59A-3.246 Licensed Programs.

(1) Adult Diagnostic Cardiac Catheterization Program. All licensed hospitals that establish adult diagnostic cardiac catheterization laboratory services under section 395.1055 408.0361, F.S., shall operate in compliance with the most recent guidelines of the American College of Cardiology/American Heart Association regarding the operation of diagnostic cardiac catheterization laboratories. Hospitals are considered to be in compliance with American College of Cardiology/American Heart Association guidelines when they adhere to standards regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety. The applicable guideline is the 2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update. J Am Coll Cardiol 2012; 59:2221–305 (2012 ACC/SCAI Guidelines) which is hereby incorporated by reference and effective at adoption. The copyrighted material is available for public inspection at the Agency for Health Care Administration, Hospital and Outpatient Services Unit, 2727 Mahan Drive, Tallahassee, FL 32308 and the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee, FL 32399. A copy may be obtained from Elsevier Inc, Reprint Department by email at reprints@elsevier.com or online at https://www.sciencedirect.com/.-Aspects of the guideline related to pediatric services or outpatient cardiac catheterization in freestanding non-hospital settings are not applicable to this rule. All such licensed hospitals shall have a department, service or other similarly titled unit which shall be organized, directed and staffed, and integrated with other units and departments of the hospitals in a manner designed to assure the provision of quality patient care.

(a) Licensure.

1. A licensee of a hospital may apply for licensure to provide a license for an adult diagnostic cardiac catheterization laboratory services program by submitting a hospital licensure application as specified in subsection 59A-3.066(2), F.A.C., indicating the addition of an adult diagnostic cardiac catheterization laboratory services program, and attaching License Application Adult Inpatient Diagnostic Cardiac Catheterization Services, AHCA Form 3130-5003, January 2018, incorporated herein by reference and available at

http://www.flrules.org/Gateway/reference.asp?No=Ref-09635. This form is Both of these forms are available at: http://ahca.myflorida.com/MCHQ/HQALicensureForms/index.shtml. The license application form must be signed by the hospital’s Chief Executive Officer or the authorized representative, confirming the hospital’s intent and
ability to comply with section 395.1055 408.0361, F.S.

2. An authorized representative of hospitals with adult diagnostic cardiac catheterization services programs must renew this licensed program their licenses at the time of the hospital licensure renewal, by completing the subsection entitled Adult Cardiovascular Services on the hospital licensure application specified in subsection 59A-3.066(2), F.A.C, providing the information in section 408.0361(1), F.S. Failure to renew the hospital’s license or failure to complete the subsection entitled Adult Cardiovascular Services, thereby not attesting to meeting the requirements, update the information in section 408.0361(1), F.S., shall cause the licensed program license to expire.

3. Hospitals licensed to provide adult diagnostic cardiac catheterization services may not provide services to patients who are under 18 years of age.

(b) Definitions. The following definitions shall apply specifically to all adult diagnostic cardiac catheterization programs, as described in this subsection:

1. “Diagnostic Cardiac Catheterization” means a procedure requiring the passage of a catheter into one or more cardiac chambers of the left and right heart, with or without coronary arteriograms, for the purpose of diagnosing congenital or acquired cardiovascular diseases, or for determining measurement of blood pressure flow; and also includes the selective catheterization of the coronary ostia with injection of contrast medium into the coronary arteries.

2. “Adult” means a person fifteen years of age or older.

(b)(e) Therapeutic Procedures. An adult diagnostic cardiac catheterization program established pursuant to section 395.1055 408.0361, F.S., shall not provide therapeutic services, such as percutaneous coronary intervention or stent insertion, intended to treat an identified condition or the administering of intra-coronary drugs, such as thrombolytic agents.

(c)(d) Diagnostic Procedures. Procedures performed in the adult diagnostic cardiac catheterization laboratory shall include the following:

1. Left heart catheterization with coronary angiography and left ventriculography;
2. Right heart catheterization;
3. Hemodynamic monitoring line insertion;
4. Aortogram;
5. Emergency temporary pacemaker insertion;
6. Myocardial biopsy;
7. Intra-coronary ultrasound (CVIS);
8. Fluoroscopy; and
9. Hemodynamic stress testing.

(d) Support Equipment. A crash cart containing the necessary medication and equipment for ventilatory support shall be located in each cardiac catheterization procedure room. A listing of all crash cart contents shall be readily available. At the beginning of each shift, the crash cart shall be checked for intact lock; the defibrillator and corresponding equipment shall be checked for function and operational capacity. A log shall be maintained indicating review.

(e) Radiographic Cardiac Imaging Systems. A quality improvement program for radiographic imaging systems shall include patient and operator safety, measures of image quality, dynamic range, and modulation transfer function. Documentation indicating the manner in which this requirement will be met shall be available for the Agency’s review.

(f) Physical Plant Requirements. The Florida Building Code contains the physical plant requirements for cardiac catheterization facilities.

(g) Personnel Requirements. There shall be trained personnel available to meet the needs of the patient. At a minimum, a team involved in cardiac catheterization shall consist of a physician, one registered nurse, and one technician.

(h) Quality Improvement Program. A quality improvement program for the adult diagnostic cardiac catheterization program laboratory shall include an assessment of proficiency in diagnostic coronary procedures, as described in the 2012 ACC/SCAI Guidelines. Essential data elements for the quality improvement program include the individual physician procedural volume and major complication rate; the institutional procedural complication rate; patient clinical and demographic information; verification of data accuracy; and procedures for patient, physician and staff confidentiality. Documentation indicating the manner in which this requirement will be met shall be available for the Agency’s review.

(i) Emergency Services.

1. All hospitals providing adult diagnostic cardiac catheterization program services, except hospitals licensed as a Level II adult cardiovascular services provider, shall have written transfer agreements developed specifically for
diagnostic cardiac catheterization patients with one or more hospitals licensed as a Level II adult cardiovascular services provider. Written agreements must be in place with a ground ambulance service capable of advanced life support and Intra-Aortic Balloon Pump (IABP) transfer. Agreements may include air ambulance service, but must have ground ambulance backup. A transport vehicle must be on-site to begin transport within 30 minutes of a request and have a transfer time within 60 minutes. Transfer time is defined as the number of minutes between the recognition of an emergency as noted in the hospital’s internal log and the patient’s arrival at the receiving hospital. Transfer and transport agreements must be reviewed and tested once every 6 months, with appropriate documentation maintained, including the hospital’s internal log or emergency medical services data.

2. Patients at high risk for diagnostic catheterization complications shall be referred for diagnostic catheterization services to hospitals licensed as a Level II adult cardiovascular services provider. Hospitals not licensed as a Level II adult cardiovascular services provider must have documented patient selection and exclusion criteria and provision for identification of emergency situations requiring transfer to a hospital with a Level II adult cardiovascular services program. Documentation indicating the manner in which this requirement will be met shall be available for the Agency’s review.


1. Each provider of adult diagnostic cardiac catheterization services shall maintain a policy and procedure manual, available for review by the Agency, which documents a plan to provide services to Medicaid and charity care patients.

2. The policy and procedure manual shall document specific outreach programs directed at Medicaid and charity care patients for adult diagnostic cardiac catheterization services.

(l) Enforcement. Enforcement of these rules shall follow procedures established in rule 59A-3.253, F.A.C.

(k)(m) In case of conflict between the provisions of this rule and the 2012 ACC/SCAI Guidelines, the provisions of this part shall prevail.

(2) Level I Adult Cardiovascular Services.

(a) Licensure.

1. A licensee of a hospital may apply for licensure to provide a license for a Level I adult cardiovascular services program by submitting a hospital licensure application as specified in subsection 59A-3.066(2), F.A.C., indicating the addition of a Level I adult cardiovascular diagnostic cardiac catheterization services program, and

This form is Both of these forms are available at:

http://ahca.myflorida.com/MCHQ/HQALicensureForms/index.shtml. The hospital licensure application and AHCA Form 3130-8010, January 2018, must be signed by the hospital’s Chief Executive Officer or the authorized representative, confirming that for the most recent 12-month period, 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 a minimum of 300 patients with the principal diagnosis of ischemic heart disease (defined by ICD-10-CM codes I20-I25).

a. Reportable cardiac catheterization procedures are defined as single sessions with a patient in the hospital’s cardiac catheterization procedure room(s), irrespective of the number of specific procedures performed during the session.

b. Reportable cardiac catheterization procedures shall be limited to those provided and billed for by the Level I licensure applicant and shall not include procedures performed at the hospital by physicians who have entered into block leases or joint venture agreements with the applicant.

2. The request shall confirm the hospital’s intent and ability to comply with the American College of Cardiology and the American Heart Association guidelines for the performance of adult percutaneous cardiac intervention without onsite cardiac surgery. The following publications, herein incorporated by reference and effective at adoption, are applicable to this section and will be referred to as the Guidelines:

a. Bashore TM, Balter S, Barac A, Byrne JG, Cavendish JJ, Chambers CE, Hermiller JB Jr, Kinlay S, Landzberg JS, Laskey WK, McKay CR, Miller JM, Moliterno DJ, Moore JWM, Oliver-McNeil SM, Popma JJ, Tommaso CL. 2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update. J Am Coll Cardiol 2012;59:2221–305. The copyrighted material is available for public inspection at the Agency for Health Care Administration, Hospital and Outpatient Services Unit, 2727 Mahan Drive, Tallahassee, FL 32308 and the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee, FL 32399. A copy may be obtained from Elsevier Inc, Reprint Department by email at reprints@elsevier.com or online at https://www.sciencedirect.com/.


2012 ACC/SCAI Guidelines and the 2014 Update on Percutaneous Coronary Intervention Without Onsite Surgical Backup: Dehmer et al. SCAI/ACC/AHA Expert Consensus Document, Circulation. 2014; 129:2610–2626 (2014 SCAI/ACC/AHA Update), which is hereby incorporated by reference and effective at adoption. The copyrighted material is available for public inspection at the Agency for Health Care Administration, Hospital and Outpatient Services Unit, 2727 Mahan Drive, Tallahassee, FL 32308 and the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee, FL 32399. A copy may be obtained from Elsevier Inc, Reprint Department by email at reprints@elsevier.com or online at https://www.sciencedirect.com/.

3. Requests shall confirm the hospital’s intent and ability to comply with the guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.

43. The request shall confirm the hospital’s intent and ability to comply with physical plant requirements regarding cardiac catheterization laboratories and operating rooms found in the Florida Building Code.
54. The request shall confirm the hospital has one or more written transfer agreements with hospitals that operate a Level II adult cardiovascular services program, as specified in paragraph (2)(c), below.

55. All providers of Level I adult cardiovascular services programs shall operate in compliance with subsection 59A-3.246(1), F.A.C., and the 2012 ACC/SCAI Guidelines and the 2014 SCAI/ACC/AHA Update regarding the operation of adult diagnostic cardiac catheterization laboratories and the provision of percutaneous coronary intervention. Level I adult cardiovascular services may be provided to adult patients. Level I adult cardiovascular services may be provided to patients 15 to 17 years of age provided the physician in charge of the procedure is a pediatric cardiologist or an adult cardiologist with specialized training in adult congenital heart disease.

56. The applicable guidelines are the 2012 ACC/SCAI Guidelines and the 2014 SCAI/ACC/AHA Update. Aspects of the Guidelines guideline related to pediatric services or outpatient cardiac catheterization in freestanding non-hospital settings are not applicable to this rule. Aspects of the Guidelines guideline related to the provision of elective percutaneous coronary intervention only in hospitals authorized to provide open heart surgery are not applicable to this rule.

57. Hospitals are considered to be in compliance with the 2012 ACC/SCAI Guidelines and the 2014 SCAI/ACC/AHA Update when they adhere to standards regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety. Hospitals must also document an ongoing quality improvement plan to ensure that the cardiac catheterization program and the percutaneous coronary intervention program meet or exceed national quality and outcome benchmarks reported by the American College of Cardiology-National Cardiovascular Data Registry. Hospitals providing Level I adult cardiovascular services must have available upon request of the Agency the number of diagnostic and therapeutic adult cardiac catheterizations performed during the most recent 12-month period.

58. Level I adult cardiovascular service providers shall report to the American College of Cardiology-National Cardiovascular Data Registry in accordance with the timetables and procedures established by the Registry. All data shall be reported using the specific data elements, definitions and transmission format as set forth by the American College of Cardiology-National Cardiovascular Data Registry. By submitting data to the American College of Cardiology-National Cardiovascular Data Registry in the manner set forth herein, each hospital shall be deemed to have certified that the data submitted for each time period is accurate, complete and verifiable. The licensee of each hospital licensed to provide Level I adult cardiovascular services shall:
a. Execute the required agreements with the American College of Cardiology-National Cardiovascular Data Registry to participate in the data registry;

b. Stay current with the payment of all fees necessary to continue participation in the American College of Cardiology-National Cardiovascular Data Registry;

c. Release the data reported by the American College of Cardiology-National Cardiovascular Data Registry to the Agency;

d. Use the American College of Cardiology-National Cardiovascular Data Registry data sets and use software approved by the American College of Cardiology for data reporting;

e. Ensure that software formats are established and maintained in a manner that meets American College of Cardiology-National Cardiovascular Data Registry transmission specifications and encryption requirements. If necessary, each hospital shall contract with a vendor approved by the American College of Cardiology-National Cardiovascular Data Registry for software and hardware required for data collection and reporting;

f. Implement procedures to transmit data via a secure website or other means necessary to protect patient privacy to the extent required by the American College of Cardiology-National Cardiovascular Data Registry;

g. Ensure that all appropriate data is submitted on every patient that receives medical care and is eligible for inclusion in the American College of Cardiology-National Cardiovascular Data Registry;

h. Maintain an updated and current institutional profile with the American College of Cardiology-National Cardiovascular Data Registry;

i. Ensure that data collection and reporting will only be performed by trained, competent staff and that such staff shall adhere to the American College of Cardiology-National Cardiovascular Data Registry standards;

j. Submit corrections to any data submitted to the American College of Cardiology-National Cardiovascular Data Registry as discovered by the hospital or by the American College of Cardiology-National Cardiovascular Data Registry. Such corrections shall be submitted within thirty days of discovery of the need for a correction or within such other time frame as set forth by the American College of Cardiology-National Cardiovascular Data Registry. Data submitted must be at a level that the American College of Cardiology-National Cardiovascular Data Registry will include the data in national benchmark reporting; and

k. Designate an American College of Cardiology-National Cardiovascular Data Registry site manager that will serve as a primary contact between the hospital and the American College of Cardiology-National Cardiovascular
Data Registry with regard to data reporting.

9. Notwithstanding guidelines to the contrary in the 2012 ACC/SCAI Guidelines and the 2014 SCAI/ACC/AHA Update all providers of Level I adult cardiovascular services programs may provide emergency and elective percutaneous coronary intervention procedures. Aspects of the guidelines related to pediatric services or outpatient cardiac catheterization in freestanding non-hospital settings are not applicable to this rule.

10. Hospitals with Level I adult cardiovascular services programs are prohibited from providing the following procedures:
   a. Any therapeutic procedure requiring transseptal puncture,
   b. Any lead extraction for a pacemaker, biventricular pacer or implanted cardioverter defibrillator.
   c. Any rotational or other atherectomy devices, or
   d. Treatment of chronic total occlusions.

11. An authorized representative of hospitals with Level I adult cardiovascular services must renew this licensed program at the time of the hospital licensure renewal by completing the subsection entitled Adult Cardiovascular Services on the hospital licensure application specified in subsection 59A-3.066(2), F.A.C. Hospitals with Level I adult cardiovascular services programs must renew their licenses at the time of the hospital licensure renewal, providing the information in two through five above. Failure to renew the hospital’s license or failure to complete the subsection entitled Adult Cardiovascular Services, thereby attesting to meeting at least the minimum requirements, update the information in two through five above shall cause the licensed program license to expire.

   (b) Staffing. All staff participating as members of the catheterization team, including physicians, nurses, and technical catheterization laboratory staff shall maintain Advanced Cardiac Life Support certification, and must participate in a 24-hour-per-day, 365 day-per-year call schedule.

   1. At initial licensure, each cardiologist shall be an experienced physician who has performed a minimum of 50 interventional cardiology procedures, including at least 11 primary cardiology interventional procedures, exclusive of fellowship training, and within the previous 12 months from the date of the Level I adult cardiovascular licensure application.

   2. At licensure renewal, interventional cardiologists shall perform a minimum of 50 interventional cardiology procedures per year averaged over a 2-year period or be confirmed by the review process described in subparagraph 59A-3.246(3)(b)3., F.A.C.
3. The providers of Level I adult cardiovascular services shall develop internal review processes to assess interventional cardiologists performing less than the required annual volume. Low volume operators must be evaluated and confirmed by an independent institutional committee consisting of physicians and other healthcare personnel as selected by the hospital, or an external review organization. Factors that shall be considered in assessing operator competence include operator volume, lifetime experience, institutional volume, individual operator’s other cardiovascular interventions and quality assessment of the operator’s ongoing performance.

4. Technical catheterization laboratory staff shall be credentialed as Registered Cardiovascular Invasive Specialists or shall complete a hospital based education and training program at a hospital providing Level I or Level II adult cardiovascular services. This training program shall include a minimum of 500 hours proctored clinical experience, including participation in a minimum of 120 interventional cardiology procedures and didactic education components of hemodynamics, pharmacology, arrhythmia recognition, radiation safety, and interventional equipment.

5. Coronary care unit nursing staff must be trained and experienced with invasive hemodynamic monitoring, operation of temporary pacemaker, management of Intra-Aortic Balloon Pump (IABP), management of in-dwelling arterial/venous sheaths and identifying potential complications such as abrupt closure, recurrent ischemia and access site complications.

(c) Emergency Services. All providers of Level I adult cardiovascular services shall have written transfer agreements developed specifically for emergency transfer of interventional cardiology patients with one or more hospitals licensed as a Level II adult cardiovascular services provider. Written agreements must be in place with a ground ambulance service capable of advanced life support and IABP transfer. Agreements may include air ambulance service, but must have ground ambulance backup. A transport vehicle must be on-site to begin transport within 30 minutes of a request and have a transfer time within 60 minutes. Transfer time is defined as the number of minutes between the recognition of an emergency as noted in the hospital’s internal log and the patient’s arrival at the receiving hospital. Transfer and transport agreements must be reviewed and tested once every 6 months, with appropriate documentation maintained, including the hospital’s internal log or emergency medical services data.

(d) Policy and Procedure Manual for Medicaid and Charity Care.

1. Each provider of Level I adult cardiovascular services shall maintain a policy and procedure manual, available for review by the Agency, which documents a plan to provide services to Medicaid and charity care
patients.

2. The policy and procedure manual shall document specific outreach programs directed at Medicaid and charity care patients for Level I adult cardiovascular services.

(e) Physical Plant Requirements. Each provider of Level I adult cardiovascular services must comply with The Florida Building Code regarding contains the physical plant requirements for cardiac catheterization laboratories operated by a licensed hospital.

(f) Enforcement.

1. Enforcement of these rules shall follow procedures established in rule 59A-3.253, F.A.C.

2. Unless in the view of the Agency there is a threat to the health, safety or welfare of patients, Level I adult cardiovascular services programs that fail to meet the provisions of this rule shall be given 15 days to develop a plan of correction that must be accepted by the Agency.

3. Failure of the hospital with a Level I adult cardiovascular services program to make improvements specified in the plan of correction shall result in the revocation of the program license. The hospital may offer evidence of mitigation and such evidence could result in a lesser sanction.

(f)(g) In case of conflict between the provisions of this rule and the guidelines in the 2012 ACC/SCAI Guidelines, and the 2014 SCAI/ACC/AHA Update the provisions of this part shall prevail.

(3) Level II Adult Cardiovascular Services.

(a) Licensure.

1. A licensee of a hospital may apply for licensure to provide a license for a Level II adult cardiovascular services program by submitting a hospital licensure application as specified in subsection 59A-3.066(2), F.A.C., indicating the addition of a Level II adult cardiovascular cardiac catheterization services program, and attaching License Application Level II Adult Cardiovascular Services, AHCA Form 3130-8011, January 2018, incorporated herein by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-09637. This form is Both of these forms are available at: http://ahca.myflorida.com/MCHQ/HQALicensureForms/index.shtml. The hospital licensure application and AHCA Form 3130-8011, January 2018, and must be signed by the hospital’s Chief Executive Officer or the authorized representative, confirming that for the most recent 12-month period, the hospital has provided a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic cardiac catheterizations, or, for the most recent 12-month period, has discharged at least 800
patients with the principal diagnosis of ischemic heart disease (defined by ICD-10-CM codes I20-I25). Reportable cardiac catheterization procedures shall be limited to those provided and billed for by the Level II licensure applicant and shall not include procedures performed at the hospital by physicians who have entered into block leases or joint venture agreements with the applicant.

2. The request shall confirm to the hospital’s intent and ability to comply with applicable guidelines in the 2012 ACC/SCAI Guidelines and the 2014 SCAI/ACC/AHA Update including guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.

3. The request shall confirm to the hospital’s intent and ability to comply with physical plant requirements regarding cardiac catheterization laboratories and operating rooms found in the Florida Building Code.

4. All providers of Level II adult cardiovascular services programs shall operate in compliance with subsections (1) and (2) of this rule and the applicable Guidelines of the American College of Cardiology/American Heart Association regarding the operation of diagnostic cardiac catheterization laboratories, the provision of percutaneous coronary intervention and the provision of coronary artery bypass graft surgery. Level II adult cardiovascular services may be provided to adult patients. Level II adult cardiovascular services may be provided to patients 15 to 17 years of age provided the physician in charge of the procedure is a pediatric cardiologist or an adult cardiologist with specialized training in adult congenital heart disease.

a. The applicable guidelines are the 2012 ACC/SCAI Guidelines and the 2014 SCAI/ACC/AHA Update; and

b. Aspects of the Guidelines related to pediatric services or outpatient cardiac catheterization in freestanding non-hospital settings are not applicable to this rule.

5. Hospitals are considered to be in compliance with the guidelines in the 2012 ACC/SCAI Guidelines and the 2014 SCAI/ACC/AHA Update when they adhere to standards regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety. Hospitals must also document an ongoing quality improvement plan to ensure that the cardiac catheterization program, the percutaneous coronary intervention program and the cardiac surgical program meet or exceed national quality and outcome benchmarks reported by the American College of Cardiology-National Cardiovascular Data Registry and the Society of Thoracic Surgeons. Hospitals providing Level II adult cardiovascular services must have available upon request of the Agency the number of diagnostic and therapeutic adult cardiac catheterizations.
performed during the most recent 12-month period.

6. In addition to the requirements set forth in subparagraph (2)(a)(8), (2)(a)(7) of this rule, each hospital licensed to provide Level II adult cardiovascular services programs shall participate in the Society of Thoracic Surgeons National Database. By submitting data to the Society of Thoracic Surgeons National Database and the American College of Cardiology National Cardiovascular Data Registry in the manner set forth herein, each hospital shall be deemed to have certified that the data submitted for each time period is accurate, complete and verifiable. The licensee of each hospital licensed to provide Level II adult cardiovascular services shall:

a. Report to the Society of Thoracic Surgeons National Database in accordance with the timetables and procedures established by the Database. All data shall be reported using the specific data elements, definitions and transmission format as set forth by the Society of Thoracic Surgeons;

b. Stay current with the payment of all fees necessary to continue participation in the Society of Thoracic Surgeons National Database;

c. Release the data reported by the Society of Thoracic Surgeons National Database to the Agency;

d. Use the Society of Thoracic Surgeons National Database and use software approved by the Society of Thoracic Surgeons for data reporting;

e. Ensure that software formats are established and maintained in a manner that meets Society of Thoracic Surgeons transmission specifications and encryption requirements. If necessary, each hospital shall contract with a vendor approved by the Society of Thoracic Surgeons National Database for software and hardware required for data collection and reporting;

f. Implement procedures to transmit data via a secure website or other means necessary to protect patient privacy. To the extent required by the Society of Thoracic Surgeons National Database;

g. Ensure that all appropriate data is submitted on every patient who receives medical care and is eligible for inclusion in the Society of Thoracic Surgeons National Database;

h. Each hospital licensed to provide Level II adult cardiovascular services shall maintain an updated and current institutional profile with the Society of Thoracic Surgeons National Database;

i. Each hospital licensed to provide Level II adult cardiovascular services shall ensure that data collection and reporting will only be performed by trained, competent staff and that such staff shall adhere to Society of Thoracic Surgeons National Database standards.
j. Submit corrections to any data submitted to the Society of Thoracic Surgeons National Database as discovered by the hospital or by the Society of Thoracic Surgeons National Database. Such corrections shall be submitted within thirty days of discovery of the need for a correction or within such other time frame as set forth by the Society of Thoracic Surgeons National Database. Data submitted must be at a level that the Society of Thoracic Surgeons National Database will include the data in national benchmark reporting; and

k. Designate a Society of Thoracic Surgeons National Database site manager that will serve as a primary contact between the hospital and the Society of Thoracic Surgeons National Database with regard to data reporting.

67. An authorized representative of hospitals with Level II adult cardiovascular services must renew this licensed program at the time of the hospital licensure renewal by completing the subsection entitled Adult Cardiovascular Services on the hospital licensure application specified in subsection 59A-3.066(2), F.A.C. Hospitals with Level II adult cardiovascular services programs must renew their licenses at the time of the hospital licensure renewal, providing the information in two through four above. Failure to renew the hospital’s license or failure to complete the subsection entitled Adult Cardiovascular Services, thereby attesting to meeting at least the minimum requirements, update the information in two through four above shall cause the licensed program license to expire.

(b) Staffing. All staff participating as members of the catheterization team, including physicians, nurses, and technical catheterization laboratory staff shall maintain Advanced Cardiac Life Support certification, and must participate in a 24-hour-per-day, 365 day-per-year call schedule.

1. Each cardiac surgeon shall be Board certified.
   a. New surgeons shall be Board certified within 4 years after completion of their fellowship.
   b. Experienced surgeons with greater than 10 years experience shall document that their training and experience preceded the availability of Board certification.

2. All interventional At initial licensure and licensure renewal, interventional cardiologists shall perform a minimum of 50 coronary interventional procedures per year averaged over a 2-year period which includes at least 11 primary cardiology interventional procedures per year or be confirmed by an internal the review process described in this subsection in subparagraph 59A-3.246(4)(b)3., F.A.C.

3. The providers of Level II adult cardiovascular services shall develop internal review processes to assess interventional cardiologists performing less than the required annual volume. Low volume operators must be evaluated and confirmed by an independent institutional committee consisting of physicians and other healthcare
personnel as selected by the hospital, or an external review organization. Factors that shall be considered in assessing operator competence include operator volume, lifetime experience, institutional volume, individual operator’s other cardiovascular interventions and quality assessment of the operator’s ongoing performance.

4. Technical catheterization laboratory staff shall be credentialed as Registered Cardiovascular Invasive Specialists Specialist or shall complete a hospital based education and training program at a hospital providing Level I or Level II adult cardiovascular services. This training program shall include a minimum of 500 hours proctored clinical experience, including participation in a minimum of 120 interventional cardiology procedures and didactic education components of hemodynamics, pharmacology, arrhythmia recognition, radiation safety, and interventional equipment.

5. Coronary care unit nursing staff must be trained and experienced with invasive hemodynamic monitoring, operation of temporary pacemaker, management of IABP, management of in-dwelling arterial/venous sheaths and identifying potential complications such as abrupt closure, recurrent ischemia and access site complications.

(c) Policy and Procedure Manual for Medicaid and Charity Care.

1. Each provider of Level II adult cardiovascular services shall maintain a policy and procedure manual, available for review by the Agency, which documents a plan to provide services to Medicaid and charity care patients.

2. The policy and procedure manual shall document specific outreach programs directed at Medicaid and charity care patients for Level II adult cardiovascular services.

(d) Physical Plant Requirements. Each provider of Level II adult cardiovascular services must comply with The Florida Building Code regarding contains the physical plant requirements for cardiac catheterization laboratories and operating rooms for cardiac surgery operated by a licensed hospital.

(e) Enforcement.

1. Enforcement of these rules shall follow procedures established in rule 59A-3.253, F.A.C.

2. Unless in the view of the Agency there is a threat to the health, safety or welfare of patients, Level II adult cardiovascular services programs that fail to meet the provisions of this rule shall be given 15 days to develop a plan of correction that must be accepted by the Agency.

3. Failure of the hospital with a Level II adult cardiovascular services program to make improvements specified in the plan of correction shall result in the revocation of the program license. The hospital may offer evidence of
mitigation and such evidence could result in a lesser sanction.

(e)(4) In case of conflict between the provisions of this rule and the guidelines in the 2012 ACC/SCAI Guidelines and the 2014 SCAI/ACC/AHA Update, the provisions of this part shall prevail.

(4) Stroke centers. Hospitals providing acute stroke ready center, primary stroke center, thrombectomy-capable stroke center, or comprehensive stroke center services shall have the services available 24 hours per day, 7 days per week.

(a) Licensure. A licensee of a hospital may apply for designation as an acute stroke ready center, primary stroke center, thrombectomy-capable stroke center, or comprehensive stroke center by submitting a hospital licensure application as specified in subsection 59A-3.066(2), F.A.C., and attaching documentation verifying stroke center certification through:

1. Center for Improvement in Healthcare Quality;
2. DNV GL Healthcare;
3. Health Facilities Accreditation Program; or
4. The Joint Commission. License Application Stroke Center Affidavit, AHCA Form 3130-8009, January 2018, incorporated herein by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09638. The application and affidavit are available at: http://ahca.myflorida.com/MCHQ/HQALicensureForms/index.shtml and must be signed by the hospital’s Chief Executive Officer, attesting that the stroke program meets:

1. The criteria for one of the designations as specified in this rule, or
2. Is certified as a stroke center by The Joint Commission, the Health Facilities Accreditation Program, or DNV GL.

(b) Documentation must include a copy of a certificate identifying the level of stroke services provided and the effective and expiration dates of the certification. Screening. Organized medical staff shall establish specific procedures for screening patients that recognize that numerous conditions, including cardiac disorders, often mimic stroke in children. Organized medical staff shall ensure that transfer to an appropriate facility for specialized care is provided to children and young adults with known childhood diagnoses.

(c) Documentation verifying continued certification must be attached to each subsequent license renewal application. Acute Stroke Ready Centers (ASR). An ASR shall have an acute stroke team available 24 hours per day, 7 days per week, capable of responding to patients who are in the emergency department or an inpatient unit
within 15 minutes of being called.

1. An ASR team shall consist of a physician and one or more of the following:
   a. A registered professional nurse;
   b. An advanced registered nurse practitioner; or
   c. A physician assistant.

2. Each ASR team member must receive 4 or more hours of education related to cerebrovascular disease annually.

3. An ASR shall fulfill the educational needs of its acute stroke team members, emergency department staff, and prehospital personnel by offering ongoing professional education at least twice per year.

4. An ASR shall designate a physician with knowledge of cerebrovascular disease to serve as the ASR medical director. The medical director shall be responsible for implementing the stroke services protocols. The qualifications for the medical director shall be determined by the hospital’s governing board.

5. An ASR shall have the following services available 24 hours per day, 7 days per week:
   a. A dedicated emergency department;
   b. Clinical laboratory services as specified in paragraph 59A-3.255(6)(g), F.A.C.;
   c. Diagnostic imaging to include head computed tomography (CT) and magnetic resonance imaging (MRI);
   d. Administration of intravenous thrombolytic;
   e. Reversal of anticoagulation;
   f. Neurologist services, available in person or via telemedicine; and
   g. A transfer agreement with a primary stroke center or comprehensive stroke center.

   (d) Primary Stroke Centers (PSC). A PSC shall have an acute stroke team available 24 hours per day, 7 days per week, capable of responding to patients who are in the emergency department or an inpatient unit within 15 minutes of being called.

1. A PSC team shall consist of a physician and one or more of the following:
   a. A registered professional nurse;
   b. An advanced registered nurse practitioner; or
   c. A physician assistant.

2. Each acute stroke team member must receive 8 or more hours of education related to cerebrovascular disease.
3. A PSC shall fulfill the educational needs of its acute stroke team members, emergency department staff, and prehospital personnel by offering ongoing professional education at least twice per year.

4. A PSC shall designate a physician with knowledge of cerebrovascular disease to serve as the PSC medical director. The medical director shall be responsible for implementing the stroke services protocols. The qualifications for the medical director shall be determined by the hospital’s governing board.

5. A PSC shall have the following services available 24 hours per day, 7 days per week:
   a. A dedicated emergency department;
   b. Clinical laboratory services as specified in paragraph 59A 3.255(6)(g), F.A.C.;
   c. Diagnostic imaging to include head computed tomography (CT), CT angiography (CTA), brain and cardiac magnetic resonance imaging (MRI), magnetic resonance angiography (MRA), and transthoracic and/or transesophageal echocardiography;
   d. Administration of intravenous thrombolytic;
   e. Reversal of anticoagulation; and
   f. Neurologist services, available in person or via telemedicine.

6. The following services may be available on-site or via a transfer agreement:
   a. Neurosurgical services within 2 hours of being deemed clinically necessary;
   b. Physical, occupational, or speech therapy; and
   c. Neurovascular interventions for aneurysms, stenting of carotid arteries, carotid endarterectomy, and endovascular therapy.

   a. The PSC shall develop a quality improvement program designed to analyze data, correct errors, identify system improvements and ongoing improvement in patient care and delivery of services.
   b. A multidisciplinary institutional Quality Improvement Committee shall meet on a regular basis to monitor quality benchmarks and review clinical complications.
   c. Specific benchmarks, outcomes, and indicators shall be defined, monitored, and reviewed by the Quality Improvement Committee on a regular basis for quality assurance purposes.

(c) Comprehensive Stroke Center (CSC). A comprehensive stroke center shall have health care personnel with...
clinical expertise in a number of disciplines available.

1. Health care personnel disciplines in a CSC shall include:
   a. A designated comprehensive stroke center medical director;
   b. Neurologists, neurosurgeons, surgeons with expertise performing carotid endarterectomy, diagnostic neuroradiologist(s), and physician(s) with expertise in endovascular neurointerventional procedures and other pertinent physicians;
   c. Emergency department (ED) physician(s) and nurses trained in the care of stroke patients;
   d. Nursing staff in the stroke unit with particular neurologic expertise who are trained in the overall care of stroke patients;
   e. Nursing staff in intensive care unit (ICU) with specialized training in care of patients with complex and/or severe neurological/neurosurgical conditions;
   f. Advanced Practice Nurse(s) with particular expertise in neurological and/or neurosurgical evaluation and treatment;
   g. Physician(s) with specialized expertise in critical care for patients with severe and/or complex neurological/neurosurgical conditions;
   h. Physician(s) with expertise in performing and interpreting trans-thoracic echocardiography, transesophageal echocardiography, carotid duplex ultrasound and transcranial Doppler;
   i. Physician(s) and therapist(s) with training in rehabilitation, including physical, occupational and speech therapy; and
   j. A multidisciplinary team of health care professionals with expertise or experience in stroke, representing clinical or neuropsychology, nutrition services, pharmacy (including a Pharmacist with neurology/stroke expertise), case management and social work.

2. A CSC shall have the following availability of medical personnel:
   a. Neurosurgical expertise must be available in a CSC on a 24 hours per day, 7 days per week basis and in-house within 2 hours. The attending neurosurgeon(s) at a CSC shall have expertise in cerebrovascular surgery.
   b. Neurologist(s) with special expertise in the management of stroke patients shall be available 24 hours per day, 7 days per week.
   c. Endovascular/Neurointerventionist(s) shall be on active full-time staff. However, when this service is
temporarily unavailable, pre-arranged transfer agreements must be in place for the rapid transfer of patients needing these treatments to an appropriate facility.

3. A CSC shall have the following advanced diagnostic capabilities:
   a. Magnetic resonance imaging (MRI) and related technologies;
   b. Catheter angiography;
   c. Computed Tomography (CT) angiography;
   d. Extracranial ultrasonography;
   e. Carotid duplex;
   f. Transcranial Doppler;
   g. Transthoracic and transesophageal echocardiography;
   h. Tests of cerebral blood flow and metabolism;
   i. Comprehensive hematological and hypercoagulability profile testing;

4. Neurological Surgery and Endovascular Interventions:
   a. Angioplasty and stenting of intracranial and extracranial arterial stenosis;
   b. Endovascular therapy of acute stroke;
   c. Endovascular treatment (coiling) of intracranial aneurysms;
   d. Endovascular and surgical repair of arteriovenous malformations (AVM) and arteriovenous fistulae (AVF);
   e. Surgical clipping of intracranial aneurysms;
   f. Intracranial angioplasty for vasospasm;
   g. Surgical resection of AVMs and AVFs;
   h. Placement of ventriculostomies and ventriculoperitoneal shunts;
   i. Evacuation of intracranial hematomas;
   j. Carotid endarterectomy; and
   k. Decompressive craniectomy.

5. A CSC shall have the following specialized infrastructure:
   a. Emergency Medical Services (EMS) Link — The CSC collaborates with EMS leadership:
      (I) To ensure that EMS assessment and management at the scene includes the use of a stroke triage assessment tool (consistent with the Florida Department of Health sample);
(II) To ensure that EMS assessment/management at the scene is consistent with evidence-based practice.

(III) To facilitate inter-facility transfers; and

(IV) To maintain an ongoing communication system with EMS providers regarding availability of services.

b. Referral and Triage — A CSC shall maintain:

(I) An acute stroke team available 24 hours per day, 7 days per week, including: ED physician(s), nurses for ED patients, neurologist, neurospecialist RNs, radiologist with additional staffing/technology including: 24 hours per day, 7 days per week CT availability, STAT lab testing/pharmacy and registration;

(II) A system for facilitating inter-facility transfers; and

(III) Defined access telephone numbers in a system for accepting appropriate transfer.

c. Inpatient Units — These specialized units must have a subspecialty Medical Director with particular expertise in stroke (neurologist, neurosurgeon or neuro-intensivist) who demonstrates ongoing professional growth by obtaining at least 8 hours of cerebrovascular care education annually. A CSC shall provide:

(I) An Intensive Care Unit with medical and nursing personnel who have special training, skills and knowledge in the management of patients with all forms of neurological/neurosurgical conditions that require intensive care; and

(II) An Acute Stroke Unit with medical and nursing personnel who have training, skills and knowledge sufficient to care for patients with neurological conditions, particularly acute stroke patients, and who are trained in neurological assessment and management.

d. Rehabilitation and Post Stroke Continuum of Care —

(I) A CSC shall provide inpatient post-stroke rehabilitation.

(II) A CSC shall utilize healthcare professionals who can assess and treat cognitive, behavioral, and emotional changes related to stroke (i.e., clinical psychologists or clinical neuropsychologists).

(III) A CSC shall ensure discharge planning that is appropriate to the level of post-acute care required.

(IV) A CSC shall ensure continuing arrangements post-discharge for rehabilitation needs and medical management.

(V) A CSC shall ensure that patients meeting acute care rehabilitation admission criteria are transferred to a CARF or TJC accredited acute rehabilitation facility.

e. Education —
(I) The CSC shall fulfill the educational needs of its medical and paramedical professionals by offering ongoing professional education for all disciplines.

(II) The CSC shall provide education to the public as well as to inpatients and families on risk factor reduction/management, primary and secondary prevention of stroke, the warning signs and symptoms of stroke, and the medical management and rehabilitation for stroke patients.

(III) The CSC shall supplement community resources for stroke and stroke support groups.

f. Professional standards for nursing — The CSC shall provide a career development track to develop neuroscience nursing, particularly in the area of cerebrovascular disease.

(I) ICU and neuroscience/stroke unit nursing staff will be familiar with stroke specific neurological assessment tools such as the National Institute for Health (NIH) Stroke Scale.

(II) ICU nursing staff must be trained to assess neurologic function and be trained to provide all aspects of neurocritical care.

(III) Nurses in the ICU caring for stroke patients, and nurses in neuroscience units must obtain at least 8 hours of continuing education credits.

g. Research — A CSC shall have the professional and administrative infrastructure necessary to conduct clinical trials, have participated in stroke clinical trials within the last year, and be actively participating in ongoing clinical stroke trials.

6. A CSC will have a quality improvement program for the analysis of data, correction of errors, systems improvements, and ongoing improvement in patient care and delivery of services that include:

a. A multidisciplinary institutional Quality Improvement Committee that meets on a regular basis to monitor quality benchmarks and review clinical complications;

b. Specific benchmarks, outcomes, and indicators defined, monitored, and reviewed on a regular basis for quality assurance purposes. Outcomes for procedures such as carotid endarterectomy, carotid stenting, intravenous tissue plasminogen activator (IVtPA), endovascular/interventional stroke therapy, intracerebral aneurysm coiling, and intracerebral aneurysm clipping will be monitored;

c. An established database and/or registry that allows for tracking of parameters such as length of stay, treatments received, discharge destination and status, incidence of complications (such as aspiration pneumonia, urinary tract infection, deep venous thrombosis), and discharge medications and comparing to institutions across the
United States; and

d. Participation in a national and/or state registry (or registries) for acute stroke therapy clinical outcomes, including IVtPA and endovascular/interventional stroke therapy.

(5) Burn Units.

(a) All licensed hospitals that operate burn units under Section 395.1055(17) 408.0361(2), F.S., shall comply with the guidelines published by the American College of Surgeons, Committee on Trauma. Hospitals are considered to comply with the American College of Surgeons guidelines when they adhere to guidelines regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety. The applicable guidelines, herein incorporated by reference, are “Guidelines for the Operation of Burn Centers,” in Resources for Optimal Care of the Injured Patient, Committee on Trauma, American College of Surgeons, (2014); Chapter 14, pages 100 through 106. The copyrighted material is available for public inspection at the Agency for Health Care Administration, Hospital and Outpatient Services Unit, 2727 Mahan Drive, Tallahassee, FL 32308 and the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee, FL 32399. A copy may be obtained from the American Burn Association, 311 South Wacker Drive, Suite 4150, Chicago, IL 60606 or online at http://ameriburn.org/. The determination of compliance with the guidelines is based on the burn unit providing evidence of verification from the American Burn Association.

(b) A hospital may apply for the initial licensure of a burn unit by submitting a hospital licensure application as specified in subsection 59A-3.066(2), F.A.C., indicating the addition of burn unit services, and attaching License Application Burn Unit Services, AHCA Form 3130-8012, January 2018, herein incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09639. This form is Both of these forms are available at: http://ahca.myflorida.com/MCHQ/HQALicensureForms/index.shtml. The Burn Unit Services Application must be signed by the hospital’s Chief Executive Officer. Applicants documenting the applicant shall complete this form indicating the date that burn unit services will begin and that the hospital is in compliance with the “Guidelines for the Operation of Burn Centers” but have has not received initial verification as a burn unit from the American Burn Association shall be licensed as a provisional burn unit. During this initial licensure period, the hospital license will indicate that the burn unit is “provisional.” Applicants that have received verification as a burn unit from the American Burn Association and documented compliance with the “Guidelines for the Operation of Burn Centers” shall be licensed as a burn unit.
(c) At the time of licensure renewal, burn unit operators shall submit current documentation from the American Burn Association that verifies the hospital’s adherence to the guidelines incorporated in subsection paragraph (5)(b)(5)(a).

(d) Each provider of burn unit services shall maintain a policy and procedure manual, available for review by the Agency, which documents a plan to provide services to Medicaid and charity care patients.

(e) Enforcement of these rules shall follow procedures established in rule 59A-3.253, F.A.C.

(6) Organ transplant programs. Licensure designations for organ transplant programs include heart, intestines, kidney, liver, lung, pancreas and islet cells, and bone marrow. Separate designations are required for adult and pediatric programs. Bone marrow programs must have separate designations for autologous and allogeneic programs. Licensure for multi-organ transplant programs such as heart-lung must apply for each licensure designation by age group and must meet program-specific requirements separately.

(a) A licensee of a hospital may apply for licensure to provide an organ transplant program by submitting a hospital license application as specified in subsection 59A-3.066(2), F.A.C., indicating the addition of one or more organ transplant programs issued a certificate of need to establish one or more organ transplant programs must request and obtain the corresponding licensure designation(s) by submitting written notification to the Agency’s Hospital and Outpatient Services Unit prior to scheduling its first transplant procedure in each program. A licensee of a hospital must seek and maintain certification as described in Title 42 CFR Part 482 Subpart E for the comparable Medicare transplant programs.

(b) In addition to the definitions contained in Rule 59A-3.065, F.A.C., the following definitions shall apply to this subsection:

1. “Bone Marrow Transplantation” means human blood precursor cells administered to a patient to restore normal hematological and immunological functions following ablative or nonablative therapy with curative or life-prolonging intent. Human blood precursor cells may be obtained from the patient in an autologous transplant or from a medically acceptable related or unrelated donor, and may be derived from bone marrow, circulating blood, or a combination of bone marrow and circulating blood.

2. “Pediatric Patient” means a patient under the age of 15 years. Pediatric transplant programs at a Medicaid designated transplant center may perform transplants for patients under the age of 21. In case of conflict between provisions in this rule, the provision of this subsection shall prevail.
4. “Research Hospital” means a hospital which devotes clearly defined space, staff, equipment, and other resources for research purposes and has documented teaching affiliations with an accredited school of medicine in Florida or another state.

5. “Research Program” means an organized program that conducts clinical trial research, collects treatment data, assesses outcome data, and publishes statistical reports showing research activity and findings.

7. “Teaching Hospital” means any hospital which the Secretary of the Agency for Health Care Administration has determined meets the conditions specified in Section 408.07(44), F.S.

8. “Transplantation Program” means the offering of administrative, surgical, and support services by a hospital through which one or more types of organ transplants are provided to one or more patients; and the offering of some or all phases of bone marrow transplantation.

(b)(c) All hospitals providing organ transplant services must meet and maintain the general and program-specific service requirements. Hospitals providing organ transplant services for heart, intestines, kidney, liver, lung, or pancreas and islet cells must:

1. Be a member of the Organ Procurement and Transplantation Network (OPTN);

2. Have a written agreement with an Organ and Tissue Procurement Organization (OPO) licensed under chapter 765, F.S.; and

3. Have equipment for cooling, flushing, and transporting organs. If cadaveric transplants are performed, equipment for organ preservation through mechanical perfusion is required. This requirement may be met through an agreement with an OPO.

(c)(d) All hospitals providing any organ transplant service must have:

1. An age-appropriate (adult or pediatric) intensive care unit which includes facilities for prolonged reverse isolation when required;

2. A clinical review committee for evaluation and decision-making regarding the suitability of a transplant candidate;

3. Services and facilities for inpatient and outpatient care, available on a 24-hour basis, for the patient’s chronic illness prior to transplantation, during transplantation, and in the post-operative period;

4. Policies and procedures for patient care specifying patient selection criteria for patient management and evaluation during the pre-hospital, in-hospital, and immediate post-discharge phases of the program;
5. Detailed therapeutic and evaluative procedures for the acute and long-term management of each patient and the management of common complications;

6. A program for the education and training of staff regarding the special care of transplantation patients;

7. Education services including home and hospital programs to minimize interruption in the patient’s school education;

8. A program for the education of patients, their families and the patient’s primary care physician regarding post-operative and post-discharge care for transplantation patients; and

9. Clinical and pathology laboratory services meeting the requirements in Rule 59A-3.242(1), F.A.C. Services may be provided directly as a hospital service or by contract to meet the needs of the patients. CLIA certified specialties must include Histocompatibility for transplant services, Microbiology, Chemistry, Hematology, Immunohematology (blood bank), and Histopathology with the capability of studying and promptly reporting the patient’s response to the organ transplantation surgery, and analyzing appropriate biopsy material.

(d)(e) All hospitals providing organ transplant services must meet the following staffing requirements:

1. A staff of physicians licensed pursuant to chapters 458 or 459, F.S. with expertise in caring for age-appropriate patients with end-stage disease requiring organ transplantation. The physicians shall be members of the organized medical staff and have medical specialties or sub-specialties appropriate for the type of transplant program. Each transplant program shall have a designated physician member of the organized medical staff, meeting the education, training, certification, and experience qualifications required by the hospital’s governing board or delegated committee, to serve as:

   a. The program director, responsible for the day-to-day administration of the transplant program;

   b. The primary transplant physician, responsible for providing and coordinating the pre- and post-transplantation care of patients; and

   c. The primary transplant surgeon, responsible for providing and coordinating the transplantation surgical services.

2. A staff of registered professional nurses, including advanced practice registered nurses, if applicable, with experience in the care of chronically ill patients and their families;

3. A registered professional nurse or other licensed clinician approved by the program director to serve as clinical transplant coordinator;
4. **Physician** Maintain contractual agreements with consultants who have expertise in immunohematology and are capable of meeting the unique needs of transplant patients on a long-term basis;

5. A pharmacist with expertise in the pharmacological needs of transplant patients;

6. A registered dietician with expertise in the nutritional needs of transplant patients;

7. A staff of respiratory therapists with expertise in the needs of transplant patients; and,

8. A staff of social workers, psychologists, psychiatrists, and other individuals skilled in performing comprehensive psychological assessments, counselling patients and families of patients, providing assistance with financial arrangements, and making arrangements for use of community resources.

(e)(4) Liver, lung, pancreas and islet cells, intestines, multi-organ, and bone marrow programs, excluding bone marrow programs for adults providing autologous transplants only, are limited to a teaching or research hospital with training programs relevant to the transplant program.

1. Lung, pancreas and islet cells, intestines, and multi-organ transplant programs must have interactive programs of basic and applied research in organ failure, transplantation, immunoregulatory responses, and related biology.

2. Bone marrow programs, excluding bone marrow programs for adults providing autologous transplants only, must have an ongoing research program that is integrated either within the hospital or by written agreement with a bone marrow transplantation **program center** operated by a teaching hospital. The program must include outcome monitoring and long-term patient follow-up.

3. Bone marrow programs for adults providing only autologous transplants may be established at:
   a. Teaching hospitals;
   b. Research hospitals; or
   c. Community hospitals with a research program or affiliated with a research program. The research program may be integrated within the hospital, by written agreement with a bone marrow transplant center operated by a teaching hospital, or by an agreement with an outpatient provider with a research program. Under the agreement, the outpatient research program may perform one or more of the following outpatient phases of bone marrow transplantation: blood screening tests, mobilization of stem cells, stem cell rescue, chemotherapy, and reinfusion of stem cells.

(f)(6) Heart transplant programs must maintain:
1. A cardiologist member of the organized medical staff meeting the age-appropriate education, training, and certification requirements as established by the program director;

2. An anesthesiologist member of the organized medical staff meeting the age-appropriate education, training, and certification requirements as established by the program director, and experienced in both open heart surgery and heart transplantation; and

3. A single occupancy isolation room in an age-appropriate intensive care unit.

(g) Liver transplant programs must maintain:

1. Staff trained in liver transplantation and in the care of patients with hepatic diseases; and

2. The following available in the hospital or by contract:
   a. A department of gastroenterology, including clinics and procedure rooms;
   b. Radiology services to provide complex biliary procedures, including transhepatic cholangiography, portal venography and arteriography; and
   c. A patient convalescent unit for monitoring patient’s progress post-discharge.

(h) Intestine transplant programs will only be approved in conjunction with a liver transplant program.

(i) Kidney transplant programs must maintain:

1. A nephrologist member of the organized medical staff meeting the age-appropriate education, training, and certification requirements as established by the program director;

2. An anesthesiologist member of the organized medical staff meeting the age-appropriate education, training, and certification requirements as established by the program director, and experienced in kidney transplantation;

3. Nursing staff experienced in nursing care of patients with permanent kidney failure;

4. Inpatient renal dialysis available onsite at all times, including a separate pediatric dialysis unit if pediatric patients are served;

5. Outpatient services, including renal dialysis services and ambulatory renal clinic services; and

6. Ancillary services, including nutritional, radiologic, and nursing services capable of monitoring and support during dialysis and assisting with educating the patient in home care vascular access and home dialysis management, when applicable.

(j) Pediatric kidney transplant programs must meet the following additional requirements:

1. The program director must be board certified or eligible in pediatric nephrology;
2. The **head nurse manager** of the dialysis unit must have special training and expertise in pediatric dialysis;

3. The nurse to patient ratio in the pediatric dialysis unit must be 1:1;

4. The registered dietician must have expertise in nutritional needs of children with chronic renal disease; and

5. The radiology service must have specialized equipment for obtaining x-rays on pediatric patients.

(k) Pancreas transplant programs will only be approved in conjunction with a kidney transplant program.

(l) Bone marrow programs for pediatric patients must meet the following common requirements:

1. The program director must have formal training in pediatric bone marrow transplantation, and shall be board certified as a hematologist or oncologist with experience in the treatment and management of pediatric acute oncological cases involving high dose chemotherapy or high dose radiation therapy;

2. Nursing staff must be dedicated full time to the program and have experience with the care of critically ill immuno-suppressed patients;

3. The transplantation team must have expertise in hematology, oncology, immunologic diseases, neoplastic diseases, including hematopoietic and lymphopoietic malignancies, and non-neoplastic disorders;

4. An interdisciplinary team must direct permanent follow-up care of the bone marrow transplantation patients, including the maintenance of immunosuppressive therapy and treatment of complications;

5. A radiation therapy division, under the direction of a board certified radiation oncologist, must be available onsite and capable of sub-lethal x-irradiation, bone marrow ablation, and total lymphoid irradiation; and

6. Pediatric inpatient post-transplantation care must be provided in a laminar air flow room; or in a single occupancy room with positive pressure, reverse isolation procedures, and terminal high efficiency particulate aerosol filtration on air blowers. This unit can be part of a program that also manages patients with leukemia or similar disorders.

(m) In addition to paragraph (k) above, Bone marrow programs providing allogeneic transplants to pediatric patients must have:

1. A pediatric convalescent facility to provide a temporary residence for patients during the prolonged convalescence;

3. A pediatric outpatient unit for close supervision of discharged patients;

3. An onsite laboratory equipped for the evaluation and cryopreservation of bone marrow; and

4. A laboratory equipped to handle studies including the use of monoclonal antibodies, if this procedure is
employed by the hospital, T-cell depletion, and separation of lymphocyte and hematological cell subpopulations and their removal for prevention of graft versus host disease. This requirement may be met through contractual arrangements.

(m) Bone marrow programs for adults must meet the following common requirements:

1. The program director must have formal training in bone marrow transplantation and be a board certified hematologist or oncologist with experience in the treatment and management of adult acute oncological cases involving high dose chemotherapy or high dose radiation therapy. The hospital’s governing board may appoint a board eligible hematologist or oncologist with at least one year of experience performing autologous bone marrow transplants to serve as program director if transplants are limited to autologous transplantations;

2. Nursing staff must be dedicated full time to the program and have experience with the care of critically ill immuno-suppressed patients;

3. An interdisciplinary transplantation team with expertise in hematology, oncology, immunologic diseases, neoplastic diseases, including hematopoietic and lymphopoietic malignancies, and non-neoplastic disorders shall direct permanent follow-up care of the bone marrow transplantation patients, including the maintenance of immunosuppressive therapy and treatment of complications;

4. Adult inpatient post-transplantation care must be provided in a laminar air flow room or in a single occupancy room with positive pressure, reverse isolation procedures, and terminal high efficiency particulate aerosol filtration on air blowers. This unit can be part of a program that also manages patients with leukemia or similar disorders; and

5. A radiation therapy division, under the direction of a board certified radiation oncologist, must be available onsite and capable of sub-lethal x-irradiation, bone marrow ablation, and total lymphoid irradiation.

(o) In addition to paragraph (m) above, Bone marrow programs providing allogeneic transplants to adults must have:

1. A laboratory equipped to handle studies including the use of monoclonal antibodies, if this procedure is employed by the hospital, T-cell depletion, and separation of lymphocyte and hematological cell subpopulations and their removal for prevention of graft versus host disease. This requirement may be met through contractual arrangements;

2. An onsite laboratory equipped for the evaluation and cryopreservation of bone marrow;
3. An adult convalescent facility to provide a temporary residence for patients during the prolonged convalescence; and

4. An adult outpatient unit for close supervision of discharged patients.

(p) A hospital providing adult and/or pediatric heart, intestines, kidney, liver, lung, or pancreas and islet cells transplants must have available upon request of the Agency, the number of transplants performed and the one-year post transplant graft and patient survival measures. Bone marrow programs providing allogeneic transplants may also provide autologous transplants without separate licensure as an autologous bone marrow transplant program.

(q) A hospital providing adult heart, kidney, liver, or lung transplants must meet the minimum clinical experience as described in Title 42 Code of Federal Regulations section 482.80 within one year from initial licensure of each transplant program. Each licensed organ transplant program must perform a minimum of 10 transplants per year averaged over 2 years. Hospitals providing adult and pediatric programs must meet the minimum volume requirement for each age group separately.

(r) Hospitals with licensed organ transplant programs must include organ transplant utilization data with the quarterly data submission required under section 408.05 395.1055 and chapter 408. part 1, F.S.