](#).

(i) All hospitals providing organ transplantation, neonatal intensive care services, inpatient psychiatric services, inpatient substance abuse services, or comprehensive medical rehabilitation meet the minimum licensure

requirements adopted by the agency. Such licensure requirements must include quality of care, nurse staffing, physician staffing, physical plant, equipment, emergency transportation, and data reporting standards.

(2) Separate standards may be provided for general and specialty hospitals, ambulatory surgical centers, and statutory rural hospitals as defined in s. [395.602](#).

(3) The agency shall adopt rules that establish minimum standards for pediatric patient care in ambulatory surgical centers to ensure the safe and effective delivery of surgical care to children in ambulatory surgical centers. Such standards must include quality of care, nurse staffing, physician staffing, and equipment standards. Ambulatory surgical centers may not provide operative procedures to children under 18 years of age which require a length of stay past midnight until such standards are established by rule.

(4) The agency shall adopt rules with respect to the care and treatment of patients residing in distinct part nursing units of hospitals which are certified for participation in Title XVIII (Medicare) and Title XIX (Medicaid) of the Social Security Act skilled nursing facility program. Such rules shall take into account the types of patients treated in hospital skilled nursing units, including typical patient acuity levels and the average length of stay in such units, and shall be limited to the appropriate portions of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. No. 100-203) (December 22, 1987), Title IV (Medicare, Medicaid, and Other Health-Related Programs), Subtitle C (Nursing Home Reform), as amended. The agency shall require level 2 background screening as specified in s. [408.809](#)(1)(e) pursuant to s. [408.809](#) and chapter 435 for personnel of distinct part nursing units.

(5) The agency shall adopt rules with respect to the care and treatment of clients in intensive residential treatment programs for children and adolescents and with respect to the safe and healthful development, operation, and maintenance of such programs.

(6) The agency shall enforce the provisions of part I of chapter 394, and rules adopted thereunder, with respect to the rights, standards of care, and examination and placement procedures applicable to patients voluntarily or involuntarily admitted to hospitals providing psychiatric observation, evaluation, diagnosis, or treatment.

(7) No rule shall be adopted under this part by the agency which would have the effect of denying a license to a facility required to be licensed under this part, solely by reason of the school or system of practice employed or permitted to be employed by physicians therein, provided that such school or system of practice is recognized by the laws of this state. However, nothing in this subsection shall be construed to limit the powers of the agency to provide and require minimum standards for the maintenance and operation of, and for the treatment of patients in, those licensed facilities which receive federal aid, in order to meet minimum standards related to such matters in such licensed facilities which may now or hereafter be required by appropriate federal officers or agencies in pursuance of federal law or promulgated in pursuance of federal law.

(8) Any licensed facility which is in operation at the time of promulgation of any applicable rules under this part shall be given a reasonable time, under the particular circumstances, but not to exceed 1 year from the date of such promulgation, within which to comply with such rules.

(9) The agency may not adopt any rule governing the design, construction, erection, alteration, modification, repair, or demolition of any public or private hospital, intermediate residential treatment facility, or ambulatory surgical center. It is the intent of the Legislature to preempt that function to the Florida Building Commission and the State Fire Marshal through adoption and maintenance of the Florida Building Code and the Florida Fire Prevention Code. However, the agency shall provide technical assistance to the commission and the State Fire Marshal in updating the construction standards of the Florida Building Code and the Florida Fire Prevention Code which govern hospitals, intermediate residential treatment facilities, and ambulatory surgical centers.

(10) The agency shall establish a pediatric cardiac technical advisory panel, pursuant to s. [20.052](#), to develop procedures and standards for measuring outcomes of pediatric cardiac catheterization programs and pediatric cardiovascular surgery programs.

(a) Members of the panel must have technical expertise in pediatric cardiac medicine, shall serve without compensation, and may be reimbursed for per diem and travel expenses.

(b) Voting members of the panel shall include: 3 at-large members, and 3 alternate at-large members with different program affiliations, including 1 cardiologist who is board certified in caring for adults with congenital heart disease and 2 board-certified pediatric cardiologists, neither of whom may be employed by any of the

hospitals specified in subparagraphs 1.-10. or their affiliates, each of whom is appointed by the Secretary of Health Care Administration, and 10 members, and an alternate for each member, each of whom is a pediatric cardiologist or a pediatric cardiovascular surgeon, each appointed by the chief executive officer of the following hospitals:

1. Johns Hopkins All Children's Hospital in St. Petersburg.
2. Arnold Palmer Hospital for Children in Orlando.
3. Joe DiMaggio Children's Hospital in Hollywood.
4. Nicklaus Children's Hospital in Miami.
5. St. Joseph's Children's Hospital in Tampa.
6. University of Florida Health Shands Hospital in Gainesville.
7. University of Miami Holtz Children's Hospital in Miami.
8. Wolfson Children's Hospital in Jacksonville.
9. Florida Hospital for Children in Orlando.
10. Nemours Children's Hospital in Orlando.

Appointments made under subparagraphs 1.-10. are contingent upon the hospital's compliance with this section and rules adopted thereunder, as determined by the Secretary of Health Care Administration. A member appointed under subparagraphs 1.-10. whose hospital fails to comply with such standards may serve only as a nonvoting member until the hospital complies with such standards. A voting member may serve a maximum of two 2-year terms and may be reappointed to the panel after being retired from the panel for a full 2-year term.

(c) The Secretary of Health Care Administration may appoint nonvoting members to the panel. Nonvoting members may include:

1. The Secretary of Health Care Administration.
2. The Surgeon General.
3. The Deputy Secretary of Children's Medical Services.
4. Any current or past Division Director of Children's Medical Services.
5. A parent of a child with congenital heart disease.
6. An adult with congenital heart disease.
7. A representative from each of the following organizations: the Florida Chapter of the American Academy of Pediatrics, the Florida Chapter of the American College of Cardiology, the Greater Southeast Affiliate of the American Heart Association, the Adult Congenital Heart Association, the March of Dimes, the Florida Association of Children's Hospitals, and the Florida Society of Thoracic and Cardiovascular Surgeons.

(d) The panel shall meet biannually, or more frequently upon the call of the Secretary of Health Care Administration. Such meetings may be conducted telephonically, or by other electronic means.

(e) The duties of the panel include recommending to the agency standards for quality of care, personnel, physical plant, equipment, emergency transportation, and data reporting for hospitals that provide pediatric cardiac services.

(f) Beginning on January 1, 2020, and annually thereafter, the panel shall submit a report to the Governor, the President of the Senate, the Speaker of the House of Representatives, the Secretary of Health Care Administration, and the State Surgeon General. The report must summarize the panel's activities during the preceding fiscal year and include data and performance measures on surgical morbidity and mortality for all pediatric cardiac programs.

(g) Panel members are agents of the state for purposes of s. 768.28 throughout the good faith performance of the duties assigned to them by the Secretary of Health Care Administration.

(11) The Secretary of Health Care Administration shall consult the pediatric cardiac technical advisory panel for an advisory recommendation on any certificate of need applications to establish pediatric cardiac surgical centers.

(12) Based on the recommendations of the pediatric cardiac technical advisory panel, the agency shall adopt rules for pediatric cardiac programs which, at a minimum, include:

- (a) Standards for pediatric cardiac catheterization services and pediatric cardiovascular surgery including quality of care, personnel, physical plant, equipment, emergency transportation, data reporting, and appropriate

operating hours and timeframes for mobilization for emergency procedures.

(b) Outcome standards consistent with nationally established levels of performance in pediatric cardiac programs.

(c) Specific steps to be taken by the agency and licensed facilities when the facilities do not meet the outcome standards within a specified time, including time required for detailed case reviews and the development and implementation of corrective action plans.

(13) A pediatric cardiac program shall:

(a) Have a pediatric cardiology clinic affiliated with a hospital licensed under this chapter.

(b) Have a pediatric cardiac catheterization laboratory and a pediatric cardiovascular surgical program located in the hospital.

(c) Have a risk adjustment surgical procedure protocol following the guidelines established by the Society of Thoracic Surgeons.

(d) Have quality assurance and quality improvement processes in place to enhance clinical operation and patient satisfaction with services.

(e) Participate in the clinical outcome reporting systems operated by the Society of Thoracic Surgeons and the American College of Cardiology.

(14)(a) The Secretary of Health Care Administration may request announced or unannounced site visits to any existing pediatric cardiac surgical center or facility seeking licensure as a pediatric cardiac surgical center through the certificate of need process, to ensure compliance with this section and rules adopted hereunder.

(b) At the request of the Secretary of Health Care Administration, the pediatric cardiac technical advisory panel shall recommend in-state physician experts to conduct an onsite visit. The Secretary may also appoint up to two out-of-state physician experts.

(c) A site visit team shall conduct an onsite inspection of the designated hospital's pediatric medical and surgical programs, and each member shall submit a written report of his or her findings to the panel. The panel shall discuss the written reports and present an advisory opinion to the Secretary of Health Care Administration which includes recommendations and any suggested actions for correction.

(d) Each onsite inspection must include all of the following:

1. An inspection of the program's physical facilities, clinics, and laboratories.

2. Interviews with support staff and hospital administrators.

3. A review of:

a. Randomly selected medical records and reports, including, but not limited to, advanced cardiac imaging, computed tomography, magnetic resonance imaging, cardiac ultrasound, cardiac catheterization, and surgical operative notes.

b. The program's clinical outcome data submitted to the Society of Thoracic Surgeons and the American College of Cardiology pursuant to s. 408.05(3)(l).

c. Mortality reports from cardiac-related deaths that occurred in the previous year.

d. Program volume data from the preceding year for interventional and electrophysiology catheterizations and surgical procedures.

(15) The Surgeon General shall provide quarterly reports to the Secretary of Health Care Administration consisting of data from the Children's Medical Services' critical congenital heart disease screening program for review by the advisory panel.

(16) Each provider of diagnostic cardiac catheterization services shall comply with rules adopted by the agency which establish licensure standards governing the operation of adult inpatient diagnostic cardiac catheterization programs. The rules must ensure that such programs:

(a) Comply with the most recent guidelines of the American College of Cardiology and American Heart Association Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories.

(b) Perform only adult inpatient diagnostic cardiac catheterization services and will not provide therapeutic cardiac catheterization or any other cardiology services.

(c) Maintain sufficient appropriate equipment and health care personnel to ensure quality and safety.

(d) Maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.

(e) Demonstrate a plan to provide services to Medicaid and charity care patients.

(17) Each provider of adult cardiovascular services or operator of a burn unit shall comply with rules adopted by the agency which establish licensure standards that govern the provision of adult cardiovascular services or the operation of a burn unit, as applicable. At a minimum, such rules must address staffing, equipment, physical plant, operating protocols, the provision of services to Medicaid and charity care patients, accreditation, licensure periods and fees, and enforcement of minimum standards.

(18) In establishing rules for adult cardiovascular services, the agency shall include provisions that allow for:

(a) The establishment of two hospital program licensure levels, a Level I program that authorizes the performance of adult percutaneous cardiac intervention without onsite cardiac surgery and a Level II program that authorizes the performance of percutaneous cardiac intervention with onsite cardiac surgery.

(b)1. For a hospital seeking a Level I program, demonstration that, for the most recent 12-month period as reported to the agency, the hospital has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or, for the most recent 12-month period, has discharged or transferred at least 300 patients with the principal diagnosis of ischemic heart disease and that it has a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes.

2.a. A hospital located more than 100 road miles from the closest Level II adult cardiovascular services program is not required to meet the diagnostic cardiac catheterization volume and ischemic heart disease diagnosis volume requirements in subparagraph 1. if the hospital demonstrates that it has, for the most recent 12-month period as reported to the agency, provided a minimum of 100 adult inpatient and outpatient diagnostic cardiac catheterizations or that, for the most recent 12-month period, it has discharged or transferred at least 300 patients with the principal diagnosis of ischemic heart disease.

b. A hospital located more than 100 road miles from the closest Level II adult cardiovascular services program does not need to meet the 60-minute transfer time protocol requirement in subparagraph 1. if the hospital demonstrates that it has a formalized, written transfer agreement with a hospital that has a Level II program. The agreement must include written transport protocols to ensure the safe and efficient transfer of a patient, taking into consideration the patient's clinical and physical characteristics, road and weather conditions, and viability of ground and air ambulance service to transfer the patient.

3. At a minimum, the rules for adult cardiovascular services must require nursing and technical staff to have demonstrated experience in handling acutely ill patients requiring intervention, based on the staff member's previous experience in dedicated cardiac interventional laboratories or surgical centers. If a staff member's previous experience is in a dedicated cardiac interventional laboratory at a hospital that does not have an approved adult open heart surgery program, the staff member's previous experience qualifies only if, at the time the staff member acquired his or her experience, the dedicated cardiac interventional laboratory:

- a. Had an annual volume of 500 or more percutaneous cardiac intervention procedures.
- b. Achieved a demonstrated success rate of 95 percent or greater for percutaneous cardiac intervention procedures.
- c. Experienced a complication rate of less than 5 percent for percutaneous cardiac intervention procedures.
- d. Performed diverse cardiac procedures, including, but not limited to, balloon angioplasty and stenting, rotational atherectomy, cutting balloon atheroma remodeling, and procedures relating to left ventricular support capability.

(c) For a hospital seeking a Level II program, demonstration that, for the most recent 12-month period as reported to the agency, the hospital has performed a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic catheterizations, or, for the most recent 12-month period, has discharged at least 800 patients with the principal diagnosis of ischemic heart disease.

(d) Compliance with the most recent guidelines of the American College of Cardiology and the American Heart Association guidelines for staffing, physician training and experience, operating procedures, equipment, physical

plant, and patient selection criteria, to ensure patient quality and safety.

(e) The establishment of appropriate hours of operation and protocols to ensure availability and timely referral in the event of emergencies.

(f) The demonstration of a plan to provide services to Medicaid and charity care patients.

(g) For a hospital licensed for adult diagnostic cardiac catheterization that provides Level I or Level II adult cardiovascular services, demonstration that the hospital is participating in the American College of Cardiology's National Cardiovascular Data Registry or the American Heart Association's Get with the Guidelines-Coronary Artery Disease registry and documentation of an ongoing quality improvement plan ensuring that the licensed cardiac program meets or exceeds national quality and outcome benchmarks reported by the registry in which the hospital participates. A hospital licensed for Level II adult cardiovascular services must also participate in the clinical outcome reporting systems operated by the Society for Thoracic Surgeons.

(19) The agency may adopt rules to administer the requirements of part II of chapter 408.

History.—ss. 26, 30, ch. 82-182; s. 5, ch. 83-244; ss. 40, 49, ch. 83-334; s. 41, ch. 87-92; s. 27, ch. 90-344; ss. 27, 98, ch. 92-289; s. 28, ch. 93-129; s. 24, ch. 93-211; s. 1, ch. 94-317; s. 31, ch. 96-169; s. 6, ch. 98-89; s. 99, ch. 98-200; s. 7, ch. 98-303; s. 104, ch. 99-8; ss. 22, 135, ch. 2000-141; ss. 34, 37, ch. 2001-186; ss. 3, 6, ch. 2001-372; s. 6, ch. 2004-297; s. 47, ch. 2007-230; s. 271, ch. 2011-142; s. 1, ch. 2017-151; s. 32, ch. 2018-24; s. 60, ch. 2019-3; ss. 2, 3, ch. 2019-136; s. 7, ch. 2019-138; s. 2, ch. 2020-134; s. 4, ch. 2020-156.

¹**Note.**—Section 3, ch. 2019-136, deleted paragraph (1)(f), effective July 1, 2021.

Note.—Former s. 395.005.