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/ Society for Cardiovascular Angiography and Interventions ~~American Heart Association~~ regarding the operation of diagnostic cardiac catheterization laboratories. Hospitals are considered to be in compliance with American College of Cardiology/ Society for Cardiovascular Angiography and Interventions ~~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~~. ~~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 a hospital ~~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, and not Level I or Level II adult cardiovascular services may not provide diagnostic cardiac catheterization 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)~~(c)~~ Therapeutic Cardiac Catheterization 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 Cardiac Catheterization Procedures. Procedures performed in the adult diagnostic cardiac catheterization laboratory shall include the following:

1. through 9. No change.

(e) renumbered (d) No change.

(e)~~(f)~~ 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.

(g) renumbered (f) No change.

(h) renumbered (g) No change.

(i) renumbered (h) No change.

(j) renumbered (i) No change.

(k) renumbered (j) No change.

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

(m) renumbered (k) No change.

(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 attaching License Application Level I Adult Cardiovascular Services, AHCA Form 3130-8010, January 2018, incorporated herein by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-09636~~. 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 catheterizations ~~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 catheterizations ~~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/American Heart Association/Society for Cardiovascular Angiography and Interventions 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/.

b. O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, Ettinger SM, Fang JC, Fesmire FM, Franklin BA, Granger CB, Krumholz HM, Linderbaum JA, Morrow DA, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Tommaso CL, Tracy CM, Woo YJ, Zhao DX. 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol* 2013;61:e78 –140, doi:10.1016/j.jacc.2012.11.019. 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/.

c. Harold JG, Bass TA, Bashore TM, Brindis RG, Brush JE Jr., Burke JA, Dehmer GJ, Deychak YA, Jneid H, Jollis JG, Landzberg JS, Levine GN, McClurken JB, Messenger JC, Moussa ID, Muhlestein JB, Pomerantz RM, Sanborn TA, Sivaram CA, White CJ, Williams ES. ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures: A Report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training (Writing Committee to Revise the 2007 Clinical Competence Statement on Cardiac Interventional Procedures). *J Am Coll Cardiol* 2013;62:357–96. doi: 10.1016/j.jacc.2013.05.002. 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. This document is available on the World Wide Web sites of the American College of Cardiology (http://www.cardiosource.org), the American Heart Association (http://my.americanheart.org), and the Society for Cardiovascular Angiography and Interventions (http://www.scai.org). A copy may be obtained from Elsevier Inc, Reprint Department by email at reprints@elsevier.com or online at https://www.sciencedirect.com/.

d. Dehmer GJ, Blankenship JC, Cilingiroglu M, Dwyer JG, Feldman DN, Gardner TJ, Grines CL, Singh M. SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-site Surgical Backup. *J Am Coll Cardiol* 2014; 63:2624–41.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/.

e. Levine GN, O'Gara PT, Bates ER, Blankenship JC, Kushner FG, Ascheim DD, Bailey SR, Bittl JA, Brindis RG, Casey DE Jr, Cercek B, Chambers CE, Chung MK, de Lemos JA, Diercks DB, Ellis SG, Fang JC, Franklin BA, Granger CB, Guyton RA, Hollenberg SM, Khot UN, Krumholz HM, Lange RA, Linderbaum JA, Mauri L, Mehran R, Morrow DA, Moussa ID, Mukherjee D, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Ting HH, Tommaso CL, Tracy CM, Woo YJ, Zhao DX. 2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients with ST-Elevation Myocardial Infarction: An Update of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention and the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. *J Am Coll Cardiol* 2016;67:1235–50. 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 Gguidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.

3. renumbered 4. No change.

4. renumbered 5. No change.

6 ~~5~~. 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.

7 ~~6~~. ~~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.

8 ~~7~~. 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 designed to analyze data, correct errors, identify system improvements and ongoing improvement in patient care and delivery of services. Hospitals must participate in submission of data to the American College of Cardiology's National Cardiovascular Data Registry or the American Heart Association's Get with the Guidelines–Coronary Artery Disease registry to ensure that the Level I ~~cardiac catheterization program and the percutaneous coronary intervention~~ program meet or exceed national quality and outcome benchmarks in which the hospital participates ~~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.

~~8. 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 cathererization 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. through 3. No change.

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. Nursing staff within the adult coronary ~~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) through (d) No change.

(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 catheterizations ~~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. No change.

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~~ Gguidelines ~~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 Gguidelines 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 designed to analyze data, correct errors, identify system improvements and ongoing improvement in patient care and delivery of services. Hospitals must participate in submission of data to 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 participate in the clinical outcome reporting systems operated by the Society of Thoracic Surgeons to ensure that the Level II ~~cardiac catheterization program, the percutaneous coronary intervention~~ program and the cardiac surgical program meet or exceed national quality and outcome benchmarks in which the hospital participates ~~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.~~

6~~7~~. 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. No change.

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. No change.

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. No change.

(c) No change.

(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)~~(f)~~ 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 ~~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 annually.~~

~~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 endartectomy, and endovascular therapy.

7. Quality Improvement and Clinical Outcomes Measurement.

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.

(e) 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 on-going 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 neuro-critical 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 ~~408.0361(2)~~, F.S., shall comply with the verification criteria ~~guidelines~~ published by the American Burn Association ~~College of Surgeons, Committee on Trauma~~. Hospitals are considered to comply with the American Burn Association verification criteria ~~College of Surgeons guidelines~~ when they adhere to criteria ~~guidelines~~ regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety. The applicable criteria ~~guidelines~~, herein incorporated by reference and effective at adoption, are the American Burn Association Verification Criteria Effective October 1, 2019 and ~~"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 at http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX ~~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 licensee of 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~~ an application to the American Burn Association for verification as a burn center ~~compliance with the "Guidelines for the Operation of Burn Centers"~~ but have ~~has~~ not received initial verification as a burn center ~~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 center from the American Burn Association shall be licensed as a burn unit.

(c) At the time of licensure renewal, burn unit operators shall submit current burn center verification 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., Chapter 408, Part II and 395, Part I, F.S., including suspension or revocation of the burn unit license.

Rulemaking Authority 395.1055, ~~395.3038, 408.036, 408.0361~~ FS. Law Implemented 395.1055, 395.1065, 395.3038, ~~408.0361~~ FS. History–New 8-15-18, Formerly 59A-3.2085(13), 59A-3.2085(14), 59A-3.2085(15), 59A-3.2085(16), 59A-3.2085(17), 59A-3.2085(18) ~~59A-3.2085(81)~~, Amended, _____.