

The Florida Senate
COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Bean, Chair
Senator Sobel, Vice Chair

MEETING DATE: Wednesday, June 10, 2015
TIME: 1:00—4:00 p.m.
PLACE: *Pat Thomas Committee Room, 412 Knott Building*

MEMBERS: Senator Bean, Chair; Senator Sobel, Vice Chair; Senators Braynon, Flores, Gaetz, Galvano, Garcia, Grimsley, and Joyner

| TAB | BILL NO. and INTRODUCER | BILL DESCRIPTION and SENATE COMMITTEE ACTIONS | COMMITTEE ACTION |
|---------------------------------|--|---|------------------|
| 1 | Workshop: | Ambulatory Surgical Centers and Recovery Care Centers. Hospital-related Certificates of Need. | |
| 2 | Discussion of other health care issues in the Joint Proclamation: | Direct Primary Care. Drug Prescription by Advanced Registered Nurse Practitioners and Physician Assistants. Responsibilities of Health Care Facilities. | |
| Other Related Meeting Documents | | | |

Ambulatory Surgical Centers (ASCs)

Presented by Molly McKinstry, Deputy Secretary,
Health Quality Assurance

Senate Health Policy Committee

June 10, 2015



Ambulatory Surgical Centers

- Primary purpose is to provide elective surgical care.
- The patient is admitted to and discharged from the facility within the same working day.
- Overnight stays are not permitted.
- Not part of a hospital.
- An ambulatory surgical center does not include an office maintained by a physician for the practice of medicine.



State Allowed Procedures

- No specific list of procedures.
- Governing board is responsible for determining the policies and activities of the center.
- Organized Medical Staff must review and approve policies and activities of all departments.
- Written policies and procedures relative to the administration of anesthesia shall be developed by the anesthesia service, approved by the medical staff and the governing board, and be reviewed annually.



Ambulatory Surgical Centers

- Any facility or office which is certified or seeks certification as a Medicare ambulatory surgical center shall be licensed as an ambulatory surgical center.
- Is a distinct entity.
- Operates exclusively for the provision of surgical services to patients not requiring hospitalization, with the ASC's services expected not to exceed 24 hours in duration following an admission.
- Has an agreement with Medicare to participate as an ASC.
- Complies with Federal Conditions for Coverage (CfCs) in Subparts B and C, i.e., 42 CFR 416.25-52.



Federal regulations of ASCs

- The ASC must offer only surgical services. Separate ancillary services that are integral to the surgical services, i.e., those furnished immediately before, during or immediately after a surgical procedure, may be provided. The ASC may not, however, offer services unrelated to the surgeries it performs.



Federal regulations of ASCs

- An ASC is limited to providing surgical services only to patients who do not require hospitalization after the surgery. The ASC's surgical services must be those that ordinarily would not take more than 24 hours, including pre-op preparation and recovery time.
- These limitations apply to all of the ASC's surgical services, not just to surgeries for Medicare beneficiaries.



Federal Allowed Procedures

- ASC List of Covered Surgical Procedures
 - Addendum AA of the hospital outpatient prospective payment system.
 - <http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index.html>



Federal Allowed Procedures

- §416.42(a)(1) A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.
 - Guidance # 1: The purpose of the exam immediately before surgery is to evaluate, based on the patient's current condition, whether the risks associated with the anesthesia that will be administered and with the surgical procedure that will be performed fall within an acceptable range for a patient having that procedure in an ASC, given that the ASC does not provide services to patients requiring hospitalization. The assessment must be specific to each patient; it is not acceptable for an ASC to assume, for example, that coverage of a specific procedure by Medicare or an insurance company in an ASC setting is a sufficient basis to conclude that the risks of the anesthesia and surgery are acceptable generically for every ASC patient.



Federal Allowed Procedures

- §416.42(a)(1) A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.
 - Guidance #2: If a State establishes licensure limitations on the types of procedures an ASC may perform that are based on patient classifications and would permit ASCs to perform fewer procedures than they would under the CfCs, then the ASC must conform to those State requirements. However, State requirements that would expand the types of procedures an ASC may offer beyond what is permitted under the CfCs are superseded by the Federal CfC requirements.



Ambulatory Surgical Centers

- Currently there are 431 licensed ASCs in Florida.
(As of June 5, 2015)
- 413 ASCs are Medicare and/or Medicaid certified.
- 381 ASCs are accredited by a national accrediting organization
 - Accreditation Association for Ambulatory Health Care (298)
 - The Joint Commission (83)



ASC Reporting Requirements

- Reporting managed by the Agency's Office of Data Collection and Quality Assurance.
- All ASCs are required to submit a quarterly ambulatory patient data file to AHCA in accordance with Rule 59B-9.
- ASCs with fewer than 200 visits per quarter may request a quarterly exemption.



ASC Data

- During calendar year 2014, there were 2,404,537 surgical procedures performed in licensed ASCs in Florida.
- Surgical procedures involving the digestive system (which includes endoscopy and colonoscopy procedures) accounted for forty percent (960,700) of the total number of surgical procedures performed.



Top 5 CPT Surgical Code Categories Reported - 2014

| Rank | Description | ASC Procedures |
|------|--|----------------|
| 1 | Digestive System <i>(Includes colonoscopy and endoscopy procedures)</i> | 960,700 |
| 2 | Nervous System <i>(Includes steroidal & anesthetic spinal injections)</i> | 451,446 |
| 3 | Eye and Ocular Adnexa <i>(Includes cataract removal)</i> | 401,816 |
| 4 | Musculoskeletal System <i>(Includes a wide range of orthopedic surgery and arthroscopy)</i> | 282,682 |
| 5 | Integumentary System <i>(Includes plastic surgery and other procedures involving the skin and breast)</i> | 111,780 |



ASC Surveys

- Annual state licensure inspections are conducted at all non-accredited ASCs.
- Accrediting organization survey reports are provided to the Agency.
- State validation inspections are conducted annually on 5% of accredited ASCs to determine ongoing compliance with state licensure regulations.
- Federal validation and re-certification surveys for those facilities that are Medicare certified.
- Complaint Investigations (both state and federal)



Number of ASC Surveys Completed by AHCA July 1, 2012 through June 30, 2014

| Survey Type | Count |
|------------------------------|--------------|
| Complaints | 75 |
| State Licensure | 122 |
| Life Safety Code | 759 |
| Recertification | 161 |
| Recertification / Validation | 8 |
| TOTAL | 1,125 |



ASC Top 10 State Health Deficiency Citations - Statewide July 1, 2012 through June 30, 2014

| Rank | Description | Count |
|------|---|-------|
| 1 | Medical Records (Rule 59A-5.012(5) F.A.C.) | 42 |
| 2 | Nursing Service (Rule 59A-5.0085(3) F.A.C.) | 32 |
| 3 | Surveillance, Prevention & Control of Infection (Rule 59A-5.011(1) F.A.C.) | 24 |
| 4 | Governing Body (Rule 59A-5.005(1), F.A.C.) | 20 |
| 5 | Organized Medical Staff (Rule 59A-5.007(2), F.A.C.) | 20 |
| 6 | Surveillance, Prevention & Control of Infection (Rule 59A-5.011(3) F.A.C.) | 13 |
| 7 | Patient Rights (Rule 59A-5.0065, F.A.C.) | 12 |
| 8 | Quality Assessment & Improvement (Rule 59A-5.019(1) F.A.C.) | 10 |
| 9 | Comp Emergency Mgmt Plan (Rule 59A-5.018(1) F.A.C.) | 9 |
| 10 | Nursing Service (Rule 59A-5.0085(3) F.A.C.) | 8 |



ASC Top 10 Federal Health Deficiency Citations - Statewide July 1, 2012 through June 30, 2014

| Rank | Description | Count |
|------|--|-------|
| 1 | Administration of Drugs <i>42 CFR 416.48(a)</i> | 82 |
| 2 | Discharge - Order <i>42 CFR 416.52(c)(2)</i> | 74 |
| 3 | Sanitary Environment <i>42 CFR 416.51(a)</i> | 67 |
| 4 | Form And Content Of Record <i>42 CFR 416.47(b)</i> | 50 |
| 5 | Pre-Surgical Assessment <i>42 CFR 416.52(a)(2)</i> | 36 |
| 6 | Discharge With Responsible Adult <i>42 CFR 416.52(c)(3)</i> | 33 |
| 7 | Admission Assessment <i>42 CFR 416.52(a)(1)</i> | 32 |
| 8 | Infection Control Program <i>42 CFR 416.51(b)</i> | 27 |
| 9 | Verbal Orders <i>42 CFR 416.48(a)(3)</i> | 25 |
| 10 | Organization and Staffing <i>42 CFR 416.46(a)</i> | 24 |



ASC Top 10 State Life Safety Deficiency Citations - Statewide July 1, 2012 through June 30, 2014

| Rank | Description | Count |
|------|---|-------|
| 1 | Electrical Safety <i>NFPA 101-2009 LSC</i> | 150 |
| 2 | Generator Maintenance & Testing <i>NFPA 101-2009 LSC</i> | 110 |
| 3 | Sprinkler Inspection & Testing <i>NFPA 101-2009 LSC</i> | 86 |
| 4 | Fire Alarm Testing <i>NFPA 101-2009 LSC</i> | 85 |
| 5 | HVAC Equipment <i>NFPA 101-2009 LSC</i> | 51 |
| 6 | Emergency Lighting <i>NFPA 101-2009 LSC</i> | 49 |
| 7 | Emergency Management Plan <i>Rule 59A-5, FAC, NFPA 99 (2005)</i> | 46 |
| 8 | Fire Drills <i>NFPA 101-2009 LSC</i> | 44 |
| 9 | Medical Gas <i>NFPA 101-2009 LSC</i> | 35 |
| 10 | Smoke Dampers <i>NFPA 101-2009 LSC</i> | 30 |



ASC Top 10 Federal Life Safety Deficiency Citations - Statewide July 1, 2012 through June 30, 2014

| Rank | Description | Count |
|------|---------------------------------|-------|
| 1 | Electrical Wiring And Equipment | 37 |
| 2 | Fire Alarm System | 24 |
| 3 | Fire Drills | 19 |
| 4 | Other | 17 |
| 5 | Ventilating Equipment | 16 |
| 6 | Medical Gas System | 16 |
| 7 | Emergency Lighting | 14 |
| 8 | Electrical Systems | 14 |
| 9 | Hazardous Areas – Separation | 12 |
| 10 | Generators Inspected/Tested | 11 |



Infection Control

- Every ASC must establish an Infection Control Program involving members of the medical staff, nursing staff, and other professional and administrative staff as appropriate.
- The ASC must have written policies and procedures reflecting the scope of the infection control program, which are approved by the governing body of the ASC.



Infection Control

- Must include specific policies and procedures that address:
 - The shelf life of all stored sterile items.
 - Occupational exposure to blood and body fluids.
 - The handling and disposal of biomedical waste
 - The selection, storage, handling, use and disposition of disposable items.
 - Decontamination and sterilization activities.



Infection Control

(continued)

- The indications for universal precautions, body substance isolation, CDC isolation guidelines, or equivalent and the types of isolation to be used for the prevention of the transmission of infectious diseases.
- A requirement that soiled linen be collected in such a manner as to minimize microbial dissemination into the environment.
- A requirement that all cases of communicable diseases be properly reported to the Department of Health.



Construction Standards

- The *2010 Guidelines for Design and Construction of Health Care Facilities*, defines an ambulatory surgical facility as “Any surgical facility organized for the purpose of providing invasive surgical care to patients with the expectation that they will be recovered sufficiently to be discharged in less than 24 hours.”



Construction Standards

- The *2010 Florida Building Code* defines an ambulatory health care facility as “Buildings or portions thereof used to provide medical, surgical, psychiatric, nursing or similar care on a less than 24-hour basis to individuals who are rendered incapable of self-preservation.”



Construction Standards

- The current *2010 Florida Building Code*, allows the ASC physical plant to be constructed to Business Occupancy Group B ambulatory health care facility regulations.
- If patients stay beyond 24 hours, they would no longer meet the definition of an ambulatory health care facility and the ASC physical plant would be required to meet Health Care Occupancy construction standards, Industrial Type I-2, which is the same as hospitals.



Construction Standards

- The current *2010 Florida Building Code*, allows the ASC physical plant to be constructed to Business Occupancy Group B ambulatory health care facility regulations.

Federal Interpretive Guidelines: §416.44(b)

- Because ASCs are not permitted to provide care to patients exceeding 24 hours, they are, for purposes of compliance with National Fire Protection Association (NFPA) Life Safety Code (LSC) requirements, subject to a combination of healthcare and business occupancy requirements.



Recovery Care Centers

PRESENTATION BY STAFF OF THE FLORIDA SENATE COMMITTEE ON
HEALTH POLICY



What is a Recovery Care Center?

- A medical facility providing care and services to generally healthy patients for 2 or more days after a surgery.
 - Is a alternative for an inpatient stay at a hospital.
 - Generally RCC facilities may be stand-alone or attached to an ambulatory surgical center or hospital.
 - Currently, RCC services are not covered under Medicare.
 - Healthcare facility accreditation organizations may accredit recovery care / short stay facilities as ambulatory care facilities or as other specialty accreditation types.
- 

History of Recovery Care Center Legislation

- Currently, Illinois, Arizona, and Connecticut license RCCs within their state.
 - Arizona legislation passed prior to 1992.
 - Illinois legislation passed in 1994.
 - Connecticut's legislation became effective on March 2, 1995.
 - California had a pilot program licensing RCCs that passed in 1988 and which appears to have expired in 2000.
 - Other states may also allow RCC services to be provided under more general license types.
- 

Pros and Cons for Recovery Care Centers

In debate on similar legislation in Illinois:

- Proponents claimed that RCCs would:
 - Reduce healthcare costs and
 - Shorten recovery stays.
- Opponents claimed that RCCs would:
 - Take private-pay patients from hospitals.
 - Were especially concerned with hospitals in poorer areas.

Note: Staff could find little governmental or peer-reviewed evidence as to the actual costs and benefits of recovery care centers.



Differences In State Laws

| State | Arizona | Illinois | Connecticut | California |
|---|---|--|---|---------------------|
| Length of Stay | Unspecified | 48 hours | 72 hours | 48 hours |
| Extended Stay with Physician Recommendation | N/A | Yes, up to 72 hours | Yes up to 21 days | Yes, up to 72 hours |
| Allows Freestanding Centers? | Unspecified | Yes | Yes | Yes |
| Bed Limit | Unspecified | 20 | Unspecified | 20 |
| Prohibited Patients | Intensive Care. Coronary Care. Critical Care. | Patients with chronic infectious conditions. Children under 3 years of age. | Intensive Care. Coronary Care. Critical Care. | Unspecified |

State Experiences with Licensed Recovery Care Centers

| State | Arizona | Illinois | Connecticut | California |
|----------------------------|---------|--|--|--------------------------|
| # of RCCs Licensed | 3 | 7 | 0 | 0 |
| Program Still Active? | Yes | No. Demonstration project was not renewed. | Yes. However, currently no licensed RCCs | No |
| Reason for Discontinuation | N/A | Not utilized often. Cost savings not realized. | The only licensed RCC in the state went out of business. | Program expired in 2000. |

Certificate of Need (CON)

Presented by Elizabeth Dudek, Secretary

Senate Health Policy Committee

June 10, 2015



CON Basics

- Currently regulates entry into the marketplace for state-licensed hospitals, nursing homes and hospices. There are two types of batching cycles and each are reviewed twice a year
 - Decisions for applicable hospital programs are made in June and December
 - Decisions for applicable other beds and programs are made in February and August
- Expedited reviews must meet statutory criteria and can be reviewed at any time
- Allows beds to be added to health services by exemption for certain programs:
 - Added to hospitals:
 - Comprehensive medical rehabilitation
 - Neonatal intensive care unit
 - Psychological services
 - Community nursing home beds
- Hospitals can add acute care beds by notification
- Publishes four books twice-a-year on the utilization of the services monitored



CON History

Initiation

1973--Nixon administration

Part of the federal health planning system

Repealed before nationwide implementation

Largely controlled by federal law until 1986-- federal health planning legislation repealed

Reform

Eliminating CON for:

- Local Health System Agencies
- All outpatient services
- Capital expenditures
- Acquisition of major medical equipment
- Home health agencies
- Cost overruns

Deregulating:

- Acute care beds

Imposing:

- Moratorium on addition of community nursing home beds

Purview

-Originally under the Florida Department of Health and Rehabilitative Services

-Changed in July 1992 with the creation of the Florida Agency for Health Care Administration



CON Timeline

1973

CON is created

1987

Obstetric services eliminated

1982

Elimination of local Health System Agencies-- eliminated local CON review

1987

Capital expenditure of inpatient projects under \$1 million eliminated

1987

Statutory authority provided CON the authority to levy fines for non-compliance of conditions

1987

Major medical equipment subject was reclassified as equipment which costs more than \$1 million and which has been approved by the FDA for less than three years

1987

Excluded outpatient services from CON review

CON Timeline

1987

Specified tertiary services are now reviewable

1997

Acquisition of medical equipment, regardless of cost, are no longer reviewable

1988

A rule promulgated specified a list of tertiary services

2000

Eliminated CON review for all home health agencies

2000

A proposed increase of up to 10 beds or 10 percent of a hospital's or nursing home's licensed capacity can be done by exemption

2001

A moratorium is established on new community nursing home beds

2000

Cost overruns of approved projects of any kind are eliminated

2003

Rural hospitals no longer have to obtain CONs when they meet specific criteria

CON Timeline

2007

Eliminated burn units from CON review--moved regulation to licensure

2011

Eliminated the ability to fine community nursing home beds on Medicaid conditions

2007

Eliminated adult cardiac catheterization and adult open heart surgery services from CON review--moved regulation to licensure

2008

Streamlined the approval process for new acute care hospitals

2013

Modified requirements to allow deed restricted communities to apply for nursing homes through expedited review

2014

Community nursing home bed moratorium lifted

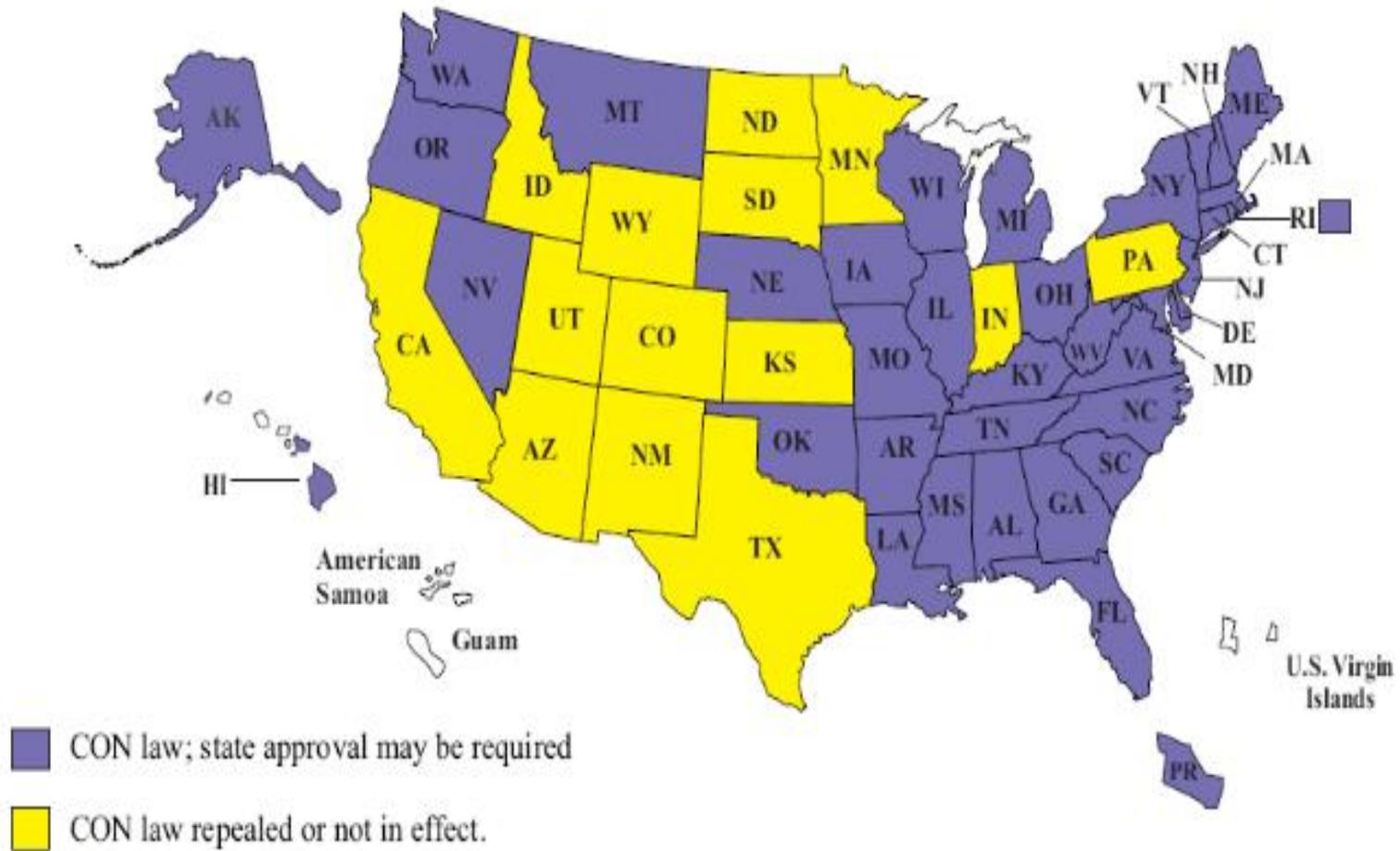
2014

The Agency published need for new community nursing home beds for the first time since 1999

Now

The Unit is preparing for the first 2015 Other Beds and Programs batch--accepting 59 letters of intent

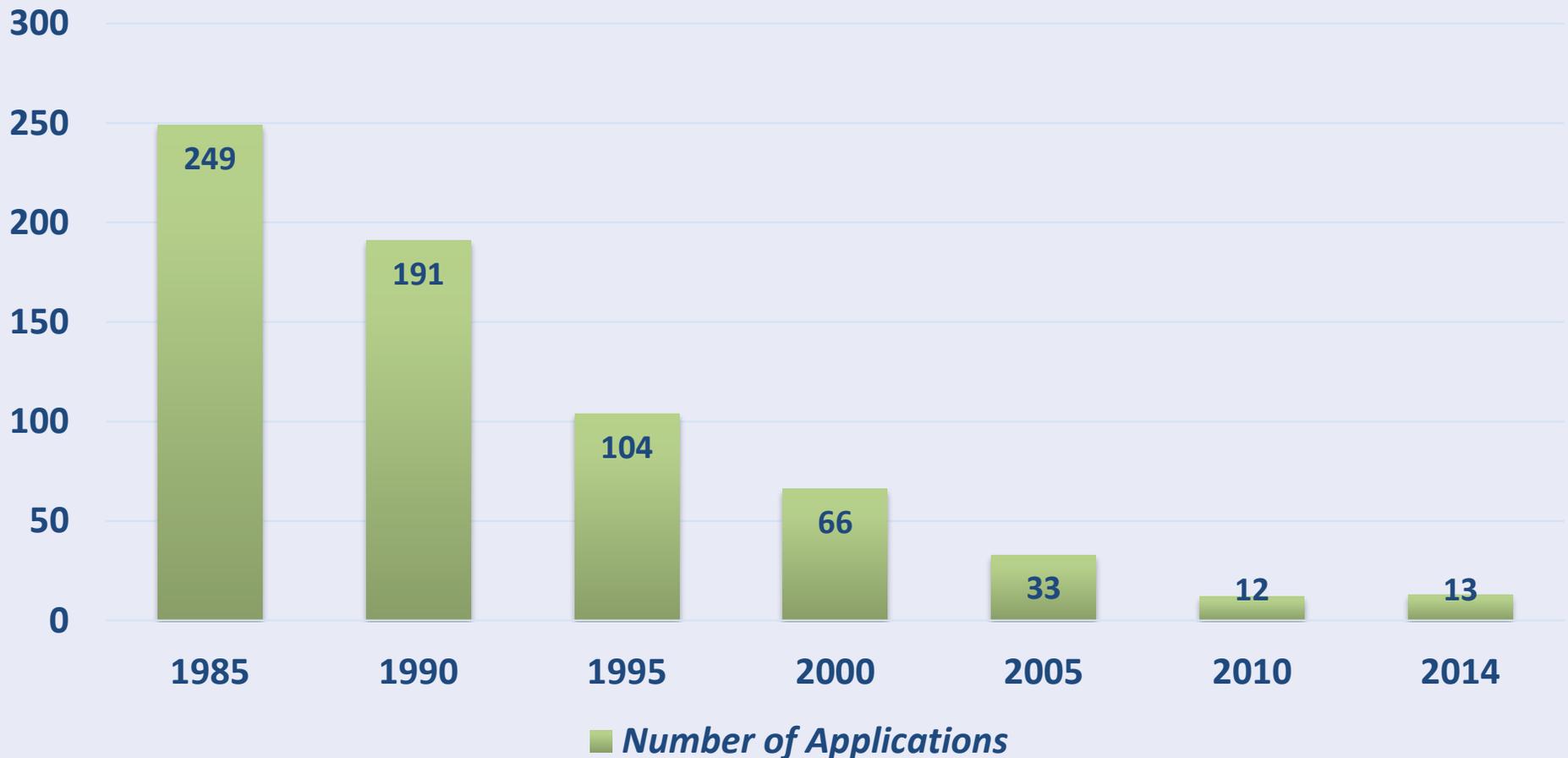
State CON Health Laws, 2013



Compiled by NCSL November 2013; based on data from AHPA & State Agencies.



Hospital Beds and Facilities Applications Received: A Snapshot



Acute Care Bed Inventory by District

July 1st of each year

| Year | District | | | | | | | | | | | | Statewide Occupancy | Percent Change* |
|---|----------|-------|-------|-------|-------|-------|-------|-------|---------------------------------|-------|-------|-----------|---------------------|-----------------|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | Statewide | | |
| 2004 | 1,813 | 1,695 | 3,569 | 4,207 | 4,394 | 5,681 | 4,668 | 3,871 | 4,413 | 4,851 | 7,817 | 46,979 | 58.00% | Baseline |
| 2005 | 1,868 | 1,723 | 3,673 | 4,321 | 4,398 | 5,756 | 4,824 | 3,965 | 4,404 | 4,991 | 7,824 | 47,747 | 58.53% | 1.63% |
| 2006 | 1,873 | 1,723 | 3,748 | 4,385 | 4,413 | 5,838 | 4,836 | 4,021 | 4,481 | 5,082 | 7,844 | 48,244 | 59.34% | 1.04% |
| 2007 | 1,873 | 1,678 | 3,851 | 4,435 | 4,446 | 5,878 | 5,088 | 4,264 | 4,494 | 5,082 | 7,761 | 48,850 | 58.71% | 1.26% |
| 2008 | 1,881 | 1,664 | 4,015 | 4,652 | 4,446 | 5,894 | 5,179 | 4,264 | 4,544 | 4,806 | 7,804 | 49,149 | 57.71% | 0.61% |
| 2009 | 1,881 | 1,629 | 4,005 | 4,674 | 4,446 | 6,101 | 5,473 | 4,066 | 4,587 | 4,767 | 7,933 | 49,562 | 57.57% | 0.84% |
| 2010 | 1,924 | 1,648 | 3,792 | 4,884 | 4,433 | 6,133 | 5,559 | 4,084 | 4,619 | 4,798 | 7,802 | 49,676 | 56.60% | 0.23% |
| 2011 | 1,936 | 1,609 | 3,798 | 4,926 | 4,389 | 6,162 | 5,641 | 4,055 | 4,634 | 4,798 | 7,927 | 49,875 | 56.68% | 0.40% |
| 2012 | 1,936 | 1,609 | 3,850 | 4,935 | 4,282 | 6,149 | 5,742 | 4,099 | 4,623 | 4,912 | 7,900 | 50,037 | 56.10% | 0.32% |
| 2013 | 1,936 | 1,631 | 4,022 | 4,851 | 4,361 | 6,208 | 5,915 | 4,130 | 4,788 | 4,912 | 7,619 | 50,373 | 55.89% | 0.67% |
| 2014 | 1,936 | 1,655 | 4,022 | 5,062 | 4,361 | 6,208 | 6,125 | 4,122 | 4,854 | 4,926 | 7,663 | 50,934 | 55.96% | 1.11% |
| 2015 | 2,024 | 1,679 | 4,106 | 5,076 | 4,190 | 6,173 | 6,102 | 4,113 | 4,898 | 4,902 | 7,699 | 50,962 | 55.63% | 0.05% |
| *Percent change from previous year Source: Florida Agency for Health Care Administration, Hospital Beds and Services List, July 2004-July 2015 and Florida Hospital Bed Need Projections and Service Utilization by District, July 2004-January 2015 | | | | | | | | | Average Percent Change per Year | | | -0.37% | 0.74% | |
| | | | | | | | | | Percent Change, 2004-2015 | | | -4.09% | 8.48% | |



Statewide Occupancy by Bed Type

| Bed Type | FY 2009-2010 | # of Beds | FY 2013-2014 | # of Beds | Total Increase In Occupancy | Total Increase in Beds |
|-----------------------|--------------|-----------|--------------|-----------|-----------------------------|------------------------|
| Long Term Care | 62.64% | 1,358 | 67.50% | 1,421 | 4.86% | 63 |
| Level II NICU | 77.84% | 939 | 72.27% | 1,032 | -0.57% | 93 |
| Level III NICU | 71.15% | 681 | 65.57% | 765 | -5.58% | 84 |
| Adult Psychiatric | 64.31% | 3,347 | 69.50% | 3,862 | 5.19% | 515 |
| Child Psychiatric | 63.44% | 795 | 60.31% | 724 | -3.13% | -71 |
| Adult Substance Abuse | 38.98% | 432 | 58.27% | 292 | 19.29% | -140 |
| CMR | 60.48% | 2,311 | 65.52% | 2,442 | 5.04% | 131 |



Statewide Procedures by Program

| Type of Program | FY 2009-2010 | | FY 2013-2014 | | Total Increase in Program | Total Increase in Procedure |
|-------------------------------|---------------|-----------------|---------------|-----------------|---------------------------|-----------------------------|
| | # of programs | # of procedures | # of programs | # of procedures | | |
| Pediatric Cath | 8 | 2,607 | 10 | 1,984 | 2 | -623 |
| Pediatric Open Heart | 8 | 1,139 | 10 | 1,159 | 2 | 20 |
| Adult Transplantation Program | 39 | 2,455 | 42 | 2,561 | 3 | 106 |
| Pediatric Transplant Programs | 20 | 174 | 21 | 182 | 1 | 8 |
| Burn Units | 4 | | 5 | | 1 | |





RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

Certificate of Need (CON)

Minimum Statutory and Rule Requirements

Applicants must attest to meeting certain minimum staffing, equipment, access and quality standards pinpointed in the Florida Statutes and the Florida Administrative Code (F.A.C.). Examples specifically related to each type of hospital or hospital service are illustrated in the table below.

| Hospital or Hospital Service and Applicable Rule or Statute | Standards |
|---|--|
| <p>General Acute Care Hospitals Florida Statute 408.035 and 59C-2.100 F.A.C. <i>59C-1.0365 F.A.C. (Repealed 7/19/2005)</i></p> | <ul style="list-style-type: none"> • The extent to which the proposed services will enhance access to health care for residents of the service district. • The extent to which the proposal will foster competition that promotes quality and cost-effectiveness. • The applicant’s past and proposed provision of health care services to Medicaid patients and the medically indigent. |
| <p>Psychiatric Hospitals 59C-1.040 F.A.C.</p> | <ul style="list-style-type: none"> • Specialty hospital--minimum total capacity of 40 beds. • Shall include, at a minimum, emergency screening services, pharmacology, individual therapy, family therapy, activities therapy, discharge planning, and referral services. • Shall also provide outpatient services, either directly or through written agreements with community outpatient mental health programs, such as local psychiatrists, local psychologists, community mental health programs, or other local mental health outpatient programs. • Shall have a screening program to assess the most appropriate treatment for the patient. • Non-Competitive Applicants: A separately organized unit for adults and for children and adolescents shall have a minimum of 15 bed and 10 beds, respectively. • Should be available within a maximum ground travel time of 45 minutes under average travel conditions for at least 90% percent of the district’s total population. • Comply with Agency standards is required. |
| <p>Substance Abuse Services 59C-1.041 F.A.C.</p> | <ul style="list-style-type: none"> • Specialty hospital--minimum total capacity of 40 beds, which may include beds used for Hospital Inpatient General Psychiatric Services • Shall include, at a minimum, emergency screening services; treatment planning services; pharmacology, if appropriate; individual therapy; family therapy; discharge planning; referral services, including written referral agreements for educational |



| | |
|---|--|
| | <p>and vocational services; and occupational and recreational therapies.</p> <ul style="list-style-type: none"> • Shall also provide outpatient or referral services, either directly or through written agreements with community outpatient substance abuse programs, such as local psychiatrists, other physicians trained in the treatment of psychiatric or substance abuse disorders, local psychologists, community mental health programs, or other local substance abuse outpatient programs. • Shall have a screening program to assess the most appropriate treatment for the patient. • Non-Competitive Applicants: A separately organized unit for adults and for children and adolescents shall have a minimum of 10 beds and five beds, respectively. • Should be available within a maximum ground travel time of 45 minutes under average travel conditions for at least 90% percent of the district’s total population. • Compliance with Agency standards is required. |
| <p>Comprehensive Medical Rehabilitation (CMR) 59C-1.039 F.A.C.</p> | <ul style="list-style-type: none"> • General hospital--Minimum of 20 CMR Inpatient Beds. • Specialty hospital--Minimum of 60 CMR Inpatient Beds. • Applicants shall state in their application that they will participate in the Medicare and Medicaid programs. • Services must be provided under a medical director of rehabilitation who is a Board certified or Board eligible physiatrist and has had at least 2 years of experience in the medical management of inpatients requiring rehabilitation services. • At least the following services provided by qualified personnel: <ol style="list-style-type: none"> 1. Rehabilitation nursing; 2. Physical therapy; 3. Occupational therapy; 4. Speech therapy; 5. Social services; 6. Psychological services; or 7. Orthotic and prosthetic services. |
| <p>Neonatal Intensive Care Unit (NICU) 59C-1.042 F.A.C.</p> | <ul style="list-style-type: none"> • New Level III NICU--at least 15 beds, and should have 15 or more Level II NICU beds. • New Level II NICU--minimum of 10 beds. • Level II and Level III NICU shall be available within 2 hours ground travel time under normal traffic conditions for 90% percent of the population in a service District. • Level II NICU shall be directed by a neonatologist or a group of neonatologists who are on active staff of the hospital with unlimited privileges and provide 24-hour coverage, and who are either board certified or board eligible in neonatal-perinatal medicine. • Level III NICU shall be directed by a neonatologist or a group of neonatologists who are on active staff of the hospital with |

unlimited privileges and provide 24 hours coverage, and who are either board certified or board eligible in neonatal-perinatal medicine. In addition, facilities with Level III NICU shall be required to maintain a maternal fetal medical specialist on active staff of the hospital with unlimited staff privileges.

- The nursing staff shall be under the supervision of a head nurse with experience and training in neonatal intensive care nursing. The head nurse shall be a registered professional nurse. At least one-half of the nursing personnel assigned to each work shift must be registered nurses.
- Nurses shall be trained to administer cardio-respiratory monitoring, assist in ventilation, administer I.V. fluids, provide pre-operative and post-operative care of newborns requiring surgery, manage neonates being transported, and provide emergency treatment of conditions such as apnea, seizures, and respiratory distress.
- At least one certified respiratory care practitioner therapist with expertise in the care of neonates shall be available at all times. There shall be at least one respiratory therapist technician for every four infants receiving assisted ventilation.
- Blood gas determination shall be available and accessible on a 24-hour basis in all hospitals with Level II or Level III NICU.
- Hospitals shall provide on-site, on a 24-hour basis, x-ray, obstetric ultrasound, and clinical laboratory services. Anesthesia shall be available on an on-call basis within 30 minutes. Clinical laboratory services shall have the capability to perform microstudies.
- Each hospital shall have a dietician or nutritionist to provide information on patient dietary needs while in the hospital and to provide the patient's family instruction or counseling regarding the appropriate nutritional and dietary needs of the patient after discharge.
- Each hospital shall make available the services of the hospital's social services department to patients' families which shall include, but not be limited to, family counseling and referral to appropriate agencies for services.
- Each hospital shall provide in-hospital intervention services for infants identified as being at high risk for developmental disabilities to include developmental assessment, intervention, and parental support and education.
- Each hospital shall have an interdisciplinary staff responsible for discharge planning.
- Level II NICU Standards:
 - Hospitals shall have a nurse to neonate ratio of at least 1:4 in Level II NICUs at all times. At least 50% percent of the nurses shall be registered nurses.

- Requirements for Level II NICU Patient Stations:
 1. Fifty square feet per infant;
 2. Two wall mounted suction outlets preferably equipped with a unit alarm to signal loss of vacuum;
 3. Eight electrical outlets;
 4. Two oxygen outlets and an equal number of compressed air outlets and adequate provisions for mixing these gases;
 5. An incubator or radiant warmer;
 6. One heated humidifier and oxyhood;
 7. One respiration or heart rate monitor;
 8. One resuscitation bag and mask;
 9. One infusion pump;
 10. At least one oxygen analyzer for every three beds;
 11. At least one non-invasive blood pressure monitoring device for every three beds;
 12. At least one portable suction device; and,
 13. Not less than one ventilator for every three beds.
- Equipment Required to be Available to Each Level II NICU:
 1. An EKG machine with print-out capability;
 2. Transcutaneous oxygen monitoring equipment; and,
 3. Availability of continuous blood pressure measurement.
- Level III NICU Standards.
 - Shall have a pediatric cardiologist, who is either board certified or board eligible in pediatric cardiology, available for consultation at all times.
 - Shall have a nurse to neonate ratio of at least 1:2 at all times. At least 50% percent of the nurses shall be registered nurses.
- Requirements for Level III NICU Patient Stations:
 1. Eighty square feet per infant;
 2. Two wall mounted suction outlets preferably equipped with an alarm to signal loss of vacuum;
 3. Twelve electrical outlets;
 4. Two oxygen outlets and an equal number of compressed air outlets with adequate provision for mixing these gases;
 5. An incubator and radiant warmer;
 6. One heated humidifier and oxyhood;
 7. One respiration or heart rate monitor;
 8. One resuscitation bag and mask;
 9. One infusion pump;
 10. At least one non-invasive blood pressure monitoring device for every three beds;
 11. At least one portable suction device; and,
 12. Availability of devices capable of measuring continuous arterial oxygenation in the patient.
- Equipment Required in Each Level III NICU:
 1. An EKG machine with print-out capability;
 2. Portable suction equipment; and,
 3. Not less than one ventilator for every three beds.

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| | <ul style="list-style-type: none"> • Each hospital shall have or participate in an emergency 24-hour patient transportation system. • Hospitals must operate a 24-hour emergency transportation system directly, or contract for this service, or participate through a written financial or non-financial agreement with a provider of emergency transportation services. • A hospital providing only Level II NICU shall provide documentation of a transfer agreement with a facility providing Level III NICU in the same or nearest service District for patients in need of Level III services. Facilities providing Level III NICU shall not unreasonably withhold consent to transfer agreements which provide for transfers based upon availability of service in the Level III facility, and which will be applied uniformly to all patients requiring transfer to Level III. |
| <p>Organ Transplantation 59C-1.044 F.A.C.</p> <p><i>Note: This table provides an overview of requirements for all transplantation programs, regardless of the type. For specialized requirements related to each specific type of transplantation program, please see the Rule.</i></p> | <ul style="list-style-type: none"> • Applicants for transplantation programs, shall have: <ul style="list-style-type: none"> ○ Staff and other resources necessary to care for the patient’s chronic illness prior to transplantation, during transplantation, and in the post-operative period. Services and facilities for inpatient and outpatient care shall be available on a 24-hour basis. ○ If cadaveric transplantation will be part of the transplantation program, a written agreement with an organ acquisition center for organ procurement is required. A system by which 24-hour call can be maintained for assessment, management and retrieval of all referred donors, cadaver donors or organs shared by other transplant or organ procurement agencies is mandatory. ○ An age-appropriate (adult or pediatric) intensive care unit which includes facilities for prolonged reverse isolation when required. ○ A clinical review committee for evaluation and decision-making regarding the suitability of a transplant candidate. ○ Written protocols for patient care for each type of organ transplantation program including, at a minimum, patient selection criteria for patient management and evaluation during the pre-hospital, in-hospital, and immediate post-discharge phases of the program. ○ Detailed therapeutic and evaluative procedures for the acute and long term management of each transplant program patient, including the management of commonly encountered complications. ○ Equipment for cooling, flushing, and transporting organs. If cadaveric transplants are performed, equipment for organ preservation through mechanical perfusion is necessary. Applicants for a bone marrow transplantation program are exempt from this requirement. This requirement may be met through an agreement with an organ procurement Agency. ○ An on-site tissue-typing laboratory or a contractual |

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| | <p>arrangement with an outside laboratory within the State of Florida, which meets the requirements of the American Society of Histocompatibility.</p> <ul style="list-style-type: none"> ○ Pathology services with the capability of studying and promptly reporting the patient’s response to the organ transplantation surgery, and analyzing appropriate biopsy material. ○ Blood banking facilities. ○ A program for the education and training of staff regarding the special care of transplantation patients. ○ Education programs for patients, their families and the patient’s primary care physician regarding after-care for transplantation patients. <ul style="list-style-type: none"> ● Applicants shall meet the following staffing requirements: <ul style="list-style-type: none"> ○ A staff of physicians with expertise in caring for patients with end-stage disease requiring transplantation. The staff shall have medical specialties or sub-specialties appropriate for the type of transplantation program to be established. The program shall employ a transplant physician, and a transplant surgeon, if applicable, as defined by the United Network for Organ Sharing (UNOS) June 1994. The UNOS definitions are incorporated herein by reference. A physician with one year experience in the management of infectious diseases in the transplant patient shall be a member of the transplant team; ○ A program director who shall have a minimum of 1 year of formal training and 1 year of experience at a transplantation program for the same type of organ transplantation program proposed. (c) A staff with experience in the special needs of children if pediatric transplantations are performed; ○ A staff of nurses, and nurse practitioners with experience in the care of chronically ill patients and their families; ○ Contractual agreements with consultants who have expertise in blood banking and are capable of meeting the unique needs of transplant patients on a long term basis; ○ Nutritionists with expertise in the nutritional needs of transplant patients; ○ Respiratory therapists with expertise in the needs of transplant patients; and, ○ 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. |
| <p>Pediatric Cardiac Catheterization 59C-1.032 F.A.C.</p> | <ul style="list-style-type: none"> ● Shall be capable of providing immediate endocardiac catheter pacemaking in cases of cardiac arrest, and pressure recording for monitoring and to evaluate valvular disease, or heart failure. |

- A range of non-invasive cardiac or circulatory diagnostic services must be available within the health care facility itself, including:
 1. Hematology studies or coagulation studies;
 2. Electrocardiography;
 3. Chest x-ray;
 4. Blood gas studies; and,
 5. Clinical pathology studies and blood chemistry analysis.
- At a minimum a cardiac catheterization program shall include:
 1. A special procedure x-ray room;
 2. A film storage and darkroom for proper processing of films;
 3. X-ray equipment with the capability in cineangiography, or equipment with similar capabilities;
 4. An image intensifier;
 5. An automatic injector;
 6. A diagnostic x-ray examination table for special procedures;
 7. An electrocardiograph;
 8. A blood gas analyzer;
 9. A multichannel polygraph; and,
 10. Emergency equipment including but not limited to a temporary pacemaker unit with catheters, ventilatory assistance devices, and a DC defibrillator.
- Shall have the capability of rapid mobilization of the study team within 30 minutes for emergency procedures 24 hours a day, 7 days a week.
- Shall indicate the projected number of medically indigent and Medicaid patients to be served annually.
- Must document that adequate numbers of properly trained personnel will be available. At a minimum, a team involved in Cardiac Catheterization consists of a physician, one nurse, and one or more technicians.
- Shall document that the following staff are available:
 1. A program director, board-certified or board-eligible in internal medicine, or radiology with subspecialty training in cardiology or cardiovascular, radiology; the program director for programs performing Pediatric Cardiac Catheterization shall be board-eligible or board-certified by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics or the American Osteopathic Association in the area of pediatric cardiology;
 2. A physician, board-certified or board-eligible in cardiology, radiology, or with specialized training in cardiac catheterization and angiographic techniques who will perform the examination;
 3. Support staff, specially trained in critical care of cardiac patients, with a knowledge of cardiovascular medication and an understanding of catheterization and angiographic equipment;
 4. Support staff, highly skilled in conventional radiographic techniques and angiographic principles, knowledgeable in every aspect of catheterization and angiographic instrumentation, with a thorough knowledge of the anatomy and physiology of the circulatory system;

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| | <p>5. Support staff for patient observation, handling blood samples and performing blood gas evaluation calculations;</p> <p>6. Support staff for monitoring physiologic data and alerting the physician of any changes;</p> <p>7. Support staff to perform systematic tests and routine maintenance on cardiac catheterization equipment, who must be available immediately in the event of equipment failure during a procedure;</p> <p>8. Support staff trained in photographic processing and in the operation of automatic processors used for both sheet and cine film; and,</p> <p>9. A Medical Review Committee which reviews medical invasive procedures such as endoscopy and cardiac catheterization.</p> |
| <p>Open Heart Surgery Program 59C-1.033 F.A.C.</p> | <ul style="list-style-type: none"> • Must have the capability to provide a full range of open heart surgery operations, including, at a minimum: <ol style="list-style-type: none"> 1. Repair or replacement of heart valves; 2. Repair of congenital heart defects; 3. Cardiac revascularization; 4. Repair or reconstruction of intrathoracic vessels; and, 5. Treatment of cardiac trauma. • Must document its ability to implement and apply circulatory assist devices such as intra-aortic balloon assist and prolonged cardiopulmonary partial bypass. • Shall provide the following services: <ol style="list-style-type: none"> 1. Cardiology, hematology, nephrology, pulmonary medicine, and treatment of infectious diseases; 2. Pathology, including anatomical, clinical, blood bank, and coagulation laboratory services; 3. Anesthesiology, including respiratory therapy; 4. Radiology, including diagnostic nuclear medicine; 5. Neurology; 6. Inpatient cardiac catheterization; 7. Non-invasive cardiographics, including electrocardiography, exercise stress testing, and echocardiography; 8. Intensive care; and, 9. Emergency care available 24 hours per day for cardiac emergencies. • Shall be available within a maximum automobile travel time of 2 hours under average travel conditions for at least 90% percent of the district's population. • Shall be available for elective open heart operations 8 hours per day, 5 days a week. Each open heart surgery program shall possess the capability for rapid mobilization of the surgical and medical support teams for emergency cases 24 hours per day, 7 days a week. • Shall be available for emergency open heart surgery operations within a maximum waiting period of 2 hours. • Shall be available to all persons in need. A patient's eligibility for open heart surgery shall be independent of his or her ability to |

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- Must document that adequate numbers of properly trained personnel will be available to perform in the following capacities during open heart surgery:
 1. A cardiovascular surgeon, board-certified by the American Board of Thoracic Surgery, or board-eligible;
 2. A physician to assist the operating surgeon;
 3. A board-certified or board-eligible anesthesiologist trained in open heart surgery;
 4. A registered nurse or certified operating room technician trained to serve in open heart surgery operations and perform circulating duties; and,
 5. A perfusionist to perform extracorporeal perfusion, or a physician or a specially trained nurse, technician, or physician assistant under the supervision of the operating surgeon to operate the heart-lung machine.
- Following an open heart surgery operation, patients shall be cared for in an intensive care unit that provides 24 hour nursing coverage with at least one registered nurse for every two patients during the first hours of post-operative care for both adult and pediatric cases. There shall be at least two cardiac surgeons on the staff of a hospital with an Adult Open Heart Surgery Program, at least one of whom is board-certified and the other at least board-eligible. One of these surgeons must be on call at all times. There shall be at least one board certified or board eligible pediatric cardiac surgeon on the staff of a hospital with a Pediatric Open Heart Surgery Program. A clinical cardiologist must be available for consultation to the surgical team and responsible for the medical management of patients as well as the selection of suitable candidates for surgery along with the cardiovascular surgical team. Backup personnel in cardiology, anesthesiology, pathology, thoracic surgery and radiology shall be on call in case of an emergency. Twenty-four hour per day coverage must be arranged for the operation of the cardiopulmonary bypass pump. All members of the team caring for cardiovascular surgical patients must be proficient in cardiopulmonary resuscitation.
- Charges for open heart surgery operations in a hospital shall be comparable with the charges established by similar institutions in the service area, when patient mix, reimbursement methods, cost accounting methods, labor market differences and other extenuating factors are taken into account.

No Materials Available