

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 1 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0000 - INITIAL COMMENTS**

**Title** INITIAL COMMENTS

**Type** Memo Tag

**Regulation Definition**

**Interpretive Guideline**

These guidelines are meant solely to provide guidance to surveyors in the survey process.

Add the most current Baker Act Regulation Set to the survey if the Hospital is a designated Baker Act Receiving Facility. To generate a list, use AHCA's Florida Health Finder website <http://www.floridahealthfinder.gov/facilitylocator/FacilitySearch.aspx> and filter by provider type and check the box at the bottom for "Baker Act Receiving Facility".

**ST - H0001 - Child Abuse & Neglect - Policy Adoption**

**Title** Child Abuse & Neglect - Policy Adoption

**Type** Rule

59A-3.280(1) FAC; 395.1023(1) FS

**Regulation Definition**

59A-3.280  
(1) Every licensed hospital admitting or treating shall adopt and incorporate a policy that requires every staff member to report any case of actual or suspected child abuse or neglect pursuant to chapter 39, F.S.

395.1023  
Each licensed facility shall adopt a protocol that, at a minimum, requires the facility to:  
(1) Incorporate a facility policy that every staff member has an affirmative duty to report, pursuant to chapter 39, any actual

**Interpretive Guideline**

- Request the Child Abuse and Neglect Policy.
- Review that the policy mandates that every staff member report actual or suspected child abuse or neglect to the Department of Children and Family Services Abuse Registry.
- Interview staff to determine how this policy of mandated reporting is distributed to staff.
- Interview staff to ascertain their knowledge of when, how, where, and what to report to DCF (1-800-962-2873).

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 2 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

or suspected case of child abuse, abandonment, or neglect

**ST - H0002 - Child Abuse & Neglect - Report A/N to DCF**

**Title** Child Abuse & Neglect - Report A/N to DCF

**Type** Rule

59A-3.280(1)(a) FAC

**Regulation Definition**

(1) Every licensed hospital admitting or treating shall adopt and incorporate a policy that requires every staff member to report any case of actual or suspected child abuse or neglect pursuant to chapter 39, F.S.

(a) Each report of actual or suspected child abuse or neglect shall be made immediately to the Department of Children and Family Services' Florida Abuse Hotline, statewide toll free number 1(800)962-2873 or to the local office of the Department of Children and Family Services responsible for investigating such reports.

**Interpretive Guideline**

- Request and review the hospital policy and procedure for reporting suspected child abuse/neglect
- Request any cases of alleged child abuse/neglect from the Risk Manager.
- Review for immediate and appropriate reporting.

**ST - H0003 - Child Abuse & Neglect -Report To Med Examiner**

**Title** Child Abuse & Neglect -Report To Med Examiner

**Type** Rule

59A-3.280(1)(b) FAC

**Regulation Definition**

(b) Any person required to report suspected child abuse or neglect, who has reasonable cause to suspect that a child died as a result of abuse or neglect, shall report his suspicion to the local medical examiner.

**Interpretive Guideline**

- Request and review records concerning suspected and actual child abuse or neglect resulting in death.
- Verify report of such suspicions to Medical Examiner.
- Review Child Abuse & Neglect Policy for the specific reporting of a death to the local/appropriate medical examiner.
- Review policy for clarity as to where to report.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 3 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

- Interview staff for knowledge of this policy.

**ST - H0004 - Child Abuse & Neglect - Physician Liaison**

**Title** Child Abuse & Neglect - Physician Liaison

**Type** Rule

59A-3.280(2) FAC; 395.1023(2) FS

**Regulation Definition**

59A-3.280

(2) Each hospital admitting or treating children shall designate, at the request of the Department of Children and Family Services, a staff physician, ARNP or PA to act as a liaison between the hospital, the child protective investigator and the child protection team.

395.1023

Each licensed facility shall adopt a protocol that, at a minimum, requires the facility to:

(2) In any case involving suspected child abuse, abandonment, or neglect, designate, at the request of the department, a staff physician to act as a liaison between the hospital and the Department of Children and Families office which is investigating the suspected abuse, abandonment, or neglect, and the Child Protection Team, as defined in s. 39.01, when the case is referred to such a team.

**Interpretive Guideline**

- Review documentation for a protocol re: appointment of a physician liaison.
- Review documentation to ensure that, in instances in which DCF has so requested, the facility has actually appointed a qualified individual to serve as the physician liaison (interview physician as appropriate)

**ST - H0005 - Child Abuse & Neglect - Policy Reporting**

**Title** Child Abuse & Neglect - Policy Reporting

**Type** Rule

59A-3.280(3) FAC

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 4 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(3) Child Abuse and Neglect Policy Reporting. Each hospital admitting or treating children shall formulate a child abuse and neglect policy and shall submit a copy of this policy to the Department of Children and Family Services, Office of Family Safety, 1317 Winewood Boulevard - Building 1, Tallahassee, Florida 32399-0700.

**Interpretive Guideline**

-Verify the submission of the facility Child Abuse and Neglect Policy to the Department of Children and Family Services, Office of Family Safety.

**ST - H0006 - Child Abuse & Neglect - Copy of Policy Sent**

**Title** Child Abuse & Neglect - Copy of Policy Sent

**Type** Rule

59A-3.280(4) FAC; 395.1023(2) FS

**Regulation Definition**

59A-3.280(4) Remedies. Failure to comply with these rules will result in a fine being imposed in accordance with the provisions of Sections 395.1023 and 39.205, F.S.

395.1023(2) ... Each general hospital and appropriate specialty hospital shall comply with the provisions of this section and shall notify the agency and the department of its compliance by sending a copy of its policy to the agency and the department as required by rule. The failure by a general hospital or appropriate specialty hospital to comply shall be punished by a fine not exceeding \$1,000, to be fixed, imposed, and collected by the agency. Each day in violation is considered a separate offense.

**Interpretive Guideline**

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 5 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0007 - COMPREHENSIVE EMERGENCY MANAGEMENT PLAN**

**Title** COMPREHENSIVE EMERGENCY MANAGEMENT PLAN

**Type** Rule

59A-3.078(2, 4-6 & 8-10); 395.1056(1)

**Regulation Definition**

59A-3.078 Comprehensive Emergency Management Plan.  
(2) The emergency management plan shall be developed in conjunction with other agencies and providers of health care services within the local community pursuant to section 395.1055(1)(c), F.S., and in accordance with the "Emergency Management Planning Criteria for Hospitals," AHCA Form 3130-8005-September 94, which is incorporated by reference. The form is available from the Agency for Health Care Administration, 2727 Mahan Drive, Mail Stop #31, Tallahassee, Florida 32308. The plan shall include:

- (a) Provisions for internal and external disasters and emergencies;
- (b) A description of the hospital's role in community wide emergency management plans;
- (c) Information about how the hospital plans to implement specific procedures outlined in the hospital's emergency management plan;
- (d) Precautionary measures, including voluntary cessation of hospital admissions, to be taken by the hospital in preparation and response to warnings of inclement weather, or other potential emergency conditions;
- (e) Provisions for the management of patients, including the discharge of all patients that meet discharge requirements, in the event of an evacuation order, at the direction of the hospital administrator, or when a determination is made by the Agency that the condition of the facility or its support services is sufficient to render it a hazard to the health and safety of

**Interpretive Guideline**

- Verify there is a plan approved by the county emergency management agency on file in the facility.
- Where is the plan located? Is it immediately accessible by hospital staff? [59A-3.078 (5)]
- Has the hospital tested the implementation of the CEMP as required?
- Review required staff training.
- Interview personnel regarding their role during emergencies.

59A-3.303(6), FAC refers to Intensive Residential Treatment Programs.

Refer to CORE Tag Z830 for additional requirements.

**Agency for Health Care Administration  
ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 6 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

patients and staff, pursuant to chapter 59A-3, F.A.C. Such provisions shall address moving patients within the hospital and relocating patients outside the hospital, including the roles and responsibilities of the physician and the hospital in the decision to move or relocate patients whose life or health is threatened;

(f) Education and training of personnel in carrying out their responsibilities in accordance with the adopted plan;

(g) A provision for coordinating with other hospitals that would receive relocated patients;

(h) Provisions for the management of staff, including the distribution and assignment of responsibilities and functions, and the assignment of staff to accompany those patients located at off-site locations;

(i) Provisions for the individual identification of patients, including the transfer of patient records;

(j) Provisions to ensure that a verification check will be made to ensure relocated patients arrive at designated hospitals;

(k) Provisions to ensure that medication needs will be reviewed and advance medication for relocated patients will be forwarded to respective hospitals, when permitted by existing supplies, and state and federal law;

(l) Provisions for essential care and services for patients who may be relocated to the facility during a disaster or an emergency, including staffing, supplies and identification of patients;

(m) Provisions for contacting relatives and necessary persons advising them of patient location changes. A procedure must also be established for responding to inquiries from patient families and the press;

(n) Provisions for the management of supplies, communications, power, emergency equipment, security, and the transfer of records;

(o) Provisions for coordination with designated agencies including the Red Cross and the county emergency

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 7 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

management office; and,

(p) Plans for the recovery phase of the operation, to be carried out as soon as possible.

(4) The hospital shall test the implementation of the emergency management plan semiannually, either in response to a disaster or an emergency or in a planned drill, and shall evaluate and document the hospital's performance to the hospital's safety committee. As an alternative, the hospital may test its plan with the frequency specified by an accrediting organization.

(5) The emergency management plan shall be located for immediate access by hospital staff.

(6) In the event a disaster or emergency conditions have been declared by the local emergency management authority, and the hospital does not evacuate the premises, a facility may provide emergency accommodations above the licensed capacity for patients. However, the following conditions must be met:

(a) The facility must report being over capacity and the conditions causing it to the Agency area office within 48 hours or as soon as practical. As an alternative, the facility may report to the Agency central office, Hospital and Outpatient Services Unit, at (850)412-4549;

(b) Life safety cannot be jeopardized for any individual;

(c) The essential needs of patients must be met; and,

(d) The facility must be staffed to meet the essential needs of patients.

(8) If a facility evacuates during or after a disaster or an emergency situation, the facility shall not be reoccupied until a determination is made by the hospital administrator that the facility can meet the needs of the patients.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 8 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(9) A facility with significant structural damage shall relocate patients until approval is received from the Agency's Office of Plans and Construction that the facility can be safely reoccupied, in accordance with rule 59A-3.080, F.A.C.

(10) A facility that must evacuate the premises due to a disaster or emergency conditions shall report the evacuation to the Agency area office within 48 hours or as soon as practical. The administrator or designee is responsible for knowing the location of all patients until the patient has been discharged from the facility. The names and location of patients relocated shall be provided to the local emergency management authority or its designee having responsibility for tracking the population at large. The licensee shall inform the Agency area office of a contact person who will be available 24 hours a day, seven days a week, until the facility is reoccupied.

395.1056(1)(a) Those portions of a comprehensive emergency management plan that address the response of a public or private hospital to an act of terrorism as defined by s. 775.30 held by the agency, a state or local law enforcement agency, a county or municipal emergency management agency, the Executive Office of the Governor, the Department of Health, or the Division of Emergency Management are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

(b) Information made confidential and exempt by this subsection may be disclosed by a custodial agency to another state or federal agency to prevent, detect, guard against, respond to, investigate, or manage the consequences of any attempted or actual act of terrorism, or to prosecute those persons who are responsible for such attempts or acts.

(c) Portions of a comprehensive emergency management plan that address the response of a public or private hospital to an



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 9 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

act of terrorism include those portions addressing:

1. Security systems or plans;
2. Vulnerability analyses;
3. Emergency evacuation transportation;
4. Sheltering arrangements;
5. Postdisaster activities, including provisions for emergency power, communications, food, and water;
6. Postdisaster transportation;
7. Supplies, including drug caches;
8. Staffing;
9. Emergency equipment; and
10. Individual identification of residents, transfer of records, and methods of responding to family inquiries.

**ST - H0008 - LICENSURE PROCEDURE (IRTP)**

**Title** LICENSURE PROCEDURE (IRTP)

**Type** Rule

59A-3.300, FAC

**Regulation Definition**

Facilities desiring licensure under this rule shall follow the procedure as described in rule 59A-3.066, F.A.C., and shall comply with the provisions of rules 59A-3.300 through 59A-3.310, F.A.C., which establishes the minimum standards for licensure as a Class IV specialty hospital. These rules emphasize the programmatic requirements designed to meet the needs of the patient in a safe therapeutic environment and are intended to be used in licensing intensive residential treatment facilities for children and adolescents as specialty hospitals pursuant to section 395.002(15), F.S. Unless otherwise specified, rules 59A-3.300 through 59A-3.310, F.A.C., supersede the requirements of rules 59A-3.240-.243, 59A-3.247, 59A-3.254, 59A-3.255 and 59A-3.278, F.A.C., for the purpose of licensing intensive treatment facilities for

**Interpretive Guideline**

Interview Administrator to verify if the hospital is licensed as an IRTP.

NOTE: Refer to Tags #H0252 through #H0297 when surveying this type facility.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 10 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

children and adolescents as specialty hospitals.

**ST - H0009 - Inf Disease Exposure Rpt - Notification**

**Title** Inf Disease Exposure Rpt - Notification

**Type** Rule

59A-3.251 FAC; 395.1025 FS

**Regulation Definition**

59A-3.251 Hospital Reporting of Exposure to Selected Infectious Diseases.

The licensed facility shall establish a written policy and procedure for notifying EMTs, paramedics or their emergency medical transportation service employer, or other persons known to have been exposed to a patient with a selected infectious disease while transporting or treating an ill or injured patient to that licensed facility. Selected infectious diseases are defined as Acquired Immunodeficiency Syndrome; anthrax; syphilis in an infectious stage; diphtheria; disseminated vaccinia; Hansen's disease; hepatitis A; hepatitis B; hepatitis non A, non B, Legionnaire's disease; malaria; measles; meningococcal meningitis; plague; poliomyelitis, psittacosis; pulmonary tuberculosis; Q fever; rabies; rubella; typhoid fever. Each licensed facility shall designate a person or persons to notify the EMT's, paramedics or their emergency medical transportation service employer or other persons known to have been exposed to a patient with a selected infectious disease.

395.1025 Infectious diseases; notification.-Notwithstanding the provisions in s. 381.004, if, while treating or transporting an ill or injured patient to a licensed facility, an emergency medical technician, paramedic, or other person comes into direct contact with the patient who is subsequently diagnosed as having an infectious disease, it shall be the duty of the

**Interpretive Guideline**

- Review the facility Infectious Diseases Policies and Procedures to determine if the facility has a written policy and procedure for notifying health care workers, transportation personnel or other persons known to have been in direct contact with a patient who has a confirmed infectious disease.
- Does the policy identify selected infectious diseases as defined in the regulation which require notification?
- Does the policy specify who must be notified?
- Interview the infection control officer(s) to determine who is responsible for this notification.
- Is there documentation that this notification process is in place and has been implemented when required?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 11 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

licensed facility receiving the patient to notify the emergency medical technician, paramedic, or his or her emergency medical transportation service employer, or other person of the individual's exposure to the patient within 48 hours, or sooner, of confirmation of the patient's diagnosis and to advise him or her of the appropriate treatment, if any. Notification made pursuant to this section shall be done in a manner which will protect the confidentiality of such patient information and shall not include any patient's name.

**ST - H0011 - Inf Disease Exposure Rpt - Written**

**Title** Inf Disease Exposure Rpt - Written

**Type** Rule

59A-3.251(1-5), FAC

**Regulation Definition**

These procedures shall include at a minimum the following:

- (1) Notification of exposure to a selected infectious disease, either verbal or written, must take place within 48 hours of a confirmed diagnosis.
- (2) Verbal notification of such exposure to a selected infectious disease must be followed by written notification within 48 hours of a confirmed diagnosis.
- (3) Identification of EMT, paramedic, or other known persons to have been in contact with the patient during treatment or transport, if notification is made to the EMS provider.
- (4) Both written and verbal notification shall contain at a minimum:
  - (a) Name of disease;
  - (b) Signs and symptoms of clinical disease;
  - (c) Date of exposure to the selected infectious disease;
  - (d) Incubation period of disease;
  - (e) Mode of spread of the disease; and,
  - (f) Advisement of appropriate diagnosis, prophylaxis, and

**Interpretive Guideline**

- Review a sample of cases of exposure and notifications for the past year.
- Is there either verbal or written documentation notifying exposure to a selected infectious disease was provided within 48 hours of a confirmed diagnosis and does it meet the requirements of the regulation?
- Interview staff to inquire how exposure notifications are completed.
- Does the facility policy and procedure for notification of exposure to selected infectious diseases require confidentiality of patient information?
- Is the patient's name excluded from both written and verbal notification?

Refer to TAG 0314

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 12 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

treatment, if any.

(5) Confidentiality of patient information must be maintained.

The name of the patient shall not be disclosed.

**ST - H0012 - LICENSURE - SPECIALTY HOSPITAL**

**Title** LICENSURE - SPECIALTY HOSPITAL

**Type** Rule

395.003(6)

**Regulation Definition**

(6)(a) A specialty hospital may not provide any service or regularly serve any population group beyond those services or groups specified in its license. A specialty-licensed children's hospital that is authorized to provide pediatric cardiac catheterization and pediatric open-heart surgery services may provide cardiovascular service to adults who, as children, were previously served by the hospital for congenital heart disease, or to those patients who are referred for a specialized procedure only for congenital heart disease by an adult hospital, without obtaining additional licensure as a provider of adult cardiovascular services. The agency may request documentation as needed to support patient selection and treatment. This subsection does not apply to a specialty-licensed children's hospital that is already licensed to provide adult cardiovascular services.

(b) A specialty-licensed children's hospital that has licensed neonatal intensive care unit beds and is located in District 5 or District 11, as defined in s. 408.032, as of January 1, 2018, may provide obstetrical services, in accordance with the pertinent guidelines promulgated by the American College of Obstetricians and Gynecologists and with verification of guidelines and compliance with internal safety standards by the Voluntary Review for Quality of Care Program of the

**Interpretive Guideline**

Paragraph (b) applies to Hospitals in the following counties:

District 5.-Pasco and Pinellas Counties.  
Johns Hopkins All Children's Hospital

District 11.-Miami-Dade and Monroe Counties  
Nicklaus Children's Hospital

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 13 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

American College of Obstetricians and Gynecologists and in compliance with the agency's rules pertaining to the obstetrical department in a hospital and offer healthy mothers all necessary critical care equipment, services, and the capability of providing up to 10 beds for labor and delivery care, which services are restricted to the diagnosis, care, and treatment of pregnant women of any age who have documentation by an examining physician that includes information regarding:

1. At least one fetal characteristic or condition diagnosed intra-utero that would characterize the pregnancy or delivery as high risk including structural abnormalities of the digestive, central nervous, and cardiovascular systems and disorders of genetic malformations and skeletal dysplasia, acute metabolic emergencies, and babies of mothers with rheumatologic disorders; or
2. Medical advice or a diagnosis indicating that the fetus may require at least one perinatal intervention.

This paragraph shall not preclude a specialty-licensed children's hospital from complying with s. 395.1041 or the Emergency Medical Treatment and Active Labor Act, 42 U.S.C. s. 1395dd.

**ST - H0014 - LICENSURE PROCEDURES - Initial Lic Documents**

**Title** LICENSURE PROCEDURES - Initial Lic Documents

**Type** Rule

59A-3.066(2), (2)(a) & (9)

**Regulation Definition**

(2) All applicants or licensees requesting licensure for the operation of a hospital under the provisions of Chapter 395, F.S., must make application to the Agency, on Health Care Licensing Application Hospital, AHCA Form 3130-8001, July 2022, incorporated by reference, and available at:

**Interpretive Guideline**

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 14 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

<https://www.flrules.org/Gateway/reference.asp?No=Ref-14971>

. Applicants for renewal and changes during licensure may submit the Health Care Licensing Online Application, Hospital, AHCA Form 3130-8001OL, July 2022, incorporated by reference and available at

<https://www.flrules.org/Gateway/reference.asp?No=Ref-14972>

. The application forms are available online at

<http://www.ahca.myflorida.com/HQALicensureforms> or, for online submissions, at:

<http://apps.ahca.myflorida.com/SingleSignOnPortal>.

Applicants must receive a standard or provisional license prior to the acceptance of patients for care or treatment.

(a) The following documents must be available for review by the Agency at the licensure inspection:

1. Governing authority bylaws, rules and regulations, or other written organization plan;
2. Organized professional staff bylaws, rules and regulations;
3. The hospital's fire and Comprehensive Emergency Management Plans;
4. Roster of organized medical staff members;
5. Nursing procedure manual;
6. Roster of registered nurses, licensed practical nurses, emergency medical technicians and paramedics with current registration number; and
7. A copy of the child abuse and neglect policy as specified in Rule 59A-3.280, F.A.C.

(9) Each hospital must be designated by a distinctive name, and the name may not be changed without first notifying the licensing agency and receiving approval in writing.

Duplication of an existing hospital name is prohibited in new hospitals. Fictitious names must be registered with the Florida Department of State Division of Corporations, as required by the Department of State.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 15 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0016 - LICENSURE PROCEDURES - Number of Beds**

**Title** LICENSURE PROCEDURES - Number of Beds

**Type** Rule

59A-3.066(4); 395.003(4) FS

**Regulation Definition**

59A-3.066(4) No licensed facility shall continuously operate a number of hospital beds greater than the number indicated by the Agency on the face of the license.

395.003(4) The agency shall issue a license that specifies the service categories and the number of hospital beds in each bed category for which a license is received. Such information shall be listed on the face of the license. A licensed facility shall not operate a number of hospital beds greater than the number indicated by the agency on the face of the license without approval from the agency under conditions established by rule.

**Interpretive Guideline**

- Review facility file prior to survey; note capacity and previous survey report.
- Review facility census reports to verify that the facility is not continuously operating a greater number of beds than indicated on the license.
- If the hospital meets the definition of specialty hospital set forth in s.395.002(28), F.S., ensure that the hospital is not providing services or regularly serving any population group beyond services/groups specified in license.
- If questionable, count the number of beds during the walk-through and verify any discrepancies. The location of beds needs to be documented for the file using a sketch of the facility's floor plan, notes of building numbers, etc.

**ST - H0017 - LICENSURE PROCEDURES - Leased Beds**

**Title** LICENSURE PROCEDURES - Leased Beds

**Type** Rule

59A-3.066(5)

**Regulation Definition**

(5) Hospitals shall not lease a portion of their licensed beds to another entity or facility, except for hospices licensed pursuant to Chapter 400, Part IV, F.S.

**Interpretive Guideline**

- Determine if the hospital is leasing a portion of their licensed beds to another entity and if so, what services that entity provides.

NOTE: Management contracts are permissible.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 16 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0018 - LICENSURE PROCEDURES - Residential Program**

**Title** LICENSURE PROCEDURES - Residential Program

**Type** Rule

59A-3.066(6)(a-c)

**Regulation Definition**

(6) The collocation of any residential program on the premises of a licensed hospital requires prior approval from the agency, based on the following criteria:

- (a) Health, safety, and welfare cannot be jeopardized for any individual;
- (b) The essential needs of patients must be met; and,
- (c) The facility must be staffed to meet the essential needs of patients.

**Interpretive Guideline**

- Verify that the required agency approval is on file if another residential program is operating on the premises of a hospital.

Examples may include:

- a crisis stabilization unit
- a Chapter 400 licensed nursing home
- substance abuse

NOTE: Check with the Central Office before citing a deficiency for this tag.

**ST - H0019 - PATIENT RIGHTS & CARE - Initial Assessment**

**Title** PATIENT RIGHTS & CARE - Initial Assessment

**Type** Rule

59A-3.254(1)(a-b) FAC

**Regulation Definition**

(1) Patient Assessment. Each hospital shall develop and adopt policies and procedures to ensure an initial assessment of the patient's physical, psychological and social status, appropriate to the patient's developmental age, is completed to determine the need and type of care or treatment required, and the need for further assessment. The scope and intensity of the initial assessment shall be determined by the patient's diagnosis, the treatment setting, the patient's desire for treatment, and response to previous treatment.

**Interpretive Guideline**

- Review sample of patient medical records to determine assessments. Are the care and services appropriate with the assessed needs? Are all appropriate facets of care covered including nutritional and evaluation for discharge planning?

If needed:

- Review written policies and procedures to determine if they contain all of the elements required by the regulation.
- Interview clinical director/nursing staff/dietary staff regarding how the facility determines the patients' needs, type of care and treatment which will be provided and ensure further assessment.



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 17 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(a) Such policies shall:

1. Specify the time period preceding or following admission within which the initial assessment shall be conducted;
2. Require that the initial assessment be documented in writing in the patient's medical record;

(b) The initial assessment shall determine the need for an assessment of the patient's nutritional and functional status, as well as discharge planning needs, when appropriate;

**ST - H0020 - PATIENT RIGHTS & CARE - Reassessment**

**Title** PATIENT RIGHTS & CARE - Reassessment

**Type** Rule

59A-3.254(1)(c-d) FAC

**Regulation Definition**

(c) The hospital shall have policies and procedures to ensure that periodic reassessments of the patient are conducted based on changes in either the patient's condition, diagnosis, or response to treatment;

(d) The hospital shall ensure that care and treatment decisions are based on the patient's identified needs and treatment priorities;

**Interpretive Guideline**

See guidance for H0019

**ST - H0021 - PATIENT RIGHTS & CARE - Indiv Treatment Plan**

**Title** PATIENT RIGHTS & CARE - Indiv Treatment Plan

**Type** Rule

59A-3.254(1)(e) FAC

**Regulation Definition**

(e) An individualized treatment plan shall be developed for each patient based upon the initial assessment and other

**Interpretive Guideline**

- Review the patient medical record to determine if the treatment plan is individualized based on the initial assessment and other diagnostic information as appropriate.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 18 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

diagnostic information as appropriate.

- If concerns, review policies and procedures.

**ST - H0022 - PATIENT RIGHTS & CARE - Coord of Care**

**Title** PATIENT RIGHTS & CARE - Coord of Care

**Type** Rule

59A-3.254(2) FAC

**Regulation Definition**

(2) Coordination of Care. Each hospital shall develop and implement policies and procedures on discharge planning which address:

- (a) Identification of patients requiring discharge planning;
- (b) Initiation of discharge planning on a timely basis;
- (c) Evaluation of prescription medications, ensuring the continued availability of medications for at least three days after discharge;
- (d) The role of the physician, other health care givers, the patient, and the patient's family in the discharge planning process; and
- (e) Documentation of the discharge plan in the patient's medical record including an assessment of the availability of appropriate services to meet identified needs following hospitalization.

**Interpretive Guideline**

- Review written policies and procedures to determine if they include provisions for identifying which patients require discharge planning, when the discharge plan is to be initiated and the role of the patient, family, and health care providers.
- Include in the patient sample patients who will be discharged during the survey, including those who may require discharge planning.
- Interview patients about their knowledge of discharge plan to determine if it corresponds to the documented plan.
- Were the physician, the appropriate health care disciplines, the patient and family involved in the plan?
- Look to see if the discharge plan includes arrangement for post-discharge services prior to discharge (i.e. home health services, specialized rehabilitative services, etc.). This should include appropriately licensed facilities as needed.
- Is discharge planning sufficient to prepare the patient for discharge to another setting without interruption of necessary care and services?  
Is the discharge plan appropriate for the post-hospital services needed? Interview the person responsible for discharge and coordination.
- Interview staff on discharge planning process. When is the discharge planning commenced? How are patients identified as required discharge planning?
- Review current and discharged patients for documentation of discharge planning and that the discharge planning meets the needs of the patients. Who played a role in the patients' discharge planning?

**ST - H0023 - PATIENT RIGHTS & CARE - Patient/Family Educat**

**Title** PATIENT RIGHTS & CARE - Patient/Family Educat

**Type** Rule

59A-3.254(3)(a)-(b) 1-2 FAC

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 19 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(3) Patient and Family Education.

(a) General Provisions. Each hospital shall develop a systematic approach to educating the patient and family to improve patient outcomes by promoting recovery, speedy return to function, promoting healthy behaviors, and involving patients in their care and care decisions.

(b) Each hospital shall provide the patient and family with education specific to the patient's assessed needs, capabilities, and readiness. Such education shall include when indicated:

1. An assessment when indicated, of the educational needs, capabilities, and readiness to learn based on cultural and religious practices, emotional barriers, desire and motivation to learn, physical and cognitive limitations, and language barriers;
2. Instruction in the specific knowledge or skills needed by the patient or family to meet the patient's ongoing health care needs including:
  - a. The use of medications.
  - b. The use of medical equipment.
  - c. Potential drug or food interactions, and nutritional intervention or modified diets.
  - d. Rehabilitation techniques.
  - e. Available community resources.
  - f. When and how to obtain further treatment; and
  - g. The patient's and family's responsibilities in the treatment process.

**Interpretive Guideline**

- Review written policies and procedures for provisions addressing patient and family education. The policies and procedures should address an interdisciplinary process for patient and family education, based on the patient's assessed needs, capabilities, and readiness. The education must be presented in a language the family and patient understand.
- Review the patient medical records to see that education was provided to the patient according to the established policies.
- Ask patients what education they have received from staff. Are identified resources provided to the patient/family?
- Review a sample of educational materials used for patient education.
- Patient education may be provided in many forms - written, verbal, television, computer based, and in individual and group settings.
- Interview patients and families identified as requiring education to ensure the provision of these services. Has the facility discussed the patient's needs once the patient has been discharged? Has the facility discussed issues (a-g)? Has the facility provided the family with any training, education, and resources to ensure continuation of care once the patient has been discharged?
- Interview case management on the policy and procedure of education, including how they identify patients and/or families that require education. Ask how the facility educates the patient and family.

**ST - H0024 - PATIENT RIGHTS & CARE - Discharge Instruction**

**Title** PATIENT RIGHTS & CARE - Discharge Instruction

**Type** Rule

59A-3.254(3)(b)3-4 FAC; 395.1053 FS

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 20 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

59A-3.254

(3) Patient and Family Education.

(b) Each hospital shall provide the patient and family with education specific to the patient's assessed needs, capabilities, and readiness. Such education shall include when indicated:

3. Information about any discharge instructions given to the patient or family shall be provided to the organization or individual responsible for providing continuing care.

4. Each hospital shall plan and support the provision and coordination of patient and family education activities by ensuring that:

a. Educational resources required are identified and made available; and

b. The educational process is interdisciplinary, as appropriate to the plan of care.

395.1053 Postpartum education.-A hospital that provides birthing services shall incorporate information on safe sleep practices and the possible causes of Sudden Unexpected Infant Death into the hospital's postpartum instruction on the care of newborns and provide to each parent the informational pamphlet on infant and childhood eye and vision disorders created by the department pursuant to s. 383.14(3)(i).

**Interpretive Guideline**

- Review the patient medical records for evidence of this communication according to the written policies and procedures. Look for form 3008 for the transfer to facility instructions.

- For example, if the patient was given discharge instructions and is being discharged to a nursing home, look to see how the hospital communicates these same discharge instructions to nursing home staff.

- Interview appropriate staff involved.

- If there are concerns, review written policies and procedures for provisions addressing how discharge instructions and educational resources are communicated to organizations or individuals responsible for providing continuing care.

**ST - H0025 - PATIENT RIGHTS & CARE -Refuse Tx, Adv Directi**

**Title** PATIENT RIGHTS & CARE -Refuse Tx, Adv Directi

**Type** Rule

59A-3.254(4)(a)-(b) FAC

**Regulation Definition**

(4) Patient Rights. Each hospital shall develop and adopt policies and procedures to ensure the following rights of the

**Interpretive Guideline**

- Review written policies and procedures for provisions for the patient's right to refuse treatment and life-prolonging procedures. Also, review these policies to determine if they address how patients are informed of their right to

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 21 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

patient:

(a) The right to refuse treatment and life-prolonging procedures as specified under section 765.302, F.S.;

(b) The right to formulate advance directives and designate a surrogate to make health care decisions on behalf of the patient as specified under chapter 765, F.S. The policies shall not condition treatment or admission upon whether or not the individual has executed or waived an advance directive. In the event of conflict between the facility's policies and procedures and the individual's advance directive, provision should be made in accordance with section 765.302, F.S. Policies shall include:

1. Provide each adult individual, at the time of the admission as an inpatient, with a copy of "Health Care Advance Directives - The Patient's Right to Decide," revised 2006, which is hereby incorporated by reference, and available at: <https://www.flrules.org/Gateway/reference.asp?No=Ref-04606> and from the Agency for Health Care Administration at: <https://floridahealthfinderstore.blob.core.windows.net/documents/reports-guides/documents/English-Health%20Care%20Advance%20Dir%202006.pdf> or with a copy of some other substantially similar document which is a written description of chapter 765, F.S., regarding advance directives;
2. Providing each adult individual, at the time of admission as an inpatient, with written information concerning the health care facility's policies respecting advance directives; and
3. The requirement that documentation of the existence of an advance directive be contained in the medical record. A health care facility which is provided with the individual's advance directive shall make the advance directive or a copy thereof a part of the individual's medical record.

formulate advanced directives.

- Request a copy of the facility information that is provided to patients upon admission for Advance Directives.
- Review the copy to determine if it provides a written description of state law regarding advance directives and includes the hospitals policies for respecting advance directives.

- Interview patients and/or representatives about advance directives.

Interview staff, how are patient's informed of the facility's rights?

Review patients' records, are there documented evidence the facility provided the patients with a copy of the "Health Care Advance Directives- The Patient's Right to Decide", patient's rights as set forth in (c-h).

- Some hospitals' religious or moral beliefs may conflict with the patient's advance directive. Section 765 of the Florida Statute for Advance Directives, titled "Transfer of a patient", states "A health care provider or facility that refuses to comply with a patient's advance directive, or the treatment decision of his or her surrogate, shall make reasonable efforts to transfer the patient to another health care provider or facility that will comply with the directive or treatment decision. This chapter does not require a health care provider or facility to commit any act which is contrary to the provider's or facility's moral or ethical beliefs."

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 22 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0029 - PATIENT RIGHTS & CARE - Add'l Policy/Procedur**

**Title** PATIENT RIGHTS & CARE - Add'l Policy/Procedur

**Type** Rule

59A-3.254(4)(c) to (5); 381.0261 & .026

**Regulation Definition**

59A-3.254

- (4)(c) The right to information about patient rights as set forth in section 381.026, F.S., and procedures for initiating, reviewing and resolving patient complaints;
- (d) The right to participate in the consideration of ethical issues that arise in the care of the patient;
- (e) The right to personal privacy and confidentiality of information including access to information contained in the patient's medical records as specified under section 395.3025, F.S.;
- (f) The right of the patient's next of kin or designated representative to exercise rights on behalf of the patient;
- (g) The right to an itemized patient bill upon request as specified under section 395.301, F.S.;
- (h) The right to be free of restraints consistent with the rights of mentally ill persons or patients as provided in section 394.459, F.S.
- (5) In addition to the provisions of this section, hospitals must comply with section 381.026, F.S.

381.0261 Summary of patient's bill of rights; distribution; penalty.-

- (1) The Department of Health shall publish on its Internet website a summary of the Florida Patient's Bill of Rights and Responsibilities. In adopting and making available to patients the summary of the Florida Patient's Bill of Rights and Responsibilities, health care providers and health care

**Interpretive Guideline**

- Review written policies and procedures for patient's rights.
- Ask staff how patients are informed of their rights and review written information given to patients.
- During patient interviews, ask the patient if he or she was informed of his or her patient rights, and, if so, how.

FOR COMPLAINTS: Review complaint/grievance policy for review/participation/resolving any complaint or grievance by a patient/family.

FS 383.50 Treatment of surrendered infant (infant means a child who a licensed physician reasonably believes is approximately 30 days old or younger). Each hospital in the state subject to 395.1041 shall, and any other hospital may, admit and provide all necessary emergency services and care, as defined in s. 395.002 (9), to any infant left with the hospital in accordance with this section. The hospital or any of its medical staff or licensed health care professionals shall consider these actions as implied consent for treatment, and a hospital accepting physical custody of an infant has implied consent to perform all necessary emergency services and care. The hospital or any of its medical staff or licensed health care professionals are immune from criminal or civil liability for acting in good faith in accordance with this section.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 23 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

facilities are not limited to the format in which the department publishes the summary.

(2) Health care providers and health care facilities, if requested, shall inform patients of the address and telephone number of each state agency responsible for responding to patient complaints about a health care provider or health care facility's alleged noncompliance with state licensing requirements established pursuant to law.

(3) Health care facilities shall adopt policies and procedures to ensure that inpatients are provided the opportunity during the course of admission to receive information regarding their rights and how to file complaints with the facility and appropriate state agencies.

(4)(a) An administrative fine may be imposed by the Agency for Health Care Administration when any health care facility fails to make available to patients a summary of their rights, pursuant to s. 381.026 and this section. Initial nonwillful violations shall be subject to corrective action and shall not be subject to an administrative fine. The Agency for Health Care Administration may levy a fine against a health care facility of up to \$5,000 for nonwillful violations and up to \$25,000 for intentional and willful violations. Each intentional and willful violation constitutes a separate violation and is subject to a separate fine.

381.026 Florida Patient's Bill of Rights and Responsibilities.-

(1) SHORT TITLE.-This section may be cited as the "Florida Patient's Bill of Rights and Responsibilities."

(2) DEFINITIONS.-As used in this section and s. 381.0261, the term:

(a) "Department" means the Department of Health.

(b) "Health care facility" means a facility licensed under chapter 395.

(c) "Health care provider" means a physician licensed under

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 24 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

chapter 458, an osteopathic physician licensed under chapter 459, a podiatric physician licensed under chapter 461, or an advanced practice registered nurse registered under s. 464.0123.

(d) "Primary care provider" means a health care provider licensed under chapter 458, chapter 459, or chapter 464 who provides medical services to patients which are commonly provided without referral from another health care provider, including family and general practice, general pediatrics, and general internal medicine.

(e) "Responsible provider" means a health care provider who is primarily responsible for patient care in a health care facility or provider's office.

(4) RIGHTS OF PATIENTS.-Each health care facility or provider shall observe the following standards:

(a) Individual dignity.-

1. The individual dignity of a patient must be respected at all times and upon all occasions.

2. Every patient who is provided health care services retains certain rights to privacy, which must be respected without regard to the patient's economic status or source of payment for his or her care. The patient's rights to privacy must be respected to the extent consistent with providing adequate medical care to the patient and with the efficient administration of the health care facility or provider's office.

However, this subparagraph does not preclude necessary and discreet discussion of a patient's case or examination by appropriate medical personnel.

3. A patient has the right to a prompt and reasonable response to a question or request. A health care facility shall respond in a reasonable manner to the request of a patient's health care provider for medical services to the patient. The health care facility shall also respond in a reasonable manner to the patient's request for other services customarily rendered by the



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 25 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

health care facility to the extent such services do not require the approval of the patient's health care provider or are not inconsistent with the patient's treatment.

4. A patient in a health care facility has the right to retain and use personal clothing or possessions as space permits, unless for him or her to do so would infringe upon the right of another patient or is medically or programmatically contraindicated for documented medical, safety, or programmatic reasons.

5. A patient receiving care in a health care facility or in a provider's office has the right to bring any person of his or her choosing to the patient-accessible areas of the health care facility or provider's office to accompany the patient while the patient is receiving inpatient or outpatient treatment or is consulting with his or her health care provider, unless doing so would risk the safety or health of the patient, other patients, or staff of the facility or office or cannot be reasonably accommodated by the facility or provider.

(b) Information.-

1. A patient has the right to know the name, function, and qualifications of each health care provider who is providing medical services to the patient. A patient may request such information from his or her responsible provider or the health care facility in which he or she is receiving medical services.

2. A patient in a health care facility has the right to know what patient support services are available in the facility.

3. A patient has the right to be given by his or her health care provider information concerning diagnosis, planned course of treatment, alternatives, risks, and prognosis, unless it is medically inadvisable or impossible to give this information to the patient, in which case the information must be given to the patient's guardian or a person designated as the patient's representative. A patient has the right to refuse this information.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 26 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

4. A patient has the right to refuse any treatment based on information required by this paragraph, except as otherwise provided by law. The responsible provider shall document any such refusal.
5. A patient in a health care facility has the right to know what facility rules and regulations apply to patient conduct.
6. A patient has the right to express grievances to a health care provider, a health care facility, or the appropriate state licensing agency regarding alleged violations of patients' rights. A patient has the right to know the health care provider's or health care facility's procedures for expressing a grievance.
7. A patient in a health care facility who does not speak English has the right to be provided an interpreter when receiving medical services if the facility has a person readily available who can interpret on behalf of the patient.
8. A health care provider or health care facility shall respect a patient's right to privacy and should refrain from making a written inquiry or asking questions concerning the ownership of a firearm or ammunition by the patient or by a family member of the patient, or the presence of a firearm in a private home or other domicile of the patient or a family member of the patient. Notwithstanding this provision, a health care provider or health care facility that in good faith believes that this information is relevant to the patient's medical care or safety, or safety of others, may make such a verbal or written inquiry.
9. A patient may decline to answer or provide any information regarding ownership of a firearm by the patient or a family member of the patient, or the presence of a firearm in the domicile of the patient or a family member of the patient. A patient's decision not to answer a question relating to the presence or ownership of a firearm does not alter existing law regarding a physician's authorization to choose his or her patients.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 27 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

10. A health care provider or health care facility may not discriminate against a patient based solely upon the patient's exercise of the constitutional right to own and possess firearms or ammunition.

11. A health care provider or health care facility shall respect a patient's legal right to own or possess a firearm and should refrain from unnecessarily harassing a patient about firearm ownership during an examination.

(c) Financial information and disclosure.-

1. A patient has the right to be given, upon request, by the responsible provider, his or her designee, or a representative of the health care facility full information and necessary counseling on the availability of known financial resources for the patient's health care.

2. A health care provider or a health care facility shall, upon request, disclose to each patient who is eligible for Medicare, before treatment, whether the health care provider or the health care facility in which the patient is receiving medical services accepts assignment under Medicare reimbursement as payment in full for medical services and treatment rendered in the health care provider's office or health care facility.

3. A primary care provider may publish a schedule of charges for the medical services that the provider offers to patients.

The schedule must include the prices charged to an uninsured person paying for such services by cash, check, credit card, or debit card. The schedule must be posted in a conspicuous place in the reception area of the provider's office and must include, but is not limited to, the 50 services most frequently provided by the primary care provider. The schedule may group services by three price levels, listing services in each price level. The posting must be at least 15 square feet in size.

A primary care provider who publishes and maintains a schedule of charges for medical services is exempt from the license fee requirements for a single period of renewal of a

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 28 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

professional license under chapter 456 for that licensure term and is exempt from the continuing education requirements of chapter 456 and the rules implementing those requirements for a single 2-year period.

4. If a primary care provider publishes a schedule of charges pursuant to subparagraph 3., he or she must continually post it at all times for the duration of active licensure in this state when primary care services are provided to patients. If a primary care provider fails to post the schedule of charges in accordance with this subparagraph, the provider shall be required to pay any license fee and comply with any continuing education requirements for which an exemption was received.

5. A health care provider or a health care facility shall, upon request, furnish a person, before the provision of medical services, a reasonable estimate of charges for such services. The health care provider or the health care facility shall provide an uninsured person, before the provision of a planned nonemergency medical service, a reasonable estimate of charges for such service and information regarding the provider's or facility's discount or charity policies for which the uninsured person may be eligible. Such estimates by a primary care provider must be consistent with the schedule posted under subparagraph 3. Estimates shall, to the extent possible, be written in language comprehensible to an ordinary layperson. Such reasonable estimate does not preclude the health care provider or health care facility from exceeding the estimate or making additional charges based on changes in the patient's condition or treatment needs.

6. Each licensed facility, except a facility operating exclusively as a state facility, shall make available to the public on its website or by other electronic means a description of and a hyperlink to the health information that is disseminated by the agency pursuant to s. 408.05(3). The facility shall place a notice in the reception area that such

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 29 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

information is available electronically and the website address. The licensed facility may indicate that the pricing information is based on a compilation of charges for the average patient and that each patient's statement or bill may vary from the average depending upon the severity of illness and individual resources consumed. The licensed facility may also indicate that the price of service is negotiable for eligible patients based upon the patient's ability to pay.

7. A patient has the right to receive a copy of an itemized statement or bill upon request. A patient has a right to be given an explanation of charges upon request.

(d) Access to health care.-

1. A patient has the right to impartial access to medical treatment or accommodations, regardless of race, national origin, religion, handicap, or source of payment.
2. A patient has the right to treatment for any emergency medical condition that will deteriorate from failure to provide such treatment.
3. A patient has the right to access any mode of treatment that is, in his or her own judgment and the judgment of his or her health care practitioner, in the best interests of the patient, including complementary or alternative health care treatments, in accordance with the provisions of s. 456.41.

(e) Experimental research.-In addition to the provisions of s. 766.103, a patient has the right to know if medical treatment is for purposes of experimental research and to consent prior to participation in such experimental research. For any patient, regardless of ability to pay or source of payment for his or her care, participation must be a voluntary matter; and a patient has the right to refuse to participate. The patient's consent or refusal must be documented in the patient's care record.

(f) Patient's knowledge of rights and responsibilities.-In

**Agency for Health Care Administration  
ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 30 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

receiving health care, patients have the right to know what their rights and responsibilities are.

(5) RESPONSIBILITIES OF PATIENTS.-Each patient of a health care provider or health care facility shall respect the health care provider's and health care facility's right to expect behavior on the part of patients which, considering the nature of their illness, is reasonable and responsible. Each patient shall observe the responsibilities described in the following summary.

(6) SUMMARY OF RIGHTS AND RESPONSIBILITIES.-Any health care provider who treats a patient in an office or any health care facility licensed under chapter 395 that provides emergency services and care or outpatient services and care to a patient, or admits and treats a patient, shall adopt and make available to the patient, in writing, a statement of the rights and responsibilities of patients, including the following:

**SUMMARY OF THE FLORIDA PATIENT'S BILL OF RIGHTS AND RESPONSIBILITIES**

Florida law requires that your health care provider or health care facility recognize your rights while you are receiving medical care and that you respect the health care provider's or health care facility's right to expect certain behavior on the part of patients. You may request a copy of the full text of this law from your health care provider or health care facility. A summary of your rights and responsibilities follows:

A patient has the right to be treated with courtesy and respect, with appreciation of his or her individual dignity, and with protection of his or her need for privacy.

A patient has the right to a prompt and reasonable response to

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 31 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

questions and requests.

A patient has the right to know who is providing medical services and who is responsible for his or her care.

A patient has the right to know what patient support services are available, including whether an interpreter is available if he or she does not speak English.

A patient has the right to bring any person of his or her choosing to the patient-accessible areas of the health care facility or provider's office to accompany the patient while the patient is receiving inpatient or outpatient treatment or is consulting with his or her health care provider, unless doing so would risk the safety or health of the patient, other patients, or staff of the facility or office or cannot be reasonably accommodated by the facility or provider.

A patient has the right to know what rules and regulations apply to his or her conduct.

A patient has the right to be given by the health care provider information concerning diagnosis, planned course of treatment, alternatives, risks, and prognosis.

A patient has the right to refuse any treatment, except as otherwise provided by law.

A patient has the right to be given, upon request, full information and necessary counseling on the availability of known financial resources for his or her care.

A patient who is eligible for Medicare has the right to know, upon request and in advance of treatment, whether the health care provider or health care facility accepts the Medicare assignment rate.

A patient has the right to receive, upon request, prior to treatment, a reasonable estimate of charges for medical care.

A patient has the right to receive a copy of a reasonably clear and understandable, itemized bill and, upon request, to have the charges explained.

A patient has the right to impartial access to medical treatment or accommodations, regardless of race, national origin,

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 32 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

religion, handicap, or source of payment.

A patient has the right to treatment for any emergency medical condition that will deteriorate from failure to provide treatment.

A patient has the right to know if medical treatment is for purposes of experimental research and to give his or her consent or refusal to participate in such experimental research.

A patient has the right to express grievances regarding any violation of his or her rights, as stated in Florida law, through the grievance procedure of the health care provider or health care facility which served him or her and to the appropriate state licensing agency.

A patient is responsible for providing to the health care provider, to the best of his or her knowledge, accurate and complete information about present complaints, past illnesses, hospitalizations, medications, and other matters relating to his or her health.

A patient is responsible for reporting unexpected changes in his or her condition to the health care provider.

A patient is responsible for reporting to the health care provider whether he or she comprehends a contemplated course of action and what is expected of him or her.

A patient is responsible for following the treatment plan recommended by the health care provider.

A patient is responsible for keeping appointments and, when he or she is unable to do so for any reason, for notifying the health care provider or health care facility.

A patient is responsible for his or her actions if he or she refuses treatment or does not follow the health care provider's instructions.

A patient is responsible for assuring that the financial obligations of his or her health care are fulfilled as promptly as possible.

A patient is responsible for following health care facility rules and regulations affecting patient care and conduct.



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 33 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0030 - EMERGENCY CARE - Signage Requirements**

**Title** EMERGENCY CARE - Signage Requirements

**Type** Rule

59A-3.255(1) FAC; 395.1041(3)(i) FS

**Regulation Definition**

(1) Signage Requirements.

(a) Each hospital offering emergency services and care shall post, in a conspicuous place in the emergency service area, a sign clearly stating a patient's right to emergency services and care as set forth in section 395.1041, F.S. The sign shall be posted in both English and in Spanish.

(b) Each hospital offering emergency services and care shall post a sign identifying the service capability of the hospital. The categories of services listed on the sign may be general in nature if the sign refers patients to another location within that facility where a list of the subspecialties is available. The sign identifying the service capability of the hospital and the additional listing of subspecialties, if a separate subspecialty list is maintained, shall be in both English and in Spanish.

(c) The signs required by this rule section shall be posted in a location where individuals not yet admitted to the hospital would reasonably be expected to present themselves for emergency services and care.

395.1041(3)(i) Each hospital offering emergency services shall post, in a conspicuous place in the emergency service area, a sign clearly stating a patient's right to emergency services and care and the service capability of the hospital.

**Interpretive Guideline**

-Verify that the sign stating a patient's right to emergency services is in a conspicuous place, is clearly readable, and that it is in both English and Spanish. Conspicuous place is defined as: a place where it is likely to be noticed by all individuals entering and in the emergency service areas.

-Compare the services capability sign for consistency with the Agency listing of the hospital's emergency services capability on the face of the hospital's license.

-At a minimum, the sign must specify the right of any individual who presents to the emergency department area to receive:

-medical screening, examination and evaluation to determine if an emergency medical condition exists, and if it does

- the care, treatment or surgery by a physician necessary to relieve or eliminate the emergency medical condition within the service capability of the facility. (review 395.1041)

This sign may be general in nature; i.e., 'This hospital offers the following services: obstetrics, neurosurgery, pediatrics, etc.'

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 34 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0031 - EMERGENCY CARE -Txfr Proc Persons Responsible**

**Title** EMERGENCY CARE -Txfr Proc Persons Responsible

**Type** Rule

59A-3.255(2)(a), FAC

**Regulation Definition**

(2) Transfer Procedures. Each hospital providing emergency services and care shall establish policies and procedures which incorporate the requirements of chapter 395, F.S., relating to emergency services. The policies and procedures shall incorporate:

(a) Decision protocols identifying the emergency services personnel within the hospital responsible for the arrangement of outgoing and incoming transfers;

**Interpretive Guideline**

- Review the policies and procedures relating to emergency services to determine:

- (a) does the policies specify the personnel positions authorized by the By Laws to conduct an appropriate transfer;
- (b) does it require documentation in the medical records of the reason(s) for the transfer;
- (c) does it specify the need to ascertain from the receiving facility that "it agrees to accept the patient", has space and qualified personnel available for the necessary services;
- (d) does it require documentation of: the name, position title of the person at the receiving facility with whom the transfer conversation took place, date and time the transfer conversation took place, and nature of the conversation that transpired.

- Draw a sample of 10 records involving patient transfers to check for evidence that these protocols are in effect. When reviewing the sample of records, the surveyor should be able to fully understand the rationale for the transfer, and the benefits vs. risks should be specified.

- Review the Transfer Log and Central Log for indicators of acuity levels of patients in the emergency department, that may explain justifiable reasons for delayed medical examination and review excessive wait times prior to commencement of medical screening.

- Look for excessive wait times prior to commencement of medical screening exam.

- Is a protocol established that identifies personnel positions that are responsible for arranging both incoming and outgoing transfers? (Transfer arrangements must be made between hospital ER personnel.)

**ST - H0032 - EMERGENCY CARE-Txfr Proc Conditions/Informed**

**Title** EMERGENCY CARE-Txfr Proc Conditions/Informed

**Type** Rule

59A-3.255(2)(b)1, FAC

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 35 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(2) Transfer Procedures. Each hospital providing emergency services and care shall establish policies and procedures which incorporate the requirements of chapter 395, F.S., relating to emergency services. The policies and procedures shall incorporate:

(b) Decision protocols stating the conditions that must be met prior to the transfer of a patient to another hospital. These conditions are:

1. If a patient, or a person who is legally responsible for the patient and acting on the patient's behalf, after being informed of the hospital's obligation under chapter 395, F.S., and of the risk of transfer, requests that the transfer be effected; or

**Interpretive Guideline**

- Is a protocol established that details the conditions that are to be met prior to the transfer of a patient to another facility.

- Is a protocol established to ensure that when a patient requests a transfer, the patient has been fully informed of the hospital's obligation to provide emergency services and care and of the associated risks involved in the patient's decision to be transferred to another facility?

**ST - H0033 - EMERGENCY CARE - Txfr Proc Written Certificat**

**Title** EMERGENCY CARE - Txfr Proc Written Certificat

**Type** Rule

59A-3.255(2)(b)2, FAC

**Regulation Definition**

(2) Transfer Procedures. Each hospital providing emergency services and care shall establish policies and procedures which incorporate the requirements of chapter 395, F.S., relating to emergency services. The policies and procedures shall incorporate:

(b) Decision protocols stating the conditions that must be met prior to the transfer of a patient to another hospital. These conditions are:

2. If a physician has signed a certification that, based upon the reasonable risks and benefits to the patient, and based upon the information available at the time of transfer, the medical

**Interpretive Guideline**

Is there a policy/protocol established to ensure that a physician certifies all transfers?  
Review medical records to view signed certification of transfer

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 36 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

benefits reasonably expected from the provision of appropriate medical treatment at another hospital outweigh the increased risks to the individual's medical condition from effecting the transfer; or

**ST - H0034 - EMERGENCY CARE - Txfr Proc Signed Certificati**

**Title** EMERGENCY CARE - Txfr Proc Signed Certificati

**Type** Rule

59A-3.255(2)(b)3, FAC

**Regulation Definition**

(2) Transfer Procedures. Each hospital providing emergency services and care shall establish policies and procedures which incorporate the requirements of chapter 395, F.S., relating to emergency services. The policies and procedures shall incorporate:

(b) Decision protocols stating the conditions that must be met prior to the transfer of a patient to another hospital. These conditions are:

3. If a physician is not physically present in the emergency services area at the time an individual is transferred, a qualified medical person may sign a certification that a physician with staff privileges at the transferring hospital, in consultation with such personnel, has determined that the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual's medical condition from effecting the transfer. The certification shall summarize the basis for such determination. The consulting physician must sign the certification within 72 hours of the transfer.

**Interpretive Guideline**

- Is there a protocol specifying the qualified medical persons who may sign a certificate of transfer when the physician is not physically present in the emergency services area?
- This protocol should be consistent with the professional practice acts at 64B-8 FAC.  
<http://www.floridahealth.gov/licensing-and-regulation/index.html>
- Verify that when someone other than a physician authorizes the transfer, that the consulting physician subsequently signs the certificate within the 72-hour time frame.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 37 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0035 - EMERGENCY CARE - Txfr Proc Closest Hospital**

**Title** EMERGENCY CARE - Txfr Proc Closest Hospital

**Type** Rule

59A-3.255(2)(c) FAC; 395.1041(3)(e) FS

**Regulation Definition**

(2) Transfer Procedures. Each hospital providing emergency services and care shall establish policies and procedures which incorporate the requirements of chapter 395, F.S., relating to emergency services. The policies and procedures shall incorporate:

(c) A provision providing that all medically necessary transfers shall be made to the geographically closest hospital with the service capability, unless another prior arrangement is in place or the geographically closest hospital is at service capacity as stated in section 395.1041(3)(e), F.S.

395.1041(3)

(e) Except as otherwise provided by law, all medically necessary transfers shall be made to the geographically closest hospital with the service capability, unless another prior arrangement is in place or the geographically closest hospital is at service capacity. When the condition of a medically necessary transferred patient improves so that the service capability of the receiving hospital is no longer required, the receiving hospital may transfer the patient back to the transferring hospital and the transferring hospital shall receive the patient within its service capability.

**Interpretive Guideline**

- Review the policies and procedures relating to emergency services to verify that there is a protocol established to ensure that the closest geographical hospital having the service capability is contacted first in transfer cases where another prior arrangement is not in place.
- If another prior arrangement is in place, review records to ensure that transfers are made in accordance with such agreement.
- Draw a sample of records involving patient transfers to check for evidence that this protocol is in effect.
- Review the Transfer Log / Manual for:
  - a list of receiving hospitals with the specified hospital's special care capabilities,
  - telephone number and contact person
- Is the Transfer Manual readily accessible to Emergency Department Staff?

(See H0047 for more guidance on the log/manual)

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 38 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0036 - EMERGENCY CARE - TRANSFER PROCEDURES**

**Title** EMERGENCY CARE - TRANSFER PROCEDURES

**Type** Rule

59A-3.255(2)(d-g) FAC;395.1041(4)(a)1 FS

**Regulation Definition**

59A-3.255

(2) Transfer Procedures. Each hospital providing emergency services and care shall establish policies and procedures which incorporate the requirements of chapter 395, F.S., relating to emergency services. The policies and procedures shall incorporate:

(d) Protocols for maintaining records of patient transfers made or received for a period of five years. Patient transfer information shall be incorporated separately in transfer logs and into the patient's permanent medical record as stated in section 395.1041(4)(a)1., F.S.

(e) Documentation of all current transfer arrangements that have been made with other hospitals and physicians.

(f) A copy of section 395.1041, F.S., Access to Emergency Services and Care, and a copy of this rule.

(g) Provisions for informing hospital emergency services personnel and medical staff of the hospital's emergency service policies and procedures, having at a minimum, the requirement to provide emergency services and care pursuant to section 395.1041, F.S.

395.1041

(4) RECORDS OF TRANSFERS; REPORT OF VIOLATIONS.-

(a)1. Each hospital shall maintain records of each transfer

**Interpretive Guideline**

- Verify that there is an established policy that provides for the maintenance of transfer records for 5 years.

- Sample transfer cases to verify records of transfers are maintained both in a transfer log as well as in the patients' medical records.

Review the medical records of the transferred patients to determine if they contain: available history, documentation related to the individual's emergency medical condition, preliminary diagnosis, results of diagnostic studies or telephone reports of the studies, treatment provided, results of any tests and the informed written consent.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 39 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

made or received for a period of 5 years. These records of transfers shall be included in a transfer log, as well as in the permanent medical record of any patient being transferred or received.

**ST - H0037 - EMERGENCY CARE - Records of Transfers**

**Title** EMERGENCY CARE - Records of Transfers

**Type** Rule

395.1041(4)(a)2. FS

**Regulation Definition**

(4) RECORDS OF TRANSFERS; REPORT OF VIOLATIONS.-

(a)2. Each hospital shall maintain records of all patients who request emergency care and services, or persons on whose behalf emergency care and services are requested, for a period of 5 years. These records shall be included in a log, as well as in the permanent medical record of any patient or person for whom emergency services and care is requested.

**Interpretive Guideline**

- Verify that there is a policy in place to ensure that a medical record is maintained on every patient seeking emergency care and that the record is incorporated into the patient's permanent medical record for a minimum of 5 years.
- Draw a sample of records to verify that complete medical records are maintained for each patient presenting to the emergency department. (Sample should be selected from the Emergency Department Logs.)

**ST - H0038 - EMERGENCY CARE - Inventory Reporting**

**Title** EMERGENCY CARE - Inventory Reporting

**Type** Rule

59A-3.255(3)(a-b) FAC

**Regulation Definition**

(3) Inventory Reporting.

(a) Pursuant to section 395.1041, F.S., the Agency is responsible for compiling an inventory of hospitals with emergency services. This inventory shall list all services within the service capability of the hospital. A copy of this

**Interpretive Guideline**

- Review the hospital's current license to determine what emergency services are provided and have been reported to the Agency as being within service capability of the hospital.
- If, during the review of sample records, the surveyor determines that the hospital is providing a service that is not included on the inventory, then a deficiency should be cited.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 40 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

inventory is available on the Agency's website at:

[http://ahca.myflorida.com/MCHQ/Health\\_Facility\\_Regulation/Hospital\\_Outpatient/hospital.shtml](http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/hospital.shtml).

(b) Every hospital offering emergency services and care shall report to the Agency for inclusion in the inventory those services which are within the service capability of the hospital.

The following services, when performed on an infrequent and short time limited basis, are not considered to be within the service capability of the hospital:

1. Services performed for investigative purposes under the auspices of a federally approved institutional review board; or
2. Services performed for educational purposes; or
3. Emergencies performed by physicians who are not on the active medical staff of the reporting hospital.

**ST - H0039 - EMERGENCY CARE - Addition of Service**

**Title** EMERGENCY CARE - Addition of Service

**Type** Rule

59A-3.255(3)(c) FAC

**Regulation Definition**

(c) Any addition of service shall be reported to the Agency prior to the initiation of the service. The Agency will act accordingly to include the service in the next publication of the inventory and to add the service on the face of the hospital license.

**Interpretive Guideline**

- If a surveyor finds the hospital is offering a service and the service was not reported on the inventory, notify the field office. The field office will notify agency (Central Office) and they will notify the hospital and provide the hospital with an opportunity to respond. The agency shall arrange for an on-site visit prior to the agency's determination of capability, with advance notice of the on-site visit.

- If, after investigation, the agency determines that a service is offered by the hospital as evidenced by the patient medical records or itemized bills, the agency shall amend the inventory and the face of the hospital license.



**Agency for Health Care Administration  
ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 41 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0040 - EMERGENCY CARE - Exemptions**

**Title** EMERGENCY CARE - Exemptions

**Type** Rule

59A-3.255(4)(a); 395.1041(3)(d)1 & 3 FS

**Regulation Definition**

59A-3.255 Emergency Services/Exemptions.

(4) Exemptions.

(a) Every hospital providing emergency services shall ensure the provision of services within the service capability of the hospital, 24 hours per day, 7 days per week either directly or indirectly through:

1. An agreement with another hospital made prior to receipt of a patient in need of the service; or
2. An agreement with one or more physicians made prior to receipt of a patient in need of the service; or
3. Any other arrangement made prior to receipt of a patient in need of the service.

395.1041(3) EMERGENCY SERVICES;  
DISCRIMINATION; LIABILITY OF FACILITY OR  
HEALTH CARE PERSONNEL.-

(d)1. Every hospital shall ensure the provision of services within the service capability of the hospital, at all times, either directly or indirectly through an arrangement with another hospital, through an arrangement with one or more physicians, or as otherwise made through prior arrangements. A hospital may enter into an agreement with another hospital for purposes of meeting its service capability requirement, and appropriate compensation or other reasonable conditions may be negotiated for these backup services.

(d)3. A hospital shall not be required to ensure service

**Interpretive Guideline**

- Review the hospitals current license to determine what emergency services are provided and hours of operation.
- Review the Central Log to determine actual services being provided.
- Ascertain if a Transfer Agreement is in place.
- Review the emergency department on call schedule to verify that 24/7 on call coverage is provided for all emergency services listed on the hospital's license. (This requirement can be met by in-house physician coverage or through a specific agreement with another hospital for a particular service. General transfer agreements would not meet this requirement.)

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 42 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

capability at all times as required in subparagraph 1. if, prior to the receiving of any patient needing such service capability, such hospital has demonstrated to the agency that it lacks the ability to ensure such capability and it has exhausted all reasonable efforts to ensure such capability through backup arrangements. In reviewing a hospital's demonstration of lack of ability to ensure service capability, the agency shall consider factors relevant to the particular case, including the following:

- a. Number and proximity of hospitals with the same service capability.
- b. Number, type, credentials, and privileges of specialists.
- c. Frequency of procedures.
- d. Size of hospital.

**ST - H0041 - EMERGENCY CARE - Exemption Application**

**Title** EMERGENCY CARE - Exemption Application

**Type** Rule

59A-3.255(4)(d) & (f) FAC

**Regulation Definition**

(4) Exemptions

(d) When a hospital has been providing 24 hour per day, 7 day per week coverage either directly or indirectly through an agreement with another hospital or physician(s) for a specialty service as evidenced by the inventory and hospital license, and the circumstances significantly change such that the hospital can no longer provide the service on a 24 hour per day, 7 day per week basis, the hospital must apply for an exemption from the Agency. The Agency will make a determination of exemption status pursuant to subsection (5) of this rule and notify the hospital of the determination within 45 days of receipt of the request.

**Interpretive Guideline**

Ask the facility if they have been granted any exemption and if so contact the Agency's Hospital and Outpatient Services Unit to determine if the facility has been granted an exemption for any emergency services.

- Contact the Agency's Hospital and Outpatient Services Unit to determine the circumstances that existed at the hospital at the time the exemption was granted.
- Verify with the Hospital and Outpatient Services Unit that the hospital has not reported any change in the circumstances that led to the granting of the exemption.
- Verify from record samples and from review of the medical staff roster that the circumstances that existed when the exemption was granted have not changed.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 43 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(f) Each hospital shall immediately report any change in the conditions which led to the granting of an exemption.

**ST - H0043 - EMERGENCY CARE - Emergency Services Personnel**

**Title** EMERGENCY CARE - Emergency Services Personnel

**Type** Rule

59A-3.255(6)(a)1 FAC

**Regulation Definition**

59A-3.255(6) Service Delivery Requirements.

(a) Every hospital offering emergency services and care shall provide emergency care available 24 hours a day within the hospital to patients presenting to the hospital. At a minimum:

1. Emergency services personnel shall be available to ensure that emergency services and care are provided in accordance with section 395.002(10), F.S.

**Interpretive Guideline**

- Review the volume of ER patients and verify that there is adequate medical and nursing personnel qualified in emergency care to provide the emergency services listed on the hospital's license as within its service capability, and to meet the needs of the patients requiring those services.
- Review patient records to determine if a medical screening, examination and evaluation was provided. (The hospital must determine through screening, triage and assessment, if an emergency medical condition exists, and if it does, must provide the care, treatment or surgery by a physician necessary to relieve or eliminate the emergency medical condition within the service capability of the facility.)

**ST - H0044 - EMERGENCY CARE - On-Call Physician Available**

**Title** EMERGENCY CARE - On-Call Physician Available

**Type** Rule

59A-3.255(6)(a)2 FAC

**Regulation Definition**

(6) Service Delivery Requirements.

(a) Every hospital offering emergency services and care shall provide emergency care available 24 hours a day within the hospital to patients presenting to the hospital. At a minimum:

2. At least one physician shall be available within 30 minutes through a medical staff call roster; initial consultation through two-way voice communication is acceptable for physician presence.

**Interpretive Guideline**

- Review Physician on-call Policy & Procedures / By Laws to determine if systematic procedures are in place to ensure there is an on- call physician available to the emergency room at all times.
- Review at the Physician on-call schedule.
- Review a sample of records to ensure that the physician on call responds within the 30 minute time frame.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 44 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0045 - EMERGENCY CARE - Specialty Consultation**

**Title** EMERGENCY CARE - Specialty Consultation

**Type** Rule

59A-3.255(6)(a)3 FAC

**Regulation Definition**

(6) Service Delivery Requirements.  
(a) Every hospital offering emergency services and care shall provide emergency care available 24 hours a day within the hospital to patients presenting to the hospital. At a minimum:  
3. Specialty consultation shall be available by request of the attending physician or by transfer to a designated hospital where definitive care can be provided.

**Interpretive Guideline**

Review rosters designating medical staff members on duty or on call for specialty consultation are posted in the emergency services care area.

**ST - H0046 - EMERGENCY CARE - Medical Records with Txfr**

**Title** EMERGENCY CARE - Medical Records with Txfr

**Type** Rule

59A-3.255(6)(b) FAC

**Regulation Definition**

(b) When a patient is transferred from one hospital to another, all pertinent medical information shall accompany the patient being transferred.

**Interpretive Guideline**

Review patient records to determine if the appropriate medical information accompanied the patient transferred.

NOTE: Individuals being transferred to another hospital must be accompanied by necessary medical information. Necessary documentation should include available history records related to the individual's emergency medical condition, observations of signs or symptoms, preliminary diagnosis, results of diagnostic studies or telephone reports of the studies, treatment provided, results of any tests and the informed written consent and physician certification.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 45 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0047 - EMERGENCY CARE - Txfr Manual Outgoing**

**Title** EMERGENCY CARE - Txfr Manual Outgoing

**Type** Rule

59A-3.255(6)(c) FAC; 395.1041(3)(d)2 FS

**Regulation Definition**

59A-3.255(6)(c) Every hospital offering emergency services and care shall maintain a transfer manual, which shall include in addition to the requirements in subsection (2) of this rule:

1. Decision protocols for when to transfer a patient;
2. A list of receiving hospitals with special care capabilities, including the telephone number of a contact person;
3. A list of all "on-call" critical care physicians available to the hospital, including their telephone numbers; and
4. Protocols for receiving a call from a transferring hospital, including:
  - a. Requirements for specific information regarding the patient's problem;
  - b. Estimated time of patient arrival;
  - c. Specific medical requirements;
  - d. A request to transfer the patient's medical record with the patient; and
  - e. The name of the transporting service.

395.1041(3)(d)2

If any arrangement requires the provision of emergency medical transportation, such arrangement must be made in consultation with the applicable provider and may not require the emergency medical service provider to provide transportation that is outside the routine service area of that provider or in a manner that impairs the ability of the emergency medical service provider to timely respond to prehospital emergency calls.

**Interpretive Guideline**

- Verify that the hospital maintains a transfer manual.
- Does the manual address decision protocols for when to transfer a patient?
- Is a list maintained of recipient hospitals having specialized service capabilities? The list should include telephone numbers and contact persons.
- Is a list of on-call specialists maintained (including telephone numbers)?
- Are protocols in place to address procedures that must be followed when a transfer request is received from another hospital?
- Verify that a specific person on each shift has responsibility for being knowledgeable of the transfer manual and maintaining it.
- Is a list of on-call specialists maintained, to include telephone numbers?
- Are protocols in place to address procedures that must be followed when a transfer request is received from another hospital?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 46 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

3. A hospital shall not be required to ensure service capability at all times as required in subparagraph 1. if, prior to the receiving of any patient needing such service capability, such hospital has demonstrated to the agency that it lacks the ability to ensure such capability and it has exhausted all reasonable efforts to ensure such capability through backup arrangements. In reviewing a hospital's demonstration of lack of ability to ensure service capability, the agency shall consider factors relevant to the particular case, including the following:
- a. Number and proximity of hospitals with the same service capability.
  - b. Number, type, credentials, and privileges of specialists.
  - c. Frequency of procedures.
  - d. Size of hospital.

**ST - H0048 - EMERGENCY CARE-Txfr Manual Incoming & Update**

**Title** EMERGENCY CARE-Txfr Manual Incoming & Update

**Type** Rule

59A-3.255(6)(d) FAC

**Regulation Definition**

(d) Both transferring and receiving hospitals shall assign a specific person on each shift who shall have responsibility for being knowledgeable of the transfer manual and maintaining it.

**Interpretive Guideline**

- Does the transfer manual and protocols consider specific medical requirements and treatment times?
- Interview the person responsible for the transfer manual.
- Review transfers to receiving facilities; were all protocols followed?
- Review a selection of patient records of patients received from other hospitals. Consider the inventory of services provided by the hospital being surveyed.
- Interview emergency department staff to determine knowledge of the on call physician list and of the transfer coordination process.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 47 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0049 - EMERGENCY CARE - Written Policies/Procedures**

**Title** EMERGENCY CARE - Written Policies/Procedures

**Type** Rule

59A-3.255(6)(e) FAC

**Regulation Definition**

(e) Each hospital offering emergency services and care shall maintain written policies and procedures specifying the scope and conduct of emergency services to be rendered to patients. Such policies and procedures must be approved by the organized medical staff, reviewed at least annually, revised as necessary, dated to indicate the time of last review, and enforced.

**Interpretive Guideline**

- Review the inventory listed for scope of care provided.
- Review the written policies and procedures approved by the medical staff and dated for last review.
- Has the policy been enforced?

**ST - H0050 - EMERGENCY CARE - Policy/Proc Physician Direc**

**Title** EMERGENCY CARE - Policy/Proc Physician Direc

**Type** Rule

59A-3.255(6)(e)1, FAC

**Regulation Definition**

Such policies shall include requirements for the following:  
1. Direction of the emergency department by a designated physician who is a member of the organized medical staff.

**Interpretive Guideline**

- Interview the physician director regarding the provision of medical care and services.
- Review the credential file of the physician director of the emergency department.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 48 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0051 - EMERGENCY CARE - Physician Coverage**

**Title** EMERGENCY CARE - Physician Coverage

**Type** Rule

59A-3.255(6)(e)2, FAC

**Regulation Definition**

Such policies shall include requirements for the following:  
2. A defined method of providing for a physician on call at all times.

**Interpretive Guideline**

- Review the physician coverage schedule. Consider the inventory of services offered.
- Interview the physician designated to direct the emergency department, for the provision of physician coverage.
- Interview staff for their understanding of on-call physician.
- Review by-laws related to the on-call medical staff.

**ST - H0052 - EMERGENCY CARE - Nursing Supervisor**

**Title** EMERGENCY CARE - Nursing Supervisor

**Type** Rule

59A-3.255(6)(e)3, FAC

**Regulation Definition**

Such policies shall include requirements for the following:  
3. Supervision of the care provided by all nursing service personnel with the emergency department by a designated registered nurse who is qualified by relevant training and experience in emergency care.

**Interpretive Guideline**

- Review the personnel record of nursing supervisor in charge or designee.
- Review a sample of nursing personnel for training and experience.
- Interview the nurse in charge for required competencies and training.
- Observe supervision of nursing staff in the emergency department.

**ST - H0053 - EMERGENCY CARE - Other Personnel**

**Title** EMERGENCY CARE - Other Personnel

**Type** Rule

59A-3.255(6)(e)4, FAC



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 49 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

Such policies shall include requirements for the following:  
4. A written description of the duties and responsibilities of all other health personnel providing care within the emergency department.

**Interpretive Guideline**

- Interview the emergency department director for clarifications of personnel assignments of duties/responsibilities.
- Interview other health personnel for understanding about their duties.

**ST - H0054 - EMERGENCY CARE - Formal Training Program**

**Title** EMERGENCY CARE - Formal Training Program

**Type** Rule

59A-3.255(6)(e)5, FAC

**Regulation Definition**

Such policies shall include requirements for the following:  
5. A planned formal training program on emergency access laws, and participation, by all health personnel working in the emergency department.

**Interpretive Guideline**

- Review the formal training on emergency access to care laws
- Review a sample of ED staff training records on the emergency access laws.
- Interview health personnel working in the emergency department regarding training on emergency access laws; to include physicians and contracted staff.

**ST - H0055 - EMERGENCY CARE - Control Register**

**Title** EMERGENCY CARE - Control Register

**Type** Rule

59A-3.255(6)(e)6 FAC

**Regulation Definition**

Such policies shall include requirements for the following:  
6. A control register adequately identifying all persons seeking emergency care be established, and that a medical record be maintained on every patient seeking emergency care that is incorporated into the patient's permanent medical record and that a copy of the Patient Care Record, in accordance with rules 64J-1.001 and 64J-1.014, F.A.C., be included in the

**Interpretive Guideline**

- Review control register for various months for items a-e.
- Sample medical records for some patients from the control register for items a-e and EMS record included if transported by ambulance.

NOTE: The hospital has the discretion of maintaining hard copy or electronic control register but items a - e must be present.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 50 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

medical record, if the patient was delivered by ambulance.  
The control register must be continuously maintained and shall include at least the following for every individual seeking care:

- a. Identification to include patient name, age and sex;
- b. Date, time and means of arrival;
- c. Nature of complaint;
- d. Disposition; and
- e. Time of departure.

**ST - H0057 - EMERGENCY CARE - QA Review**

**Title** EMERGENCY CARE - QA Review

**Type** Rule

59A-3.255(6)(f), FAC

**Regulation Definition**

(f) Every hospital offering emergency services and care shall have a method for assuring that a review of emergency patient care is performed and documented at least monthly, using the medical record and preestablished criteria.

**Interpretive Guideline**

- Interview QA person or ED Director.
- Review a sample of monthly quality assurance reviews.

**ST - H0061 - EMERGENCY CARE - Lab Services Available**

**Title** EMERGENCY CARE - Lab Services Available

**Type** Rule

59A-3.255(6)(g), FAC

**Regulation Definition**

(g) Every hospital offering emergency services and care shall insure the following:  
1. That clinical laboratory services with the capability of performing all routine studies and standard analyses of blood,

**Interpretive Guideline**

- Verify lab services are available at all times
- Review medical records to determine:
  - lab tests are processed timely.
  - radiology services are provided in a timely manner

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 51 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

urine, and other body fluids are readily available at all times to the emergency department.

2. That an adequate supply of blood is available at all times, either in-hospital or from an outside source approved by the organized medical staff, and that blood typing and cross-matching capability and blood storage facilities are readily available to the emergency department.

3. That diagnostic radiology services within the service capability of the hospital are readily available at all times to the emergency department.

4. That the following are available for immediate use to the emergency department at all times:

- a. Oxygen and means of administration;
- b. Mechanical ventilatory assistance equipment, including airways, manual breathing bag, and ventilator;
- c. Cardiac defibrillator with synchronization capability;
- d. Respiratory and cardiac monitoring equipment;
- e. Thoracenteses and closed thoracostomy sets;
- f. Tracheostomy or cricothyrotomy set;
- g. Tourniquets;
- h. Vascular cutdown sets;
- i. Laryngoscopes and endotracheal tubes;
- j. Urinary catheters with closed volume urinary systems;
- k. Pleural and pericardial drainage set;
- l. Minor surgical instruments;
- m. Splinting devices;
- n. Emergency obstetrical pack;
- o. Standard drugs as determined by the facility, common poison antidotes, syringes and needles, parenteral fluids and infusion sets, and surgical supplies;
- p. Refrigerated storage for biologicals and other supplies requiring refrigeration, within the emergency department; and
- q. Stable examination tables.

- Review policies and procedures/contracts to determine
  - acceptable levels of blood inventory.
  - diagnostic radiology services are available
  
- Verify that blood typing and cross-matching capability is readily available to the emergency department.
- Verify that blood storage facilities are readily available to the emergency department.
  
- Conduct observations in the emergency department.
- Verify that items a. through q. are present and available for immediate use in the emergency department.
- Randomly check expiration date on supplies to determine if supplies are current.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 52 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0062 - EMERGENCY CARE - Radio Communication**

**Title** EMERGENCY CARE - Radio Communication

**Type** Rule

59A-3.255(7) FAC; 395.1031 FS

**Regulation Definition**

59A-3.255(7) Each hospital offering emergency services and care shall have the capability to communicate via two-way radio with licensed EMS providers, as required by section 395.1031, F.S.

395.1031 Emergency medical services; communication.-Each licensed hospital with an emergency department must be capable of communicating by two-way radio with all ground-based basic life support service vehicles and advanced life support service vehicles that operate within the hospital's service area under a state permit and with all rotorcraft air ambulances that operate under a state permit. The hospital's radio system must be capable of interfacing with municipal mutual aid channels designated by the Department of Management Services and the Federal Communications Commission.

**Interpretive Guideline**

Verify there is a radio control system in place with the capability of radio communication between the hospital and EMS and between other hospitals and it is in working order.

**ST - H0063 - EMERGENCY CARE - No Discrimination**

**Title** EMERGENCY CARE - No Discrimination

**Type** Rule

395.1041(3)(f) & (h), FS

**Regulation Definition**

395.1041(3)

**Interpretive Guideline**

Verify the policies and procedures pertaining to triage of patients are consistent with this provision.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 53 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(f) In no event shall the provision of emergency services and care, the acceptance of a medically necessary transfer, or the return of a patient pursuant to paragraph (e) be based upon, or affected by, the person's race, ethnicity, religion, national origin, citizenship, age, sex, preexisting medical condition, physical or mental handicap, insurance status, economic status, or ability to pay for medical services, except to the extent that a circumstance such as age, sex, preexisting medical condition, or physical or mental handicap is medically significant to the provision of appropriate medical care to the patient.

Interview emergency department staff and patients regarding the emergency department admissions process.

Review medical record to see if information was obtained as requirement to provide services.

(h) A hospital may request and collect insurance information and other financial information from a patient, in accordance with federal law, if emergency services and care are not delayed. No hospital to which another hospital is transferring a person in need of emergency services and care may require the transferring hospital or any person or entity to guarantee payment for the person as a condition of receiving the transfer. In addition, a hospital may not require any contractual agreement, any type of preplanned transfer agreement, or any other arrangement to be made prior to or at the time of transfer as a condition of receiving an individual patient being transferred. However, the patient or the patient's legally responsible relative or guardian shall execute an agreement to pay for emergency services or care or otherwise supply insurance or credit information promptly after the services and care are rendered.

**ST - H0064 - NUTRITIONAL CARE - Dietetic Department**

**Title** NUTRITIONAL CARE - Dietetic Department

**Type** Rule

59A-3.240, FAC

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 54 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

Nutritional Services.

All licensed hospitals shall have a dietetic 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 appropriate nutritional care and quality food service.

**Interpretive Guideline**

- Review the hospital-wide organizational chart and the dietetic department organizational chart.
- Is the dietetic department directed and staff adequately for the size hospital?
- Interview dietetic department director and staff for integration of services with other departments.
- Observe staff to verify according to the organizational chart.

**ST - H0065 - NUTRITIONAL CARE - Dietetic Dept Director**

**Title** NUTRITIONAL CARE - Dietetic Dept Director

**Type** Rule

59A-3.240(1-2) FAC

**Regulation Definition**

- (1) The dietetic department shall be directed on a full-time basis by a registered dietitian or other individual with education or specialized training and experience in food service management, who shall be responsible to the chief executive officer or his designee for the operations of the dietetic department.
- (2) If the director of the dietetic department is not a registered dietitian, the hospital shall employ a registered dietitian at a minimum on a part-time or consulting basis to supervise the nutritional aspects of patient care and assure the provision of quality nutritional care to patients. The consulting dietitian shall regularly submit reports to the chief executive officer concerning the extent of services provided.

**Interpretive Guideline**

- Verify the dietetic department director is responsible to the CEO or his/her designee.
- Review the position description of the dietetic department director to determine if full-time.
- Review the credentials of the dietetic department director.
  - Is the director a registered dietitian?
  - If no, do they have a bachelor's degree or other food service management experience and is there a registered dietitian employed at least part-time or a consultant with the hospital for nutrition of patients?
- If they are a consulting registered dietitian, are they submitting reports on services provided?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 55 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0067 - NUTRITIONAL CARE - Registered Dietitian Svcs**

**Title** NUTRITIONAL CARE - Registered Dietitian Svcs

**Type** Rule

59A-3.240(3), FAC

**Regulation Definition**

(3) Whether employed full-time, part-time or on a consulting basis, a registered dietitian shall provide the following services to the hospital on the premises on a regularly scheduled basis:

- (a) Liaison with administration, medical and nursing staffs;
- (b) Patient and family counseling as needed;
- (c) Approval of menus and modified diets;
- (d) Required nutritional assessments;
- (e) Participation in development of policies, procedures and continuing education programs; and
- (f) Evaluation of dietetic services.

**Interpretive Guideline**

- Interview the registered dietitians to verify their involvement in these nutritional care responsibilities.
- Request the personnel record of the dietitian(s). Verify these services (1-6) are included in their job description.
- Review the regular and therapeutic menus to determine if the RD has approved them.
- Review patient medical records to determine if required nutritional assessments were completed and patient and family counseling was provided according to policies and procedures and standards of practice.
- Review staff continuing education programs to determine the RD's participation.
- Interview the RD(s) about how they act as liaisons with other departments or services related to patient care.
- Request documentation regarding how the RD evaluates dietetic services,
- If the facility employs multiple RDs, these responsibilities may be shared or delegated to one or more individuals.

**ST - H0068 - NUTRITIONAL CARE - Annual Dietetic Review**

**Title** NUTRITIONAL CARE - Annual Dietetic Review

**Type** Rule

59A-3.240(4), FAC

**Regulation Definition**

(4) Annually, a registered dietitian shall conduct a review and evaluation of the dietetic department to include:

- (a) A review of menus for nutritional adequacy;
- (b) A review of tray identification methods, patients who are not receiving oral intake, and the elapsed time between the evening meal and the next substantial meal;

**Interpretive Guideline**

- Look for documentation for annual evaluations by the RD have occurred for items 1-5.
- Interview the registered dietitian.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 56 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

- (c) A review of the counseling and instruction given to patients and their families with special dietary needs;
- (d) A review of committee activities concerning nutritional care; and
- (e) A review of the appearance, palatability, serving temperature, patient acceptability and choice, and retention of nutrient value of food served by the dietetic department.

**ST - H0069 - NUTRITIONAL CARE - Dietetic Services Contract**

**Title** NUTRITIONAL CARE - Dietetic Services Contract

**Type** Rule

59A-3.240(5), FAC

**Regulation Definition**

(5) Nothing in this section shall prevent a hospital from employing an outside food management company for the provision of dietetic services, provided the requirements of this section are met, and the contract specifies this compliance.

**Interpretive Guideline**

- Ask the Dietetic Department Director if the hospital contracts with an outside food management company.
- If the hospital contracts an outside food management company, ask to see the current contract.
- Review the contract to determine if it includes provisions that the requirements of this section are met.

**ST - H0070 - NUTRITIONAL CARE - Sufficient Personnel**

**Title** NUTRITIONAL CARE - Sufficient Personnel

**Type** Rule

59A-3.240(6), FAC

**Regulation Definition**

(6) The dietetic department, service or other similarly titled unit shall employ sufficient qualified personnel under competent supervision to meet the dietary needs of patients.

**Interpretive Guideline**

- Observe the dietetic department personnel performing various operations of the department including food preparation, food storage, tray service, sanitation, diet order processing, medical nutrition therapy, etc.
- Observe processes to determine sufficient personnel are scheduled. Poor outcomes from insufficient or unqualified staff might include poor quality meals, unsanitary kitchen conditions, late meals, and inadequate medical nutritional therapy



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 57 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0071 - NUTRITIONAL CARE - Dietetic Staff Instruction**

**Title** NUTRITIONAL CARE - Dietetic Staff Instruction

**Type** Rule

59A-3.240(7), FAC

**Regulation Definition**

(7) Personnel in the dietetic department shall receive, as appropriate to their level of responsibility, instruction in:

- (a) Personal hygiene and infection control;
- (b) Food handling, preparation, serving and storage; cleaning and safe operation of equipment;
- (c) Waste disposal;
- (d) Portion control;
- (e) Diet instruction; and
- (f) The writing of modified diets and the recording of pertinent dietetic information in the patient's medical record.

**Interpretive Guideline**

- Review staff development/ in-service records and job descriptions to determine that dietetic department personnel have received instruction, as appropriate in items 1-6.
- Interview personnel during observations of the dietetic department regarding their training, particularly if there are concerns about their competence.
- This instruction should be provided to new personnel during orientation, and updated when processes and policies change. This instruction is not required quarterly.

**ST - H0072 - NUTRITIONAL CARE - Qrtrly Training & Records**

**Title** NUTRITIONAL CARE - Qrtrly Training & Records

**Type** Rule

59A-3.240(8), FAC

**Regulation Definition**

(8) Personnel in the dietetic department shall receive quarterly in-service training of which a record shall be kept by the dietetic department.

**Interpretive Guideline**

- Review staff development or in-service records to determine if dietetic department personnel have received at least quarterly in-service training.
- Interview personnel during observations of the dietetic department regarding their duties and training.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 58 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0073 - NUTRITIONAL CARE - Dietetic Policies**

**Title** NUTRITIONAL CARE - Dietetic Policies

**Type** Rule

59A-3.240(9)(a-d), FAC

**Regulation Definition**

(9) The dietetic department, service or other similarly titled unit shall be guided by written policies and procedures that cover food procurement, preparation and service. Dietetic department policies and procedures shall be developed by the director of the dietetic department with nutritional care policies and procedures developed by a registered dietitian, shall be subject to annual review, revised as necessary, dated to indicate the time of last review, and enforced. Written dietetic policies shall include the following:

- (a) A description of food purchasing, storage, inventory, preparation, service, and disposal policies and procedures.
- (b) A requirement that diet orders be recorded in the patient's medical record by an authorized individual before the diet is served to the patient.
- (c) A requirement that the proper use and adherence to standards for nutritional care, including dietary reference intakes are specified by the provider's diet manual.
- (d) A requirement for patients who are on oral intake and do not have specific dietary requirements, that a minimum of three meals or their equivalent be provided daily, with not more than a 15 hour span between the evening meal and breakfast.

**Interpretive Guideline**

- Review the dietetic department policy and procedures to determine if they were developed by the dietetic department director.
- Review the nutritional care policies to determine if they were developed by the Registered Dietitian (RD). Look for the date of the last review of all of the policies, which must be done annually.
- Determine if the dietetic polices include the topics from a-d.
- Make observations of the dietetic department operations throughout the survey to determine if these policies are enforced and reflect current practice. If there are concerns identified regarding the enforcement of these polices, interview the dietetic department director and/or the RD about this.
- These dietetic polices should reflect current standards of practice, particularly in nutritional care.
- For a: Review the written policy regarding food purchasing, storage, inventory, preparation, service, and disposal. Make observations in the food storage areas, of food preparation, food service, and food disposal. Does the dietetic department have enough food to serve the menu? Does the dietetic personnel appear to be following the written policies for food preparation, service, and disposal? Is quality food served? If the dietetic personnel do not appear to be following the written policies, interview them about their instruction and training for their job duties. Additionally, interview the dietetic department director regarding the enforcement of these policies.
- For b: Review the written policy regarding how diet orders are recorded in the patient's medical record by an authorized individual before the diet is served to the patient. During the review of sampled medical records, look for a written diet order by an authorized individual. Verify the diet orders of these same patients in the dietetic department to determine that they match. Interview the RD about how diet orders are written and by whom. Interview other staff involved in the process of how the diet order is communicated to the dietetic department. Observe these same patients during meal service to determine if they receive the ordered diet.
- For c: Review the written policy regarding the proper use and adherence to standards for nutritional care as specified in the diet manual. The diet manual should be a current edition, including the latest standards of nutritional practice.
- This rule requires that the nutritional standards be at least in accordance with the Recommended Dietary Allowances (RDAs) (1989) of the Food and Nutrition Board, National Research Council and National Academy of Sciences. The

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 59 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

RDAs have since been replaced by the Dietary Reference Intakes (DRIs). Although the state law does not require hospitals to use the most current RDAs, they are required to use the most current nutritional standards under the federal law.

-Ask to look at the diet manual that is used by the dietetic department. Review the hospital menus to see that they reflect at least the 1989 nutritional standards. Look to see if the therapeutic and modified diets reflect the standards in the hospital diet manual.

-Also, review patient education materials to determine if they are based on current nutritional standards.

-For d: Review the written policy regarding meal service times, to determine that there is not more than a 15 hour span between the evening meal and breakfast. Observe meals to determine if they are served on time according to the policy. Interview patients regarding the timeliness of meals and the span of time between the evening meal and breakfast.

-If there are concerns identified regarding the enforcement of these policies, interview the dietetic department director and/or the RD about this.

**ST - H0074 - NUTRITIONAL CARE - Dietetic Policies**

**Title** NUTRITIONAL CARE - Dietetic Policies

**Type** Rule

59A-3.240(9)(e-p), FAC

**Regulation Definition**

Written dietetic policies shall include the following:

- (e) A requirement that temperatures for holding and serving cold foods be below 45 degrees F, and for hot foods be above 140 degrees F.
- (f) A requirement that a supply of non-perishable foods sufficient to serve a hospital's patients for a minimum of a one week period be available.
- (g) A requirement that written reports of sanitary inspections be kept on file, with a record of actions undertaken to comply with recommendations.
- (h) A description of the role of the dietetic department in the hospital's internal and external disaster plans.
- (i) Menus.

**Interpretive Guideline**

- e Review the written policy regarding the holding and serving temperatures of cold and hot foods. The current Florida Food Hygiene Code requires that cold food be held at 41 °F, rather than 45 °F. Observe cold food held under refrigeration and during meal service. Look at the refrigerator thermometers. Ask the dietetic department personnel to take temperatures of cold foods on the tray line and elsewhere to demonstrate their knowledge and skill (it is permissible for the surveyor to take temperatures, if the situation warrants). Is the cold food held under proper temperature? Observe food held hot on the tray line, in the oven, on the stove, and in warming equipment. Ask the dietetic department personnel to take temperatures of hot foods on the tray line, or elsewhere to demonstrate their knowledge and skill (it is permissible for the surveyor to take temperatures, if the situation warrants). Is the hot food held at proper temperature? If there are concerns, ask to review their temperature logs if they have them (not required).

- f Review the written policy regarding the supply of non-perishable foods sufficient to serve a hospital's patients for at least a one-week period. Obtain the patient census. Review all dry food storage areas. The one-week supply of

# Agency for Health Care Administration

## ASPEN: Regulation Set (RS)

Printed 08/07/2024

Page 60 of 318

### Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE

(j) The role of the dietetic department in the preparation, storage, distribution and administration of enteric feeding, tube feeding and total parenteral nutrition programs.

(k) Alterations in diets or diet schedules, including the provision of food service to patients who do not receive regular meal service.

(l) Ancillary dietetic services, as appropriate, including food storage and kitchens on patient care units, formula supply, cafeterias, vending operations and ice making.

(m) Personal hygiene and health of dietetic personnel.

(n) A description of dietetic department policies and procedures designed to provide for infection control including a monitoring system to assure that dietetic personnel are free from communicable infections and open skin lesions.

(o) A description of the identification system used for patient trays and other methods for assuring that each patient receives the appropriate diet as ordered,

(p) Safety practices, including the control of electrical, flammable, mechanical, and as appropriate, radiation hazards.

non-perishable food does not have to be stored separately; however, some hospitals may separate and secure their non-perishable food supply for inventory control. The hospital must have measures in place to minimize the risk of tampering or other malicious, criminal, or terrorist actions on their food supplies. Observe the non-perishable food supply to determine if sufficient to serve the hospital patients for at least a week. Food stored in the refrigerators and freezers cannot be included in the one week non-perishable supply, unless the food can be stored at room temperature without spoiling or making the food unsafe to eat. If the hospital does not have a policy regarding their one-week supply of non-perishable food, use the hospital's regular menu as a guide for portions and food groups, to evaluate whether the hospital has sufficient one week non-perishable food supplies on hand to serve their hospital patients.

- Ask the dietetic department personnel how they periodically rotate this food supply, to ensure that quality is maintained.

- g Review the written policy regarding how written reports of sanitary inspections are kept on file and acted upon to comply with recommendations. The Department of Health no longer conducts quarterly kitchen sanitation inspections. However, the local jurisdiction (county or city) may continue to require food permits and sanitation inspections.
- Ask the hospital who is conducting sanitary inspections. Review the sanitary inspection reports conducted in the last year.

Ask if the kitchen has been inspected by any regulatory agency for food safety and sanitation in the past year. If so, request the sanitation reports Review the dietetic department's corrective actions for any sanitation citations included on these reports. The dietetic department's corrective actions should be in writing, in any format they chose.

- h Review the written policy regarding the description of the role of the dietetic department in the hospital's internal and external disaster plans.
- This policy may be part of the hospital-wide internal and external disaster plans. These plans should address how the dietetic department utilizes staff, equipment, food, and supplies during various types of internal and external disaster situations.
- See also Comprehensive Emergency Management Plan at H0007 and CORE Tag Z830.
- If there are concerns identified regarding these policies, the surveyor should consult with a Life Safety Code surveyor.

- i Review the written policy regarding menus. This policy may include how menus are planned for regular, modified and therapeutic diets; the type of menus (non-selective vs. selective; restaurant style); the menu cycle; how menus are revised; how menus are reviewed for nutritional adequacy; and how menu items are substituted, etc.
- Review the hospital regular and therapeutic menu cycle. Observe a meal to determine how the menu is followed. If

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

*Printed 08/07/2024*

Page 61 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

the hospital uses a selective menu, interview dietetic department personnel about this process. Look at patient meal trays to determine if their menu selections are honored within their dietary restrictions. Interview patients about their menu selections.

- j Review the written policy regarding the role of the dietetic department in the preparation, storage, distribution, and administration of enteral feeding, tube feeding, and total parenteral nutrition programs. Many hospitals do not store their enteral formulas in the dietetic department. The enteral formulas may be stored in Central Supply and/or Pharmacy. Ask the RD if any enteral products or infant formulas are prepared in the dietetic department. If they prepare enteral products or infant formulas, observe this process for sanitary technique and accuracy of preparation. Observe how enteral products once prepared or opened are stored. Interview the RD about his/her role in nutritional assessment of patients receiving enteral nutrition support (tube feedings) and making recommendations for nutrition support. Parenteral Nutrition (PN) mixtures are usually prepared in the Pharmacy Department, not the dietetic department. Interview the RD about their role in nutritional assessment of PN patients and making recommendations for nutrition support.

- Nursing personnel usually administer enteral and parenteral nutrition. Interview the RD about their role in the distribution and administration of enteral and parenteral feedings. Observe patients receiving enteral and parenteral feeding. Check the type and amount of formula the patient is receiving to determine if it corresponds to the health care practitioner's order.

- k Review the written policy regarding the diet alterations and schedules, including the provision of food service to patients who do not receive regular meal service. These policies may include how diets are altered according to physician's orders and how they meet patient's nutritional needs. They may also include how early and late trays are served for patients in which test/treatments/procedures may interfere with regular meal service. They may include how supplemental feedings and snacks are provided and how small frequent meals are served to patients requiring these. Observe the process of diet alterations and schedules, such as late tray service and supplemental feedings.

- l Review the written policy regarding the dietetic department's ancillary dietetic services, as appropriate, including food storage and kitchens on patient care units, formula supply, cafeterias, vending operations and ice making. This may also include catering and restaurant services. Interview the dietetic department director about any ancillary dietetic services provided. Observe the ancillary services that involve patient care to determine if they reflect the written policies.

- m Review the written policy regarding personal hygiene and health of dietetic personnel. This policy may include dietetic department personnel's requirements for their cleanliness, clothing, shoes, hair, nails, jewelry specifications, tobacco use, eating and drinking, and hand washing.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 62 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

- Observe the personal hygiene of dietetic department personnel to determine if it reflects the policy.
- Observe dietetic department personnel for any signs or symptoms of infection or with conditions that cause persistent sneezing, coughing, or a runny nose or discharges from the eyes, nose, or mouth.
  
- n Review the written policy regarding infection control including a monitoring system to assure that dietetic personnel are free from communicable infections and open skin lesions.
- The policy should address those signs and symptoms that would exclude dietetic department personnel from working in any area of a food service establishment in any capacity in which there is a likelihood of such person contaminating food or food-contact surfaces with pathogenic organisms, or transmitting disease to other individuals. Some of these signs and symptoms include boils, infected wounds, sores, vomiting, diarrhea, jaundice, sore throat with fever and an acute respiratory infection. Additionally, the policy should include that if the dietetic department director has reason to suspect that an employee has contracted any disease in a communicable form or has become a carrier of such disease that can be transmitted by normal food service operation, the Department of Health shall be notified immediately.
- The policy should include that dietetic department personnel must report these signs and symptoms to the dietetic department director.
- Observe dietetic department personnel for any signs or symptoms of infection. Interview the dietetic director about how he/she monitor dietetic personnel for signs and symptoms of communicable infections and open skin lesions.
  
- o Review the written policy describing the identification system used for patient trays and other methods for assuring that each patient receives the appropriate diet as ordered.
- Some hospitals use printed menus identified with the patient name and room number and diet order. Others use computer printed menus or tray slips identified with the patient name, room number and diet order. Observe the tray identification system used for patient trays during meal service and tray delivery. Interview the dietetic department director and/or RD about this system. Interview patients about the accuracy of their meal trays.
  
- p Review the written policy regarding safety practices, including the control of electrical, flammable, mechanical, and as appropriate, radiation hazards. As you make observations of the dietetic department, make note of potential hazardous conditions, such as frayed electrical cords, a radio put on a shelf over a sink with a cord plugged into the wall outlet; paper stored near a gas stove burner, and meat slicer without protective knife guard when not in use to protect employees from injury. Look to see if the policy addresses safety practices for preventing scald burns, injuries from equipment use (slicers, mixers, food processors, etc.), falls (from slick floors, tripping over objects), and heavy lifting. Observe dietetic personnel for their safety practices during their work duties to determine if the policy is followed.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 63 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0076 - NUTRITIONAL CARE - Environment & Equipment**

**Title** NUTRITIONAL CARE - Environment & Equipment

**Type** Rule

59A-3.240(10-16), FAC

**Regulation Definition**

(10) The dietetic department shall be designed and equipped to facilitate the safe, sanitary, and timely provision of food service to meet the nutritional needs of patients.

(11) The dietetic department shall have adequate equipment and facilities to prepare and distribute food, protect food from contamination and spoilage, to store foods under sanitary and secure conditions, and to provide adequate lighting, ventilation and humidity control.

(12) The dietetic department shall thoroughly cleanse and sanitize food contact surfaces, utensils, dishes and equipment between periods of use, shall ensure that toilet, hand-washing and hand-drying facilities are conveniently available, and provide for dishwashing and utensil washing equipment that prevent recontamination and are apart from food preparation areas.

(13) The dietetic department shall ensure that all walk-in refrigerators and freezers can be opened from inside and that all food and nonfood supplies are clearly labeled. Where stored in the same refrigerator, all nonfood supplies and specimens shall be stored on separate shelves from food supplies.

(14) The dietetic department shall implement methods to prevent contamination in the making, storage, and dispensing of ice.

(15) The dietetic department shall ensure that disposable containers and utensils are discarded after one use, and that worn or damaged dishes and glassware are discarded.

**Interpretive Guideline**

(j) Determine from observations of the various functions in the dietetic department, if it is designed and equipped to facilitate safe, sanitary, and timely provision of food service to meet the nutritional needs of patients. For this requirement, look for poor outcomes, such as unsanitary conditions in the kitchen, hazardous conditions, patient complaints about poor quality food, inadequate diets, and a pattern of weight loss or nutritional deficiencies in patients.

(k) To determine if the dietetic department has adequate equipment for food storage, preparation and distribution, look for the following examples:

- Walk-in refrigeration or freezer units that are overstocked to the extent that there is insufficient airflow food, food is not properly cooled, proper temperature is not maintained, and may cause injury to dietetic personnel.
- Food not prepared properly, due to lack of appropriate equipment, such as pureed food not prepared to have a smooth even texture.
- Cold or hot food not held at proper temperature due to lack or poor design of holding equipment.
- Meal trays not served timely due to insufficient tray delivery carts or equipment.
- Meals are not served at palatable temperatures due to lack of or poor design of equipment to retain heat or cold.
- Poor nutrient retention of food due to lack of proper preparation with appropriate equipment for quantity food service.

(l) During observations in the dietetic department, look at the physical environment for evidence of:

- stagnant air ventilation,
  - poorly lit areas, and
  - High humidity conditions resulting in mold growth on equipment, walls, vents, etc.
- During observations in the dietetic department, look for evidence of:
- Adequate toilet facilities
  - Conveniently available hand washing sinks, equipped with a sanitary method for hand drying.
  - Adequate dishwashing and utensil washing equipment that is located apart from the food preparation area. Most hospitals have mechanical dishwashers and 2 or 3 compartment sinks for large equipment washing. Some may have

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(16) The dietetic department shall hold, transfer, and dispose of garbage in a manner which does not create a nuisance or breeding place for pests or otherwise permit the transmission of disease.

pot washing machines. Look to see if this equipment is operational and designed to accommodate the volume of dishes and utensils used. Observe that the soiled dishes are kept separate from the clean dishes, so that they are protected from contamination.

(m) All walk-in refrigerators and freezer unit can be opened from the inside. This is to prevent an individual from being locked inside the walk-in units. Check each walk-in door. Ask the dietetic department personnel to demonstrate how they open the door from inside the unit if it is locked on the outside. There should not be any locks installed by the hospital on the outside of the door to prevent the door from opening from the inside of the unit.

·All food and non-food supplies are clearly labeled with their identity. Look for separation of non-food supplies and specimens stored on separate shelves from food to prevent contamination.

(n) Prevention of ice contamination during making, storage and dispensing. Look at the icemakers and ice storage bins in the dietetic department to see if they are clean on the interior and exterior surfaces. Dietetic personnel should dispense ice with dispensing utensils, such as scoops or tongs that are stored on a clean surface or holder between use, and in a manner to protect it from contamination. Observe storage holders for ice scoops to determine if they are clean. Dietetic personnel should not touch ice for consumption or display with bare hands or contaminated gloves.

(o) Disposable containers, intended for single-use are discarded. Dishes and glassware are in good condition. Check the dietetic department's dishes, glassware, and eating utensils to ensure they do not have breaks, pits, chips, scratches, scoring, crazing, decomposition, distortion, and other similar imperfections. The dishes, glassware, and eating utensils should be easily cleanable and smooth.

(p) Garbage is held, transferred, and disposed of in manner that does not create a nuisance or breeding place for pests or otherwise permit transmission of disease. Check that garbage is held in leak proof, nonabsorbent containers covered with tight fitting lids. Check the dumpsters and compactors located outside to see that they are kept clean and maintained in good repair. Look for leaks from the containers, foul odors present and pests observed around the dumpster or compactor would indicate lack of cleanliness and good repair. See also housekeeping section for the storage and removal of garbage (H0124).

- Interview dietetic department personnel who are directly responsible for these procedures. Ask about their training and how they report problems to management. Review the related written policies if there are identified problems and interview the dietetic department director and/or RD about the policy development and/or enforcement.



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 65 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0077 - NUTRITIONAL CARE - Equipment Maintenance**

**Title** NUTRITIONAL CARE - Equipment Maintenance

**Type** Rule

59A-3.240(17), FAC

**Regulation Definition**

(17) Information on specifications, operation and maintenance of all major and fixed dietetic department equipment shall be maintained. A preventative and corrective maintenance program on such equipment shall be conducted and recorded.

**Interpretive Guideline**

- Request to see the information regarding the specifications, operation, and maintenance of all major and fixed dietetic department equipment (i.e. range, convection oven, floor mixer, slicer, refrigerator, freezer, dishwasher, fryer, steamer, beverage dispensers, etc., if they have these).
- Request to see the preventative and corrective maintenance program for this equipment (the Maintenance department may have these records).
- During observations in the dietetic department, make note of any essential non-operational equipment. If concerns are identified, interview the dietetic department director about the preventative and corrective maintenance program.

**ST - H0078 - NUTRITIONAL CARE - Written Orders**

**Title** NUTRITIONAL CARE - Written Orders

**Type** Rule

59A-3.240(18), FAC

**Regulation Definition**

(18) Dietetic services shall be provided in accordance with written orders by the health professional responsible for the patient and appropriate information shall be recorded in the patient's medical record. Such information shall include:

- (a) A summary of the dietary history and a nutritional assessment when the past dietary pattern is known to have a bearing on the patient's condition;
- (b) Timely and periodic assessments of the patient's nutrient intake and tolerance to the prescribed diet modification,

**Interpretive Guideline**

- During review of patients' medical records, verify diet orders, diet consults, diet instructions are written by the individual responsible for the patient (physician, physician assistant, or Advanced Registered Nurse Practitioner).
- Review nutritional assessments in the medical record, if applicable. Not all patients will have a nutritional assessment conducted. Most hospitals have a system in which patients are screened upon admission for nutritional problems (based on criteria the hospital establishes from their hospital population). If the patient is identified to have a nutritional problem, based on the hospital criteria, then the patient is referred for a nutritional assessment. Review the dietetic department policy related to this, to know their admission nutrition screening criteria.
  - Look to see if the nutritional assessment includes a summary of diet history, if relevant, and obtainable.
  - Review the medical record to see if timely and periodic assessment of the patient's nutrient intake, when applicable.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 66 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

including the effect of the patient's appetite and food habits on food intake and any substitutions made; and

(c) A description or copy of diet information forwarded to another organization when a patient is discharged.

If a patient is identified as having poor meal intake and at nutritional risk, often the RD will conduct a food intake study to determine how many calories, protein, and other nutrients were consumed.

- Review the nutrition progress notes to determine if they addressed the patient's tolerance to the prescribed modified diet, including appetite, and cultural, religious and ethnic food habits. Also, note if any substitutions were made or should have been made to accommodate the resident's appetite and food habits.
- Review the medical records of discharged patients and look for a description or copy of diet information that was forwarded to another organization, such as a nursing home or assisted living facility.
- If there are identified concerns, review the written nutritional care polices.
- Also, interview the Registered Dietitian about identified concerns

**ST - H0079 - NUTRITIONAL CARE - Order Confirmation**

**Title** NUTRITIONAL CARE - Order Confirmation

**Type** Rule

59A-3.240(19), FAC

**Regulation Definition**

(19) Within 24 hours of admission and within 24 hours of any subsequent orders for diet modification, the diet order shall be confirmed by the practitioner responsible for the patient receiving oral alimentation.

**Interpretive Guideline**

- Review the written policies regarding the dietetic department's system of how they confirm orders for diet modification by the practitioner responsible for the patient receiving oral alimentation. Oral alimentation is the act or process of affording nutriment (something that nourishes or promotes growth, provides energy, repairs body tissues, and maintains life) or nourishment through the gastrointestinal tract. Diet modification would be any diet other than a regular diet, with regular consistency.
- Review medical records to determine if this process is occurring within 24 hours of admission and within 24 hours of any subsequent orders for diet modification.
- Interview dietetic department personnel who are directly responsible for this process.
- Also, interview the Registered Dietitian about identified concerns.

**ST - H0080 - NUTRITIONAL CARE - Quality Control**

**Title** NUTRITIONAL CARE - Quality Control

**Type** Rule

59A-3.240(20), FAC

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 67 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

- (20) Each hospital shall establish appropriate quality control mechanisms to assure that:
- (a) All menus are evaluated for nutritional adequacy.
  - (b) There is a means for identifying those patients who are not receiving oral intake.
  - (c) Special diets are monitored.
  - (d) The nutritional intake of patients is assessed and recorded as appropriate.
  - (e) Effort is made to assure appetizing appearance, palatability, proper serving temperature, and retention of nutritional value of food.
  - (f) Whenever possible, patient food preferences are respected and appropriate dietary substitutions are made available.
  - (g) Surveys of patient acceptance of food are conducted, particularly for long-stay patients.

**Interpretive Guideline**

- The dietetic department should have written policies about how they implement these quality controls.
- Review these corresponding policies.
- Interview the leadership position who supervises the dietetic department director about their knowledge of these quality control mechanisms.
- a. Interview the Registered Dietitian about how menus are evaluated for nutritional adequacy. There is no directive as to how the RD evaluates the menus for nutritional adequacy. Common practice is that they have a computerized nutrient analysis of their menus, although this is not required. Request documentation to show that these menus are nutritionally adequate. Refer to H68
- b. Interview the Registered Dietitian about how they identify those patients who are not receiving oral intake. Look to see how they track these patients in writing or electronically. Patients who are not receiving oral food intake may not be receiving any nutrition orally or receiving enteral and/or parenteral feedings. Ask the RD what he/she does when patients are not receiving oral food intake without enteral and/or parenteral feedings for several days. Refer to the guidance under H68.
- c. Interview the RD about how they monitor special diets. Ask about the quality controls to ensure that the patient receives the correct diet. During meal observations, do patients ordered special diets receive the correct diet?
- d. Interview the RD about how nutritional intake of patients is assessed and recorded as appropriate. From patient record reviews, were patients' nutritional intake assessed and recorded according to the dietetic department's policy? Patients would require assessment of nutritional intake based on nutritional needs.
- e. Interview the RD and dietetic department director about how they ensure food is served with an appetizing appearance and proper serving temperature, and retains nutritive value. Common practice is that they conduct test trays and conduct meal rounds to interview patients to evaluate the food palatability, appearance and serving temperature, although not required. Ask to see written documentation of their quality control. During meal observations, did the patient meals look appetizing? From patient interviews, did patients complain about the appearance, taste, or temperature of the food? Refer to H68.
- f. Interview the RD and dietetic department director how they ensure that patient's food preferences are respected and that there are appropriate substitutions made available when a patient refuses food.
- During observations in the hospital and dietetic department, look at the system in place to obtain and document patients' food preferences. During meal observations, look to see if patient's food preferences are respected. From patient interviews, ask patients if their food preferences are honored and what happens if they refuse food. Ask them if they are offered a similar substitution if they refuse food.
- g. Interview the dietetic department director and RD about how surveys of patient food acceptance are conducted, particularly for long-stay patients. Some hospitals may conduct a written questionnaire for the patient or family to complete, although there are other methods to assess patient food acceptance.
- Request documentation on this process. Interview a few long stay patients to determine if hospital personnel surveyed their food acceptance. During meal observations, did the patient meals look appetizing? From patient

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 68 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

interviews, did patients complain about the hospital food? If so, ask who they complained to, and whether the issue was resolved.

- If concerns are identified, interview the dietetic department director and/or RD. Also, interview the leadership position who supervises the dietetic department director about identified concerns with quality control mechanisms.

**ST - H0081 - PHARMACY - Procedures**

**Title** PHARMACY - Procedures

**Type** Rule

59A-3.241, FAC

**Regulation Definition**

Each Class I and Class II hospital shall have on the premises, and each Class III hospital shall have on the premises or by contract, a pharmacy, pharmaceutical department or service, or similarly titled unit, and, when applicable, shall present evidence that it holds a current institutional or community pharmacy permit under the provisions of the Florida Pharmacy Act, chapter 465, F.S. The pharmacy department shall have a licensed pharmacist serve as pharmacy director on a full time or consulting basis. The director shall develop and monitor procedures to ensure the proper use of medications. Such procedures shall address prescription and ordering, preparation and dispensing, administration, and patient monitoring for medication effects.

**Interpretive Guideline**

- Interview the Pharmacy Director (i.e., Chief Pharmacist) and determine who the Consultant Pharmacist of Record is as required by the Florida Board of Pharmacy Permit.
- Verify the required institutional, community pharmacy permit(s) and pharmacist licensure(s) are current.
- Verify the facility has Pharmacy Policy and Procedures
- Review records for monitoring of patient adverse effects or drug complications.

**ST - H0082 - PHARMACY - Formulary**

**Title** PHARMACY - Formulary

**Type** Rule

59A-3.241(1), FAC

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 69 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(1) The director shall ensure a hospital formulary or drug list is developed, maintained, and regularly updated by authorized hospital staff. The formulary shall include the availability of non-legend medications, but does not preclude the use of unlisted drugs. Where unlisted drugs are used, there shall be a written policy and procedure for their prescription and procurement. Selection of medications for inclusion on the formulary shall be based on need, effectiveness, risks, and costs.

**Interpretive Guideline**

- What are the criteria for placing a drug on the formulary?
- Do the criteria include need, effectiveness, risks, and costs?
- Does the facility have a pharmacy policy for use of non-formulary drugs?
- How often is the formulary drug list revised and updated?
- How is the formulary drug list made available to the facility professional staff?
- Does the Pharmacy Department monitor formulary drugs for safety and/or recall, and disseminate this information to the hospital professional staff?
- Does the policy preclude the use of unlisted drugs?

**ST - H0083 - PHARMACY - Auth to Prescribe Medications**

**Title** PHARMACY - Auth to Prescribe Medications

**Type** Rule

59A-3.241(2), FAC

**Regulation Definition**

(2) The director shall ensure that individuals who prescribe or order medications are legally authorized through the granting of clinical privileges.

**Interpretive Guideline**

- Review the Pharmacy Department policy regarding staff clinical privileges.
- Is there a Pharmacy procedure in place to ensure only authorized hospital staff can prescribe or order medications Florida Statutes Chapter 465?

**ST - H0084 - PHARMACY - Preparing & Storing**

**Title** PHARMACY - Preparing & Storing

**Type** Rule

59A-3.241(3), FAC

**Regulation Definition**

(3) All drugs shall be prepared and stored under proper conditions of sanitation, temperature, light, moisture, ventilation, security and segregation to promote patient safety

**Interpretive Guideline**

- Tour the drug storage area to determine drugs and biologicals are stored in accordance with manufacturer's directions and State and Federal requirements.
- Are all drugs checked by a pharmacist prior to dispensing?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 70 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

and proper utilization and efficacy.

- Does the Pharmacy Policy regarding storage specify only staff licensed in accordance with Federal and State law can have legal access to facility drugs and biologicals?
- All drugs and biologicals must be kept in locked storage areas accessible only to staff who in accordance with their license and practice act may have access to facility drugs and biologicals.
- Review medication storage areas documentation for periodic inspection in accordance with facility policy.

**ST - H0085 - PHARMACY - Labeling**

**Title** PHARMACY - Labeling

**Type** Rule

59A-3.241(4), FAC

**Regulation Definition**

(4) All medications shall be appropriately labeled as to applicable accessory or cautionary statements and their expiration date, shall be dispensed in as ready-to-administer forms as possible, and in quantities consistent with the patient's needs which are designed to ensure minimization of errors and diversion.

**Interpretive Guideline**

- Review the Pharmacy labeling policy and determine how the Pharmacy ensures outdated, mislabeled or otherwise unusable drugs and biologicals are not available for patient use.
- Spot-check patient drug labels to ensure they conform with applicable state law; State law regarding patient's full name, prescriber's name, strength and quantity of drug dispensed.
- Are appropriate accessory and cautionary statements including expiration date, lot and control number on the label as required?
- Verify through observation, staff interview, and record review as required for the dispensing operation including labeling is performed under the supervision of a Pharmacist.
- Is this supervision in accordance with applicable State laws and in a manner to promote patient safety?

**ST - H0086 - PHARMACY - Prescription Review Process**

**Title** PHARMACY - Prescription Review Process

**Type** Rule

59A-3.241(5), FAC

**Regulation Definition**

(5) A pharmacist shall review each order before dispensing the medication, with the exception of situations in which a licensed independent practitioner with appropriate clinical

**Interpretive Guideline**

- Review Pharmacy policy to determine the facility prescription review process.
- Interview staff pharmacists to verify that prescriptions or medication orders are reviewed by a pharmacist prior to dispensing.

# Agency for Health Care Administration

## ASPEN: Regulation Set (RS)

Printed 08/07/2024

Page 71 of 318

### Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE

privileges controls prescription ordering, preparation and administration of medicine. The pharmacist shall verify the order with the prescriber when there is a question.

- How are medication orders reviewed by a pharmacist when the medication is removed from an automated dispensing machine or an on-site licensed pharmacy which is not open 24 hours a day, seven days a week?
- If concerns are identified regarding the prescription or drug order, are these concerns clarified with the individual prescriber?

#### ST - H0087 - PHARMACY - Preparing & Dispensing

**Title** PHARMACY - Preparing & Dispensing

**Type** Rule

59A-3.241(6), FAC

##### Regulation Definition

(6) All medications shall be prepared and dispensed consistent with applicable law and rules governing professional licensure and pharmacy operation and in accordance with professional standards of pharmacy practice.

##### Interpretive Guideline

- Review pharmacy dispensing policies and procedures to ensure the dispensing process is in accordance with applicable laws and promotes patient safety.
- Interview pharmacy and hospital staff to determine how drugs and biologicals are prepared and dispensed and do observation of on-site dispensing operations.

#### ST - H0088 - PHARMACY - Patient Medication Profiles

**Title** PHARMACY - Patient Medication Profiles

**Type** Rule

59A-3.241(7), FAC

##### Regulation Definition

(7) A medication profile shall be developed and maintained by the pharmacy department for each patient and shall be available to staff responsible for the patient's care. The medication profile shall include the name, birth date, sex, pertinent health problems and diagnoses, current medication therapy, medication allergies or sensitivities, and potential drug or food interactions.

##### Interpretive Guideline

- Review the Pharmacy policy regarding patient profile information.
- Interview pharmacists and do on-site observation to verify this information is maintained and updated for all current patients.
- How is this information made available to facility health care staff involved in medication management?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 72 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0089 - PHARMACY - After Hour Process**

**Title** PHARMACY - After Hour Process

**Type** Rule

59A-3.241(8), FAC

**Regulation Definition**

(8) The director shall develop and implement a process for providing medications when the pharmacy is closed that ensures control, accountability, and the appropriate use of medications.

**Interpretive Guideline**

If the pharmacy is not computerized and/or not open 24/7, how is the patient medication profile implemented and the information made available to facility patient care staff

- If the pharmacy does not provide 24/7 service, review the Pharmacy Policy for after-hours Pharmacy entry by non-pharmacist health care professionals.
- Who is designated to remove medications from the Pharmacy when a pharmacist is not on-site? Medications only in amounts sufficient for immediate patient needs should be removed.
- Review required documentation (i.e., log) of any after-hour Pharmacy entry by a non-pharmacist.
- Is there documentation of pharmacist review of this removal activity and the removal correlates with current medication orders in the patient medication profile?
- Is a pharmacist responsible for reviewing after hour medication supplies to ensure they are adequate and thereby minimize the need for non-pharmacist after hour's entry into the pharmacy?

**ST - H0090 - PHARMACY - Emergency Drugs**

**Title** PHARMACY - Emergency Drugs

**Type** Rule

59A-3.241(9), FAC

**Regulation Definition**

(9) The director shall ensure there is an adequate and proper supply of emergency drugs within the pharmacy and in designated areas of the hospital.

**Interpretive Guideline**

- Review Pharmacy policy regarding emergency drugs and their availability in patient care areas.
- How are these drugs secured and who has the responsibility for monitoring these drugs?
- If used, are they immediately replaced by Pharmacy services?
- If crash carts are used, who monitors the crash carts and how are supplies other than drugs replaced on the crash carts?
- Who has the responsibility of periodically reviewing and updating what emergency drugs and supplies are available



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 73 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

in the patient care areas?

**ST - H0091 - PHARMACY - Controlled Drugs**

**Title** PHARMACY - Controlled Drugs

**Type** Rule

59A-3.241(10), FAC

**Regulation Definition**

(10) Receipt, distribution and administration of controlled drugs are documented by the pharmacy, nursing service and other personnel, to ensure control and accountability in accordance with state and federal law.

**Interpretive Guideline**

- Determine if there is a system to track movement of all scheduled drugs from point of entry into the hospital to point of departure.
- Determine Pharmacy responsibility of reviewing records of receipt, disposition and reconciliation of all scheduled drugs.
- Does the system provide capability of readily identifying loss or diversion of all controlled substances?
- Has the Pharmacy had a problem with loss or diversion of controlled drugs?
- If so, was it investigated and reported in accordance with State and Federal laws?

**ST - H0092 - PHARMACY - Drug Administration**

**Title** PHARMACY - Drug Administration

**Type** Rule

59A-3.241(11), FAC

**Regulation Definition**

(11) The director shall ensure that the administration of drugs shall take place in accordance with written policies, approved by the professional staff and designed to ensure that all medications are administered safely and efficiently.

**Interpretive Guideline**

- Review Pharmacy policies regarding drug administration.
- Do their policies include drug delivery systems such as automated dispensing machines?
- In addition to review of the patient profile do the policies address reporting and monitoring of adverse drug reactions, drug interactions, high risk medications, sound-alike drugs, including drug recall, etc.?
- How are identified drug concerns and/or safety information provided to the facility patient care staff responsible for medication administration?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 74 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0093 - PHARMACY - Consultant Pharmacist of Record**

**Title** PHARMACY - Consultant Pharmacist of Record

**Type** Rule

59A-3.241(12), FAC

**Regulation Definition**

(12) The director may supervise satellite pharmacies. The director of the hospital pharmacy, or other licensed pharmacists who are properly designated, shall be available to the hospital at all times, whether on duty or on call.

**Interpretive Guideline**

- State law requires a hospital Pharmacy have a Consultant Pharmacist of Record. This pharmacist may be the Director of Pharmacy or a designee, but this pharmacist must be licensed as a Consultant Pharmacist by the Florida Board of Pharmacy.
- The pharmacist may be full-time or part-time in a small hospital, but is responsible for the overall administration of pharmacy services and development of the Hospital Pharmacy Policy and Procedures.
- Review staffing schedules to ensure sufficient staff to provide quality pharmacy services. Pharmacy services may be full-time 24/7 or part-time in small hospitals.
- Quality pharmacy services include accurate and timely medication delivery, providing appropriate clinical services and participating in the hospital QI program.
- Pharmacy services must meet the needs of the patient population.

**ST - H0094 - PHARMACY - Administration of Drugs**

**Title** PHARMACY - Administration of Drugs

**Type** Rule

59A-3.241(13), FAC

**Regulation Definition**

(13) Administration of drugs shall be undertaken only upon the orders of authorized members of the professional staff, where the orders are verified before administration, the patient is identified, and the dosage and medication is noted in the patient's chart or medical record.

**Interpretive Guideline**

- The Hospital Pharmacy must ensure medication orders are accurate and administered as ordered.
- If medications are returned to the pharmacy, is the reason for the return evaluated by a pharmacist (medication refusal, order change, medication error, etc.)?
- Does the Pharmacy Department periodically observe medication administration? If so, review the documentation.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 75 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0095 - PHARMACY - Investigational Medications**

**Title** PHARMACY - Investigational Medications

**Type** Rule

59A-3.241(14), FAC

**Regulation Definition**

(14) Investigational medications shall be used only in accordance with specific hospital policy which addresses:

- (a) Review and approval of hospital participation in investigational studies by the appropriate hospital committee;
- (b) Requirements for informed consent by the patient;
- (c) Administration in accordance with an approved protocol;
- (d) Administration by personnel approved by the principal investigator after they have received information and demonstrated an understanding of the basic pharmacologic information about the medications; and
- (e) Documentation of doses dispensed, administered and destroyed.

**Interpretive Guideline**

- Review the Pharmacy Policy and Procedures for use of investigational medications.
- Have they developed and implemented a process for investigational medications?

**ST - H0096 - PHARMACY - Monitoring System**

**Title** PHARMACY - Monitoring System

**Type** Rule

59A-3.241(15), FAC

**Regulation Definition**

(15) Each hospital shall have a system for the ongoing monitoring of each patient for medication effectiveness and actual or potential adverse effects or toxicity which includes:

- (a) A collaborative assessment of the effect of the medication on the patient based on observation and information gathered

**Interpretive Guideline**

- Review the Pharmacy Policy and Procedures for reporting adverse drug reactions and medication errors.
- Review Pharmacy documentation of prompt investigation and reporting of findings to appropriate health care personnel and the hospital QI Committee.
- Interview staff (Nursing, Pharmacy, Medical) regarding their awareness of the policy on reporting and documentation of medication errors and adverse drug reactions.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 76 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

and maintained in the patient's medical record and medication profile;

(b) A process for the definition, identification, and review of significant medication errors and adverse drug reactions are reported in a timely manner in accordance with written procedures. Significant adverse drug reactions shall be reported promptly to the Food and Drug Administration;

(c) Information from the medication monitoring is used to assess the continued administration of the medication; and

(d) Conclusions and findings of the medication monitoring are communicated to the appropriate health care personnel involved in the patient's care.

- How does the Pharmacy do on-going evaluation of the reporting system?
- What sources of drug information are available in the pharmacy? Is this information (i.e., Drug Interactions, ADR, Dosage, etc.) hard- copied or computerized?
- How is drug information made available to the facility patient care staff?

**ST - H0097 - PHARMACY - Written Policies & Procedures**

**Title** PHARMACY - Written Policies & Procedures

**Type** Rule

59A-3.241(16), FAC

**Regulation Definition**

(16) Each hospital shall have written policies and procedures governing the selection, procurement, distribution, administration, and record-keeping of all drugs, including provision for maintaining patient confidentiality. The policies and procedures shall be reviewed at least annually, dated to indicate time of last review, revised as necessary, and enforced.

**Interpretive Guideline**

- Ask the Pharmacy Director to provide documentation that their policies, which cover all areas of Pharmacy services, are reviewed annually and revised as necessary?
- How are the Pharmacy policies distributed?

**ST - H0098 - PHARMACY - Parenteral Nutrition**

**Title** PHARMACY - Parenteral Nutrition

**Type** Rule

59A-3.241(17), FAC

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 77 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(17) Parenteral nutrition services, when provided, shall be designed, implemented, and maintained to address assessment and reassessment of the patient, initial ordering and ongoing maintenance of medication orders, preparation and dispensing, administration, and assessing the effects on the patient.

**Interpretive Guideline**

- Review the Pharmacy Policy and Procedures for parenteral nutrition.
- Does the pharmacist participate in a nutritional support team?
- Is the parenteral nutrition prepared by Pharmacy or is it ordered from the manufacturer already prepared?
- If possible, observe the preparation (prepared under IV hood).
- How does pharmacy monitor the effectiveness if there is not a nutritional support team?

Refer to tag 0074 for additional information on parenteral nutrition.

**ST - H0099 - SURGICAL DEPT - Policies & Procedures**

**Title** SURGICAL DEPT - Policies & Procedures

**Type** Rule

59A-3.245(1)(a-g), FAC

**Regulation Definition**

(1) Surgical Department. Each Class I and Class II hospital, and each Class III hospital providing operative and other invasive procedures, shall have a functionally and physically distinct surgical department within the hospital, organized under written policies and procedures regarding surgical privileges, maintenance of the operating rooms, and evaluation and recording of treatment of the patient. The surgical department shall have a physician member of the organized medical staff serve as medical advisor to the surgical department and a registered nurse to direct nursing services within the operating rooms of a surgical department. All surgical department policies and procedures shall be available to the Agency, shall be reviewed annually, dated to indicate time of last review, revised as necessary, and enforced.

(a) The determination of the appropriateness of the procedure for a patient shall be based on:

1. The patient's medical, anesthetic, and drug history;
2. The patient's physical status;

**Interpretive Guideline**

REVIEW:

- Policy and Procedure for items listed in tag. Are policy and procedures reviewed annually and revised as needed?
- Patient's record, did the facility follow its own policies and procedures?

Risk benefit information may be documented in the patient's medical record.

If non-compliance is identified; review risk management and quality improvement requirements.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 78 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

3. Diagnostic data;
  4. The risks and benefits of the procedure; and,
  5. The need to administer blood or blood components.
- (b) The risks and benefits of the procedure shall be discussed with the patient prior to documenting informed consent and include:
1. Other treatment options, if they exist;
  2. The need and risk of blood transfusions and available alternatives; and
  3. Anesthesia options and risks.
- (c) A preanesthesia evaluation of the patient shall be performed prior to surgery, except in the case of extreme emergency.
- (d) Plans of care for the patient shall be formulated and documented in the medical record prior to the performance of surgery and shall include a plan for anesthesia, nursing care, the operative or invasive procedure, and the level of post-procedure care.
- (e) The measurement of the patient's physiological status shall be assessed during the administration of anesthesia and the surgical procedure.
- (f) The post-procedure status of the patient shall be assessed on admission to the recovery area and prior to discharge from the recovery area.
- (g) The patient shall be discharged from the recovery area by a member of the organized medical staff.

**ST - H0100 - SURGICAL DEPT - Distinct Location**

**Title** SURGICAL DEPT - Distinct Location

**Type** Rule

59A-3.245(1)(h), FAC

**Regulation Definition**

(h) The operating room and accessory services shall be located

**Interpretive Guideline**

- Observe the surgical area to ensure the facility is following infection control standards.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 79 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

in a manner to prevent through traffic, control traffic in and out, and maximize infection control.

- Review organizational charts and facility maps for location of operating rooms and traffic flow.

**ST - H0101 - Operating Room Nurse**

**Title** Operating Room Nurse

**Type** Rule

395.0191(2)(d) FS

**Regulation Definition**

(d) Each hospital shall meet the requirements of the Medicare and Medicaid Conditions of Participation for Hospitals under 42 C.F.R. s. 482.51(a)(3) as they apply to registered nurses performing circulating duties in the operating room and as provided in the interpretive guidelines provided by the United States Department of Health and Human Services. A circulating nurse shall be present in the operating room for the duration of a surgical procedure.

**Interpretive Guideline**

**ST - H0102 - SURGICAL DEPT - Nursing Annual Education**

**Title** SURGICAL DEPT - Nursing Annual Education

**Type** Rule

59A-3.245(1)(j), FAC

**Regulation Definition**

(j) The registered nurse shall document that all surgical nursing staff have received annual continuing education in safety, infection control and cardiopulmonary resuscitation.

**Interpretive Guideline**

Review: Employees record of the surgical nursing staff to ensure they have been receiving their annual education.  
Review the facility's Policy and Procedures regarding surgical staff continuation training

Interview: Surgical Department nursing staff to see how they keep up with the annual trainings.  
Verify appropriate continuing education.

**Agency for Health Care Administration  
ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 80 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0103 - SURGICAL DEPT - Surgeons and Privileges**

**Title** SURGICAL DEPT - Surgeons and Privileges

**Type** Rule

59A-3.245(1)(k), FAC

**Regulation Definition**

(k) A roster of members of the organized medical staff specifying the surgical privileges of each, shall be maintained, reviewed annually and revised as necessary.

**Interpretive Guideline**

Interview: The O.R. scheduler how he/she knows what surgical privileges each surgeon has and how they know if those privileges change, especially on week-ends or holidays. What happens if a surgeon wants to perform a surgery the scheduler doesn't know if they have privileges to do?

Record Review: Review credentialing file of selected surgeons to ensure the surgeons scheduled for surgery have been granted privileges.

Review the facility's policy and procedure to determine the facility's process for granting surgeons privileges.

**ST - H0104 - SURGICAL DEPT - On Call Surgeons**

**Title** SURGICAL DEPT - On Call Surgeons

**Type** Rule

59A-3.245(1)(l), FAC

**Regulation Definition**

(l) A roster of "on-call" surgeons shall be promptly available at the operating room nursing stations. An on-call surgeon must be available to the hospital when a call for services has been placed.

**Interpretive Guideline**

Review: The on call roster. Review the grievance log to determine if there have been any complaints of physician's failing to come in when they are on call. If there have been any, review the patient's record to determine what occurred and if there were any negative outcomes. If there have been any complaints, determine what the facility has done to address this issue.

Interview: Staff to determine how they know who is on call. Do they have an on-call book or list? Where is it kept? How is it accessed?

ASK: Staff what they do when there is an unplanned/emergency case.  
How do they know who is on call?  
How do they know the surgeon is qualified to do the procedure?



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 81 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

What is a prompt response time? Does anyone track response time?  
Is someone in house at all times if they have an OB department?

**ST - H0105 - SURGICAL DEPT - Records**

**Title** SURGICAL DEPT - Records

**Type** Rule

59A-3.245(1)(m), FAC

**Regulation Definition**

(m) A record shall be maintained on a current basis that contains the following information:

1. Patient's name;
2. Hospital number;
3. Preoperative diagnosis;
4. Post-operative diagnosis;
5. Procedure;
6. Names of surgeon, first assistant, and anesthesiologist;
7. Type of anesthetic; and,
8. Complications, if any.

**Interpretive Guideline**

Review a sample of medical records of patients who had a surgical encounter. Verify the record contains a surgical report, is dated and signed by the responsible surgeon and includes the information specified in the regulation.

**ST - H0106 - SURGICAL DEPT - H&P and Consent**

**Title** SURGICAL DEPT - H&P and Consent

**Type** Rule

59A-3.245(1)(n), FAC

**Regulation Definition**

(n) Regardless of whether surgery is classified as major or minor, the surgical department shall ensure, prior to any surgery being performed, except in emergency situations:

1. That there is a complete history and physical workup in the chart of every patient or, if such has been transcribed, but not

**Interpretive Guideline**

Review a sample of patient records. Did the patient have the information specified in the regulation (except in an emergency situation)?  
Review the facility's policies and procedures regarding pre-surgical assessment.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 82 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

yet recorded in the patient's chart, that there is a statement to that effect in the chart; and,  
2. That there is evidence of informed consent for the operation in the patient's chart.

**ST - H0107 - SURGICAL DEPT - Operative Report**

**Title** SURGICAL DEPT - Operative Report

**Type** Rule

59A-3.245(1)(o), FAC

**Regulation Definition**

(o) The surgical department shall ensure that immediately following each surgery, there is an operative report describing techniques and findings that is written or dictated and signed by the surgeon.

**Interpretive Guideline**

REVIEW: Post-operative charts for required information. If the report is not there or not signed by the surgeon, review the policy as to when it must be completed and signed.

**ST - H0108 - SURGICAL DEPT - Equipment**

**Title** SURGICAL DEPT - Equipment

**Type** Rule

59A-3.245(1)(p), FAC

**Regulation Definition**

(p) The following equipment shall be in each operating room suite:

1. Call-in system;
2. Oxygen, and means of administration;
3. Mechanical ventilatory assistance equipment, including airways, manual breathing bag, and ventilator and respirator;
4. Cardiac defibrillator with synchronization capability;
5. Respiratory and cardiac monitoring equipment;
6. Thoracentesis and closed thoracostomy sets;

**Interpretive Guideline**

TOUR: The operating room suites to ensure each room has the required equipment. Ask about/review preventive maintenance on equipment.

Check all electrical equipment for current Biomedical inspections.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 83 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

7. Tracheostomy set, tourniquets, vascular cutdown sets, infusion pumps, laryngoscopes and endotracheal tubes;
8. Tracheobronchial and gastric suction equipment; and
9. A portable x-ray which shall be available, but need not be physically present in the operating suite.

**ST - H0109 - SURGICAL DEPT - Infections**

**Title** SURGICAL DEPT - Infections

**Type** Rule

59A-3.245(1)(i), FAC

**Regulation Definition**

(i) All infections of clean surgical cases shall be recorded and reported to the appropriate infections control authority, and a procedure shall exist for the investigation of such cases.

**Interpretive Guideline**

Interview key surgical / risk management personnel: What their procedure is for recording, reporting, and investigating infections of clean surgical cases. Who do they report the cases to? Who investigates? Do they have any cases reported and investigated? If concerns, review their policy and a sample of cases investigated.

**ST - H0111 - ANESTHESIA DEPT - Physician Director**

**Title** ANESTHESIA DEPT - Physician Director

**Type** Rule

59A-3.245(2), FAC

**Regulation Definition**

(2) Anesthesia Department. Each Class I and Class II hospital, and each Class III hospital providing surgical or obstetrical services, shall have an anesthesia department, service or similarly titled unit directed by a physician member of the organized professional staff.

**Interpretive Guideline**

REVIEW: Medical staff credentialing files for qualifications of physician director. Check Director's file to see if he/she meets the requirements. Check organization chart to ensure anesthesia department staff report to Director. What are his/her responsibilities?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 84 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0112 - ANESTHESIA DEPT - Written Policies & Procedur**

**Title** ANESTHESIA DEPT - Written Policies & Procedur

**Type** Rule

59A-3.245(2)(a), FAC

**Regulation Definition**

(a) The anesthesia department of each hospital shall have written policies and procedures that are approved by the organized medical staff, are reviewed annually, dated at time of last review, revised, and enforced as necessary. Such written policies and procedures shall include the following requirements:

1. A preanesthesia evaluation of the patient by the physician, or qualified oral surgeon in the case of patients without medical problems admitted for dental procedures, or certified registered nurse anesthetist where authorized by established protocol approved by the medical staff, except in the case of emergencies.
2. A review of the patient's condition immediately prior to induction of anesthesia.
3. A mechanism for release of patients from postanesthesia care.
4. A recording of all pertinent events taking place during the induction of, maintenance of, and emergence from anesthesia.
5. Guidelines for the safe use of all general anesthetic agents used in the hospital.

**Interpretive Guideline**

REVIEW:

- Are policies and procedures approved by medical staff and reviewed annually?
- How are policies enforced?
- Review surgical charts for compliance with requirements.

Interview Staff:

- What measures do you use with general anesthetic agents in the hospital to ensure safety?
- Ask for the facility's definition of immediately.

Are patients released via protocol or are they seen by anesthesia before discharge or return to room?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 85 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0113 - ANESTHESIA DEPT - Staff Respon & Qualif**

**Title** ANESTHESIA DEPT - Staff Respon & Qualif

**Type** Rule

59A-3.245(2)(b), FAC

**Regulation Definition**

(b) The responsibilities and qualifications of all anesthesia personnel, including physician, nurse and dentist anesthetists and all trainees, must be defined in a policy statement, job description, or other appropriate document.

**Interpretive Guideline**

ASK: For a list of all anesthesia staff. Select a small sample to review. Does the hospital have a policy statement, job description, or other documentation listing responsibilities and qualifications of the staff?

Interview anesthesia staff regarding their responsibilities and qualifications.

**ST - H0114 - ANESTHESIA DEPT - Safety Regulations**

**Title** ANESTHESIA DEPT - Safety Regulations

**Type** Rule

59A-3.245(2)(c), FAC

**Regulation Definition**

(c) Anesthetic safety regulations shall be developed, posted, and enforced. Such regulations shall include the following:

1. A requirement that all operating room electrical and anesthesia equipment be inspected on an annual basis and at intervals not exceeding the manufacturer's recommendations. A written record of the inspection results and corrective action shall be maintained by the hospital.
2. A requirement that flammable anesthetic agents be employed only in areas in which a conductive pathway can be maintained between the patient and a conductive floor.
3. A requirement that each anesthetic gas machine have a pin-index or equivalent safety system.
4. A requirement that all reusable anesthesia equipment

**Interpretive Guideline**

TOUR: Look for inspections of all operating room electrical and anesthesia equipment.

ASK: What flammable anesthetic agents are used.

- How do they ensure these agents are used only in a conductive pathway?
- Do all anesthetic gas machines have a pin index or equivalent safety system?
- How is all reusable equipment coming in direct contact with the patient cleaned?
- Are the safety regs developed? Posted? Enforced?
- Are there written report of results and corrective action?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 86 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

coming in direct contact with the patient be cleaned or sterilized in the manner prescribed by current medical standards.

**ST - H0115 - NURSING SERVICE - Organized & Staffed**

**Title** NURSING SERVICE - Organized & Staffed

**Type** Rule

59A-3.243, FAC

**Regulation Definition**

Each hospital shall have a nursing department organized and staffed to provide quality nursing care to each patient. The relationship of the nursing department to other units of the hospital shall be documented by an organizational chart.

**Interpretive Guideline**

- Observe the nursing care being provided to assess the delivery of care and determine the adequacy of staffing; Review staffing schedules and tabulate/cross reference with actual assignments.
- Ask for an organizational chart for nursing services for all locations where the hospital provides nursing services;
- Verify the director of nursing services is involved with and approves the development of nursing service staffing policies and procedures.
- How does nursing relate to other departments?
- If the hospital does not have a nursing department or service, ask how they assure oversight of the quality of nursing care for each patient.

**ST - H0116 - NURSING SERVICE - Management**

**Title** NURSING SERVICE - Management

**Type** Rule

59A-3.243(1 & 4), FAC

**Regulation Definition**

- (1) The nursing department shall have a written organizational plan that delineates lines of authority, accountability and communication, and shall assure that the following nursing management functions are fulfilled:
- (a) Review and approval of policies and procedures that relate to qualifications and employment of nurses.

**Interpretive Guideline**

- Ask for an organizational chart. Review the org. chart to determine if nursing service is under the direction of "one" RN; determine if this RN is "responsible" for the operation of nursing services, which includes the quality of patient care provided by Nursing Services;
- Are policies and procedures related to qualifications for employment of nurses reviewed and approved?
- How are standards of nursing care and mechanisms for evaluating care established?
- How are approved nursing policies implemented?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 87 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(b) Establishment of standards for nursing care and mechanisms for evaluating such care.

(c) Implementing approved policies of the nursing department.

(d) Assuring that a written evaluation is made of the performance of registered nurses and ancillary nursing personnel at the end of any probationary period and at a defined interval thereafter.

(4) Each hospital shall employ a registered nurse on a full time basis who shall have the authority and responsibility for managing nursing services and taking all reasonable steps to assure that a uniformly optimal level of nursing care is provided throughout the hospital.

- How is staff made aware of new or changed policies?

- How often is a written evaluation of the performance of registered nurses and ancillary nursing personnel done?

- If the hospital uses agency staffing, traveling nurses, or other temporary services, how are they made aware of policies and evaluated?

**ST - H0117 - NURSING SERVICE - Care Reviews & Evaluation**

**Title** NURSING SERVICE - Care Reviews & Evaluation

**Type** Rule

59A-3.243(4)(a), FAC

**Regulation Definition**

(a) The registered nurse shall be responsible for ensuring that a review and evaluation of the quality and appropriateness of nursing care is accomplished. The review and evaluation shall be based on written criteria, shall be performed quarterly, and shall examine the provision of nursing care and its effect on patients.

**Interpretive Guideline**

- Review a sample of closed and current medical records for nursing care.

- Interview patients and families. Observe care being provided. Ask how the hospital reviews and evaluates nursing care.

- How often is this done? What are the criteria? If the effect on patients is not positive, what if any action is taken?

**ST - H0118 - NURSING SERVICE - Education & Training**

**Title** NURSING SERVICE - Education & Training

**Type** Rule

59A-3.243(4)(b), FAC

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 88 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(b) The registered nurse shall ensure that education and training programs for nursing personnel are available and are designed to augment nurses' knowledge of pertinent new developments in patient care and maintain current competence. Cardiopulmonary resuscitation training shall be conducted as often as necessary, but not less than annually, for all nursing staff members who cannot otherwise document their competence.

**Interpretive Guideline**

- Ask how the hospital selects education and training programs for nursing personnel? How do they ensure nurses are kept up to date on new developments in patient care and maintain competencies?
- Review a sample of personnel files for annual CPR training. The same files can be reviewed for current license and other required training.
- Ask staff members about education programs they attended in current year. Do they have input into suggestions for in-services?
- How does the hospital ensure that temporary staff is competent?

**ST - H0119 - NURSING SERVICE-Std of Practice & Policy/Proc**

**Title** NURSING SERVICE-Std of Practice & Policy/Proc

**Type** Rule

59A-3.243(2), FAC

**Regulation Definition**

(2) The nursing department shall have written standards of nursing practice and related policies and procedures to define and describe the scope and conduct of patient care provided by the nursing staff. These policies and procedures shall be reviewed annually, revised as necessary, dated to indicate the time of the last review, signed by the responsible reviewing authority, and enforced.

**Interpretive Guideline**

- Observe patient care.
- Review a sample of current medical records.  
Are staff aware and follow hospital policies and procedures?
- Interview patients and staff regarding care.
- Is the policy reviewed annually, revised as necessary, dated and signed to indicate the time of last review and enforced?

**ST - H0120 - NURSING SERVICE - Care Process**

**Title** NURSING SERVICE - Care Process

**Type** Rule

59A-3.243(5), FAC



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 89 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(5) The nursing process of assessment, planning, intervention and evaluation shall be documented for each hospitalized patient from admission through discharge.

(a) Each patient's nursing needs shall be assessed by a registered nurse at the time of admission or within the period established by each hospital's policy.

(b) Nursing goals shall be consistent with the therapy prescribed by the responsible member of the organized medical staff.

(c) Nursing intervention and patient response, and patient status on discharge from the hospital, must be noted on the medical record.

**Interpretive Guideline**

Observe nursing care. Are patients assessed by a Registered Nurse?

- Review a sample of medical records. Are patients appropriately assessed? Are nursing goals defined based on the patient's condition? Are care plans current and followed:

- Are interventions evaluated and updated as needed?

- Do nurses document the patient's condition on discharge?

- If there are abnormal labs or vital signs, is the physician made aware prior to discharge?

**ST - H0121 - NURSING SERVICE - Sufficient Staffing**

**Title** NURSING SERVICE - Sufficient Staffing

**Type** Rule

59A-3.243(4)(c), FAC

**Regulation Definition**

(c) The registered nurse shall be responsible for determining the number of qualified registered nurses to be on duty at all times. The number of qualified nurses shall be sufficient to ensure immediate availability of a registered nurse for bedside care of any patient when needed, to assure prompt recognition of an untoward change in a patient's condition, and to facilitate appropriate intervention by nursing, medical or other hospital staff members.

**Interpretive Guideline**

- Observe staff patient ratio. Review assignment and schedule for two week period, if there are concerns.

Interview patients to ensure needs are met and call lights answered.

- Review a sample of medical records.

- Are patients appropriately assessed?

- Observe care and services of sample patients - are Registered Nurses sufficient and qualified to provide care needed by the patient?

**Agency for Health Care Administration  
ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 90 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0122 - NURSING SERVICE - RN On Duty**

**Title** NURSING SERVICE - RN On Duty

**Type** Rule

59A-3.243(6), FAC

**Regulation Definition**

(6) Each Class I and Class II hospital shall have a minimum of one licensed registered nurse on duty at all times on each nursing unit or similarly titled part of the hospital for rendering patient care services.

**Interpretive Guideline**

Ask how the facility ensures sufficient RN staff at all times. Observe RNs present on units.

**ST - H0123 - NURSING SERVICE - List of Licensed Staff**

**Title** NURSING SERVICE - List of Licensed Staff

**Type** Rule

59A-3.243(3), FAC

**Regulation Definition**

(3) The nursing department shall maintain a list of licensed personnel, including private duty and per diem nurses, with each individual's current license number, and documentation of the nurses' hours of employment, and unit of employment within the hospital.

**Interpretive Guideline**

- Ask to see a list of licensed staff. Review a sample for current licenses.  
- Ask how the facility ensures all staff for whom licensure is required is current. How do they document hours of employment and unit worked? How do they maintain that information on private duty and per diem nurses?

**ST - H0124 - HOUSEKEEPING SERVICE - Staffing/Contract/Plan**

**Title** HOUSEKEEPING SERVICE - Staffing/Contract/Plan

**Type** Rule

59A-3.247(1-3), FAC

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 91 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

Each hospital shall have an organized housekeeping department with a qualified person designated as responsible for all housekeeping functions. The designated supervisor of housekeeping shall be responsible for developing written policies and procedures for coordinating housekeeping services with other departments, developing a work plan and assignments for housekeeping staff, and developing a plan for obtaining relief housekeeping personnel.

(1) A sufficient number of housekeeping personnel shall be employed to fulfill the responsibilities of the housekeeping department seven days a week.

(2) When housekeeping services are provided by a third party, the hospital shall have a formal written agreement with the third party provider on file.

(3) The designated supervisor of housekeeping shall develop, implement, and maintain an effective housekeeping plan to ensure that the facility is maintained in compliance with the following:

(a) The facility and its contents shall be kept free from dust, dirt, debris, and noxious odors;

(b) All rooms and corridors shall be maintained in a clean, safe, and orderly condition, and shall be properly ventilated to prevent condensation, mold growth, and noxious odors;

(c) All walls and ceilings, including doors, windows, skylights, screens, and similar closures shall be kept clean;

(d) All mattresses, pillows, and other bedding; window coverings, including curtains, blinds, and shades, cubicle curtains and privacy screens; and furniture shall be kept clean;

(e) Floors shall be kept clean and free from spillage, and non-skid wax shall be used on all waxed floors;

(f) Articles in storage shall be elevated from the floor;

(g) Aisles in storage areas shall be kept unobstructed;

(h) All garbage and refuse from patient areas shall be collected daily and stored in a manner to make it inaccessible to insects and rodents;

**Interpretive Guideline**

- Identify and interview the person responsible for the housekeeping department and verify qualifications for the job.
- Review the written policies and procedures. Is there a documented work plan and is there always adequate staff to perform this function? Verify by interviewing staff. Is the housekeeping service contracted and, if so, review the contract.
- Tour the facility to observe cleaning of rooms, corridors, procedure rooms, food preparation areas; to ensure compliance. Is the hospital equipment clean? Is the housekeeping department a part of the hospital QI program? What are the QI requirements and is the hospital in compliance?
- Consider infection control and the impact of the environment on patient care, safety, or potential for food borne illness. Also reference Tag 0199-0203 for additional infection control standards.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 92 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

- (i) Garbage or refuse storage rooms, if used, shall be kept clean, shall be vermin-proof, and shall be large enough to store the garbage and refuse containers that accumulate. Outside garbage or refuse storage areas or enclosures shall be large enough to store the garbage and refuse containers that accumulate, and shall be kept clean. Outside storage of unprotected plastic bags, wet strength paper bags, or baled units containing garbage or refuse is prohibited. Garbage and refuse containers, dumpsters, and compactor systems located outside shall be stored on or above a smooth surface of non-absorbent material, such as concrete or machine-laid asphalt, that is kept clean and maintained in good repair; and
- (j) Garbage and refuse shall be removed from both interior and outside storage areas as often as necessary to prevent sanitary nuisance conditions. If garbage and refuse are disposed of on the facility premises, the method of disposal shall not create a sanitary nuisance.

**ST - H0125 - HOUSEKEEPING SERVICE - Linen/Laundry**

**Title** HOUSEKEEPING SERVICE - Linen/Laundry

**Type** Rule

59A-3.247(4), FAC

**Regulation Definition**

- (4) The designated supervisor of housekeeping shall ensure that:
- (a) There is a sufficient quantity of linen, including at least sheets, pillow cases, drawsheets or their alternative, blankets, towels and washcloths to provide comfortable, clean and sanitary conditions for each patient at all times;
- (b) Written policies and procedures for linen and laundry services, including methods of collection, storage, and transportation are developed, implemented, and maintained in conjunction with the policies and procedures developed by the

**Interpretive Guideline**

- Does the hospital have a laundry or is this service contracted? If contracted, review the contract. If not, then continue.
- Review the written policies and procedures for linen and laundry services.
- Tour and observe if there is adequate linen. Observe how soiled linen and clean linen are handled in patient rooms, in clean and soiled utility rooms, during transport and laundry.
- Are linen services policies developed by the infection control committee?
- Are infection control procedures followed by staff when handling linen?
- How is clean linen stored to prevent contamination?
- What ongoing monitoring procedures are in place to ensure the proper quantity and handling of linen?
- What standards are required for the laundry?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 93 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

infection control committee;

(c) Soiled linen and laundry are collected in a way that minimizes microbial dissemination into the environment;  
(d) Separate containers are used for transporting clean linen and laundry, and soiled linen and laundry;

(e) Soiled linen and laundry are stored in a ventilated area separate from any other supplies, and are not stored, sorted, rinsed, or laundered in patient rooms, bathrooms, areas of food preparation or storage, or areas in which clean material and equipment are stored; and

(f) When linen and laundry services are provided by a third party, the third party provider shall be required to maintain the standards contained herein, and shall ensure that clean linen is packaged and protected from contamination until received by the facility.

- How does the hospital ensure this?

**ST - H0126 - HOUSEKEEPING SERVICE - Pest Control**

**Title** HOUSEKEEPING SERVICE - Pest Control

**Type** Rule

59A-3.247(5), FAC

**Regulation Definition**

(5) Effective control methods shall be employed to protect against the entrance into the facility and the breeding or presence on the premises of flies, roaches, rodents, and other vermin.

**Interpretive Guideline**

- Does the facility have methods to protect against pest entry?
- Does the facility provide its own pest control service or is the service contracted? If contracted, review the service contract. Ask for documentation that pest control is done on a regular basis. Do the reports indicate any problems? Is there follow-through on pest issues?
- Tour the facility to observe for any indication of pests. Also, interview patients and staff to ensure this is not a previously or currently identified problem.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 94 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0127 - HOUSEKEEPING SERVICE - Written Procedures**

**Title** HOUSEKEEPING SERVICE - Written Procedures

**Type** Rule

59A-3.247(6), FAC

**Regulation Definition**

(6) The designated supervisor of housekeeping shall develop and implement, in coordination with the infection control committee, written procedures for the cleaning of the physical plant, equipment, and reusable supplies. Such procedures shall include:

- (a) Special written procedures for cleaning all infectious disease areas;
- (b) Special written procedures for cleaning all operating room suites, delivery suites, nurseries, intensive and other critical care units, the emergency suite, and other areas performing similar functions; and
- (c) Special written procedures for the separate handling and storage of both clean and dirty linen, with special attention being given to identification, separation and handling of linens from isolation or infectious disease areas.

**Interpretive Guideline**

- Does the hospital housekeeping department have written policies and procedures developed in conjunction with the hospital infection control committee that specify cleaning requirements for physical plant, equipment and reusable supplies?
- Observe how housekeeping is done in infectious disease areas and special patient care areas (i.e., operating room, intensive care, nursery, etc.).
- Are there special written policies and procedures for handling of linens from isolation areas?
- Interview and observe staff to be sure these special housekeeping procedures are followed.
- Consider the impact of the cleaning, isolation, and isolation on patient safety and infection control.
- Observe a terminal cleaning of the operating room suites, if possible.

**ST - H0128 - AMBULATORY CARE SVCS - Policy/Procedures**

**Title** AMBULATORY CARE SVCS - Policy/Procedures

**Type** Rule

59A-3.244(1), FAC

**Regulation Definition**

(1) Ambulatory Care Services. Each hospital offering ambulatory care services under its hospital license shall

**Interpretive Guideline**

- Does the facility offer ambulatory care services? Ambulatory care services may include outpatient rehabilitative therapies, diagnostic procedures, outpatient counseling, wound care, outpatient surgery, urgent care, etc. If no or if the

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 95 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

establish policies and procedures to ensure that quality care based on the needs of the patient will be delivered at all times.

services are under a separate license, do not review tags 128- 138. If so, continue.

- Review the written policies regarding ambulatory care services. How does the hospital ensure quality care based on the needs of the patient?
- These policies and procedures must address that these services meet the current standards of practice for the care and treatment being provided. They should also address the provision of supplies and equipment necessary for ensuring quality care.
- Tour all areas of ambulatory care services offered under the hospital license.
- Interview staff from the ambulatory care services.
- Include a sample of staff for licensure, competence, and training for personnel record reviews.
- Include patients selected from the ambulatory care services for record and observation reviews.

**ST - H0129 - AMBULATORY CARE SVCS -Physician(s) Responsibl**

**Title** AMBULATORY CARE SVCS -Physician(s) Responsibl

**Type** Rule

59A-3.244(1)(a), FAC

**Regulation Definition**

(a) Ambulatory care services shall be under the direction of a licensed physician(s) responsible for the clinical direction of patient care and treatment services, and whose qualifications, authority, and responsibilities are defined in writing as approved by the governing board.

**Interpretive Guideline**

- Interview the licensed physician(s) who provide the clinical direction for patient care and treatment. There may be physician specialists for different specialty ambulatory care services, such as a radiologist for radiological diagnostic services.
- Review the licenses of the physician(s). Review the governing body bylaws to determine that the physician's qualifications, authority, and responsibilities are defined in writing and approved by the governing body.
- Interview the physician if issues are identified during the survey and as needed.

**ST - H0130 - AMBULATORY CARE SVCS - Staffing**

**Title** AMBULATORY CARE SVCS - Staffing

**Type** Rule

59A-3.244(1)(b), FAC

**Regulation Definition**

(b) Ambulatory care services shall be staffed with

**Interpretive Guideline**

- Observe all of the ambulatory care settings and interview the staff about their credentials and responsibilities.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 96 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

appropriately trained and qualified individuals to provide the scope of services anticipated to meet the needs of the patients.

Interview some ambulatory care patients about the quality of their services.  
- Review the hospital policies and procedures about the qualifications of staff necessary to provide the scope of services anticipated to meet the needs of patients. Review a sample of staff training records.

**ST - H0131 - AMBULATORY CARE SVCS -Physicians & Privileges**

**Title** AMBULATORY CARE SVCS -Physicians & Privileges

**Type** Rule

59A-3.244(1)(c), FAC

**Regulation Definition**

(c) Each patient's general medical condition shall be managed by a member of the organized medical staff with appropriate clinical privileges, as determined by medical staff bylaws.

**Interpretive Guideline**

- Review the ambulatory care patient record to determine if they have been managed by a physician with appropriate clinical privileges.  
- Review medical staff bylaws to determine which physicians have appropriate clinical privileges  
- Review a sample of physician credential files from the ambulatory care services.

**ST - H0132 - AMBULATORY CARE SVCS - Safety NonHosp Employee**

**Title** AMBULATORY CARE SVCS - Safety NonHosp Employee

**Type** Rule

59A-3.244(1)(d), FAC

**Regulation Definition**

(d) When any ambulatory care services are provided by non-hospital employees, the provider shall meet all safety requirements, abide by all pertinent rules and regulations of the hospital and medical staff, and document the quality improvement measures to be implemented.

**Interpretive Guideline**

- When visiting the ambulatory care settings, ask which services utilize non-hospital employees.  
- Interview non-hospital employees regarding their knowledge of safety requirements, pertinent hospital and medical staff rules and regulations. Review the training files of these non-hospital staff to determine if they have received training about safety and pertinent hospital and medical staff rules and regulations.  
- Review documentation of quality improvement measures implemented.



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 97 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0133 - AMBULATORY CARE SVCS -RN Supervision & Qualif**

**Title** AMBULATORY CARE SVCS -RN Supervision & Qualif

**Type** Rule

59A-3.244(1)(e), FAC

**Regulation Definition**

(e) The provisions of ambulatory nursing care shall be supervised by a registered nurse who is qualified by relevant training and experience in ambulatory care.

**Interpretive Guideline**

- Interview the Registered Nurse (RN) who supervises the provisions of ambulatory nursing care about his/her qualifications and training and experience in ambulatory care.
- Review the personnel file of the RN staff to verify credentials and training.

**ST - H0134 - AMBULATORY CARE SVCS - Sufficient Staff**

**Title** AMBULATORY CARE SVCS - Sufficient Staff

**Type** Rule

59A-3.244(1)(f), FAC

**Regulation Definition**

(f) Sufficient personnel shall be on duty to provide efficient and effective patient care services.

**Interpretive Guideline**

- Review schedule of personnel to determine if enough staff are available.
- Observe patient care.
- Interview ambulatory care patients to determine if they feel if their services are efficient and effective.

**ST - H0135 - AMBULATORY CARE SVCS - Scope/Relationship**

**Title** AMBULATORY CARE SVCS - Scope/Relationship

**Type** Rule

59A-3.244(1)(g), FAC

**Regulation Definition**

(g) The scope of services offered, and the relationship of the

**Interpretive Guideline**

- Review the governing board's bylaws and the rules and regulations of the medical staff to determine if the following

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 98 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

ambulatory services program to other hospital units, as well as all supervisory relationships within the program, shall be defined in writing, and must be provided in accordance with the standards set by the governing board's bylaws and the rules and regulations of the medical staff.

are defined in writing:

- The scope of services offered.
- Relationship with other hospital units and supervisory relationships within the program.
- Look to see there are established methods of communication, as well as established procedures, to assure integration with inpatient services that provide for continuity of care.
- If there are concerns, interview the director of ambulatory care.

**ST - H0136 - AMBULATORY CARE SVCS - Program Operation**

**Title** AMBULATORY CARE SVCS - Program Operation

**Type** Rule

59A-3.244(1)(h), FAC

**Regulation Definition**

(h) Written policies and procedures to guide the operation of the ambulatory services program shall be developed, reviewed, and revised as necessary, dated to indicate the time of last revision, and enforced.

**Interpretive Guideline**

- Review policies and procedures to determine if they meet the criteria listed.
- Determine if observations and interviews of the operations during visits to the ambulatory care settings correspond to these policies and procedures.

**ST - H0137 - AMBULATORY CARE SVCS - Medical Records**

**Title** AMBULATORY CARE SVCS - Medical Records

**Type** Rule

59A-3.244(1)(i-i); 59A-3.270(5) FAC

**Regulation Definition**

59A-3.244(1)  
(i) A medical record must be maintained on every patient who receives ambulatory care services. Medical records shall be managed and maintained in accordance with acceptable professional standards and practices. Confidentiality and disclosure of patient information contained in the medical record must be maintained in accordance with hospital policy

**Interpretive Guideline**

- Interview the personnel charged with the responsibility for the medical records.
- Request and review policies and procedures about how records are managed and maintained.
- Review policy regarding confidentiality of patient information.
- Visit the area where patient medical records are kept. Are they electronic? Is the area secured? Ask the personnel who has access to this area.
- During the visit to the ambulatory care setting, look for evidence that patient information is kept confidential or not disclosed without patient's knowledge through patient and employee interactions and environment.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 99 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

and state and federal law. Each patient's medical record must include the following information, and be updated as necessary:

1. Patient identification;
2. Relevant history of the illness or injury and of physical findings;
3. Diagnostic and therapeutic orders;
4. Clinical observations, including the results of treatment;
5. Reports of procedures and tests, and their results;
6. Diagnosis or impression;
7. Allergies;
8. Referrals to practitioners or providers of services internal or external to the hospital;
9. Communications to and from practitioners or providers of service external to the hospital;
10. Growth charts for children and adolescents as needed when the service is the source of primary care; and
11. Immunization status of children and adolescents and others as determined by law and/or hospital policy.

(j) To facilitate the ongoing provision of care, a problem list of known significant diagnoses, conditions, procedures, drug allergies and medications shall be maintained for each patient who receives ambulatory services. The problem list shall be initiated no later than the third visit and include items based on any initial medical history and physical examination, and updated on subsequent visits with additional information as necessary. The problem list shall include the following items:

1. Known significant medical diagnoses and conditions;
2. Known significant surgical and invasive procedures;
3. Known adverse and allergic reactions to drugs; and
4. Medications known to be prescribed for and/or used by the patient.

59A-3.270

- Review a sample of ambulatory care patient medical records based on the type and scope of services to determine if they include .

- If there is information missing from the ambulatory care medical records, interview personnel responsible for enforcing.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 100 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(5) Medical records for ambulatory care patients must consist of the information specified in paragraph 59A-3.244(1)(i), F.A.C.

**ST - H0139 - OBSTETRICAL DEPT - Organization & Operation**

**Title** OBSTETRICAL DEPT - Organization & Operation

**Type** Rule

59A-3.244(2)(a), FAC

**Regulation Definition**

(2) Obstetrical Department. If provided, obstetrical services shall include labor, delivery, and nursery facilities, and be formally organized and operated to provide complete and effective care for each patient.

(a) Except in hospitals licensed for 75 beds or less, the obstetrical service shall be separated from other patient care rooms and shall have separate nursing staff. When obstetrical services are provided in hospitals of 75 beds or less, there shall be:

1. A written and enforced policy concerning the placement of obstetrical patients in a manner most conducive to meet their special needs, and
2. Nursing staff who possess specialized skills in obstetrics and neonatal care, whether by training or experience, and can provide service to obstetrical patients and their infants on a 24 hour basis, whether on duty, on call, or on a consultative basis.

**Interpretive Guideline**

- Review Obstetrical services according to size of facility beds.

For over 75 beds:

- Is the obstetrical services separated from other patients?
- Is the nursing staff separate from other units?

For 75 bed or less:

- Select a sample of staff training records to assure specialized skills training or experience.
- Are nurses specifically assigned to the OB unit only?
- How is Specialized Staffing covered on a 24 hour basis?
- Are staff utilized from other areas in emergencies and how are they qualified.
- Review staff competency requirements.

**ST - H0140 - OBSTETRICAL DEPT - Gyn & Surgical Patients**

**Title** OBSTETRICAL DEPT - Gyn & Surgical Patients

**Type** Rule

59A-3.244(2)(b), FAC

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 101 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(b) In those hospitals with a formally organized obstetrical department, clean gynecological and surgical patients may be admitted to the unit under specific written controls approved by the medical staff and governing board when there is a written demonstrated need in each case.

**Interpretive Guideline**

- Review Admission Log and Surgical Schedule for the past three months of specialized approved gynecological or surgical patients.
- Review a sample of records of gynecological or surgical cases for compliance with this.

**ST - H0141 - OBSTETRICAL DEPT - Infant Identification**

**Title** OBSTETRICAL DEPT - Infant Identification

**Type** Rule

59A-3.244(2)(c), FAC

**Regulation Definition**

(c) Every infant born in a hospital shall be properly identified immediately at the time of birth. Identification of the infant shall be done in the delivery room, birthing room, or other place of birth within the hospital, before either the mother or the infant is transferred to another part of the facility.

**Interpretive Guideline**

- Interview the head of obstetrics or the Emergency Department. Ask how infants are identified.
- Observe infant identification is consistent throughout the hospital.

**ST - H0142 - LAB & PATH SVCS - Lab Cert/Tests/Avail/Rpts**

**Title** LAB & PATH SVCS - Lab Cert/Tests/Avail/Rpts

**Type** Rule

59A-3.242(1)(a)-(c), FAC

**Regulation Definition**

(1) Clinical and Pathology Laboratory Services. Each hospital must provide on the premises, or by contract, clinical and pathology laboratory services commensurate with the hospital's needs. The hospital laboratory, and any contracted laboratory providing services for hospital patients, must be

**Interpretive Guideline**

- Interview administrative and/or laboratory management personnel to determine where laboratory services are performed?
- If contracted with an off-site lab, review contracts.
- If performed on-site, review the following:
  - What level and types of testing are performed?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 102 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments (CLIA) and the federal rules adopted thereunder in all specialties or subspecialties in which testing is performed. Hospitals may operate more than one CLIA certified laboratory. Each hospital laboratory shall have a qualified laboratory director. Qualifications for laboratory director, supervisor, technologist, and technician are found in Chapter 483, part II, F.S., and the rules adopted thereunder.

(a) The laboratory director is responsible for the supervision of the laboratory, including alternate-site testing locations, and shall maintain and enforce policies and procedures for the provision of clinical and pathology laboratory examinations.

(b) Provision shall be made for assuring the availability of emergency laboratory services. Such services shall be available 24 hours a day, seven days a week, including holidays.

(c) Reports of all examinations shall be filed with the patient's medical record.

- Are services available 24/7 and in emergency situations?
  - Are results/reports included in patient medical records? It is acceptable for these to be either individual reports or in cumulative report formats.
- Request a copy of the federal Clinical Laboratory Improvement Amendments (CLIA) Certificate. This certificate should be current (not beyond the expiration date). If the hospital cannot produce a copy of a CLIA Certificate, the Laboratory Unit should be contacted for further information regarding potential testing outside the scope of their certificate or verification of specialties.
- The term "alternate-site testing" includes any laboratory testing done under the administrative control of a hospital but performed out of the physical or administrative confines of the central laboratory.

**ST - H0143 - LAB & PATH SVCS - Path Lic/Specimens/Rpts**

**Title** LAB & PATH SVCS - Path Lic/Specimens/Rpts

**Type** Rule

59A-3.242(1)(d), FAC

**Regulation Definition**

(d) All specimens removed in operations shall be examined by a pathologist, except when another suitable means of verification of removal is routinely employed, when there is an authenticated report to document the removal, and when quality of care will not be compromised by the exception. Hospitals may establish a policy for excepting certain categories of specimens from examination when it determines quality of care will not be compromised or examination will

**Interpretive Guideline**

- Is path lab in the hospital or contracted?
  - If contracted, do they have a policy to address transporting of specimens?
  - If lab is in the hospital, review the following:
    - Interview personnel to determine how tissue samples from surgery are handled and tested.
    - Observe how the pathology specimens are handled and reported.

If this is an issue contained in a complaint, observe the tissue transfer process from OR to lab

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 103 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

yield no useful information. Signed reports on all specimens removed in an operation, whether documented by a pathologist or through an alternative means, shall be filed with the patient's medical record.

**ST - H0145 - LAB & PATH SVCS - Blood Bank Records**

**Title** LAB & PATH SVCS - Blood Bank Records

**Type** Rule

59A-3.242(1)(e)7, FAC

**Regulation Definition**

(e) All hospitals utilizing blood and blood products, shall:  
7. Records shall be kept on file indicating the receipt and disposition of all blood provided to patients in the facility.

**Interpretive Guideline**

- Records of blood receipt and disposition should be available regardless of who provides services. Review a sample of blood bank records, may include any logs or patient medical records.  
- Lack of sufficient records may represent deficient record systems and clarification can be provided by personnel walking you through their process.

**ST - H0146 - LAB & PATH SVCS-Blood Procure/Store/Transfuse**

**Title** LAB & PATH SVCS-Blood Procure/Store/Transfuse

**Type** Rule

59A-3.242(1)(e)1-6, FAC

**Regulation Definition**

(e) All hospitals utilizing blood and blood products, shall:  
1. Maintain facilities for procurement, safekeeping and transfusion of blood and blood products, or have them readily available.  
2. Maintain a temperature alarm system for blood storage facilities, where applicable, which is tested and inspected quarterly and is otherwise safe.  
3. The alarm system must be audible, and must monitor proper blood and blood product storage temperature over a 24-hour

**Interpretive Guideline**

- Based on the level of blood and transfusion services determined to be offered at the facility, observation of blood/blood product storage shall be conducted. This may consist of refrigerators (specifically designated for this purpose) and/or temperature monitored ice chests for temporary storage.  
- Refrigerators may be located in a main laboratory area or in specialty care areas such as surgery, emergency department, or obstetrics.  
- Records of alarm system testing should be reviewed, and may consist of log sheet documentation and/or refrigerator graphs. Temperature recording on the graph will usually have a peak in the line indicating an abrupt change of temperature and rapid return to normal range (1-6 degrees C).  
- Request a demonstration of the alarm system. Laboratory personnel will assist with chilling/warming the refrigerator

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 104 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

period.  
4. Tests of the alarm system must be documented.  
5. If blood is stored or maintained for transfusion outside of a monitored refrigerator, the hospital must ensure and document that storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.  
6. Promptly dispose of blood which has exceeded its expiration date.

temperature probes to activate the alarm. Observation of this process may help resolve questions regarding the system efficacy.  
- Observation of the blood refrigerator(s) should be made to assure that blood products are not expired, and units which are no longer acceptable for transfusion (expired, contaminated, etc.) are physically separated in the storage compartment and labeled appropriately.

**ST - H0147 - LAB & PATH SVCS -Blood Storage Class III Hosp**

**Title** LAB & PATH SVCS -Blood Storage Class III Hosp

**Type** Rule

59A-3.242(1)(f), FAC

**Regulation Definition**

(f) Hospitals not utilizing blood and blood products need not maintain blood storage facilities.

**Interpretive Guideline**

Verify the hospital is a Class III.

**ST - H0148 - RADIOLOGY SVCS - Diagnostic Imaging Provided**

**Title** RADIOLOGY SVCS - Diagnostic Imaging Provided

**Type** Rule

59A-3.242(2), FAC

**Regulation Definition**

(2) Radiology Services. Each Class I and Class II hospital shall provide on the premises, and each Class III hospital shall provide on the premises or by contract, diagnostic imaging facilities commensurate with the hospital's needs. The radiology department or similarly titled unit shall have a radiologist to serve as medical director on a full time or part time consulting basis to discharge professional radiology

**Interpretive Guideline**

Determine Class of hospital.

If Class III hospital, is services provided on premise or by contract. If by contract, review the contract.

For on premise,

Verify with the Director of Radiology Services that the hospital has diagnostic radiologic services that is available at all times to meet the needs of their patients:

- Review the facility policy that specifies the scope and complexity of radiologic services as approved by the medical staff and governing body.



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 105 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

services.

- Is the department in compliance with Federal and State regulations?

Chapter 404, F. S. (Fla. Rule for Radiation) Refers to the Department of Health Part IV, Chapter 468, F.S( Radiological Personnel Certification)  
Chapter 64E-3, F.A.C. (Radiologic technology)

**ST - H0149 - RADIOLOGY SVCS - Hazard Free**

**Title** RADIOLOGY SVCS - Hazard Free

**Type** Rule

59A-3.242(2)(a), FAC

**Regulation Definition**

(a) The radiology department or other similarly titled part shall be maintained free of hazards for patients and personnel.

**Interpretive Guideline**

- Review the radiology department policies and procedures regarding safety for patients and hospital personnel.
- Interview staff and observe locations where radiological services are provided to determine if there are any hazards to patients or hospital personnel.
- Review documentation of annual inspection reports regarding protective shielding and calibration of all equipment.
- Concerns regarding maintenance and safety, refer to Life Safety Code.

**ST - H0150 - RADIOLOGY SVCS - Radiologist**

**Title** RADIOLOGY SVCS - Radiologist

**Type** Rule

59A-3.242(2)(b), FAC

**Regulation Definition**

(b) Each hospital shall have certified radiologic technologists or basic x-ray machine operators in hospitals of 150 beds or less, and shall be on duty or on call at all times.

**Interpretive Guideline**

- Interview and review the personnel file of the radiologist - (full or part time)
- Review Radiology Program for adequacy - consider if services are properly discharged to meet patient needs.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 106 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0151 - RADIOLOGY SVCS - Techs & Operators**

**Title** RADIOLOGY SVCS - Techs & Operators

**Type** Rule

59A-3.242(2)(d), FAC

**Regulation Definition**

(d) The credentials of each person providing diagnostic and therapeutic radiation, imaging and nuclear medicine services, including formal training, on-the-job experience, and certification or licensure where applicable, shall be maintained on file at all times.

**Interpretive Guideline**

Part IV, Chapter 468, FS; and Chapter 64E-3, FAC

- Review a sample personnel file of Certified Radiologic Technologists.
- Ask, how credentials, training, and certifications are maintained by the facility
- Tour the various units, diagnostic and therapeutic.

Verify that a certified radiologic technologists or basic x-ray machine operator are on duty or on call at all times  
Interview staff and review a sample of personnel records to verify that: radiological staff may not use radiation or otherwise practice radiologic technology on a human being unless licensed or certified to do so.

-Verify the licensee or registrant shall not permit any individual to act as a radiographer's assistant until such individual receive the required training

Verify that the RSO or the RSO's designee audits the job performance of each radiographer and radiographer's assistant to ensure that the department's regulations, license requirements, and the licensee's or registrant's operating and the licensee's or registrant's operating and emergency procedures are followed. The audits shall include observation of the performance of each radiographer or radiographer's assistant during an actual radiographic operation at intervals not to exceed 6 months

**ST - H0152 - RADIOLOGY SVCS - Apparatus Use Limited**

**Title** RADIOLOGY SVCS - Apparatus Use Limited

**Type** Rule

59A-3.242(2)(c), FAC

**Regulation Definition**

(c) The use of all diagnostic imaging apparatus shall be limited to Florida licensed or certified individuals working within their scope of practice, as determined by their

**Interpretive Guideline**

Observe and interview staff to ensure that:

- d) The use of all diagnostic imaging apparatus shall be limited to personnel designated as specified in Part IV, Chapter 468, F.S., and Chapter 64E-3, F.A.C.

**Agency for Health Care Administration**

**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 107 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

regulatory board.

468.302, F.S. The general radiographer identified under this section must successfully complete a training program which include the following areas before assisting with radiation therapy technology duties:

1. Principles of radiation therapy treatment;
2. Biological effects of radiation;
3. Radiation exposure and monitoring;
4. Radiation safety and protection;
5. Evaluation and handling of radiographic treatment equipment and accessories; and
6. Patient positioning for radiation therapy treatment. (some exclusions apply)

**ST - H0153 - RADIOLOGY SVCS - Policies & Procedures**

**Title** RADIOLOGY SVCS - Policies & Procedures

**Type** Rule

59A-3.242(2)(e), FAC

**Regulation Definition**

(e) The medical director shall maintain and enforce policies and procedures for the provision of all diagnostic and therapeutic radiation, imaging, and nuclear medicine services. Such policies and procedures shall be written, reviewed annually, and revised as necessary, and shall be dated as to time of last review.

**Interpretive Guideline**

64E-5, FAC (refers to Department of Health)

- The scope and complexity of radiology services provided must meet the needs of the hospital patients.

- There must be radiology policies and procedures for each type of services provided (all diagnostic and therapeutic radiation, imaging, and nuclear medicine services).

Observe the diagnostic and therapeutic radiation, imaging, and nuclear medicine services, to ensure compliance with the requirements

Review documentation that the policies are reviewed annually including date of last review and the policies are revised as necessary.

Interview the Radiology Director to be sure the policies reflect the current status of patient care provided.

Review the requirements in the interpretive guidelines H-149 to H-152

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 108 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0154 - RADIOLOGY SVCS - Written Orders**

**Title** RADIOLOGY SVCS - Written Orders

**Type** Rule

59A-3.242(2)(f), FAC

**Regulation Definition**

(f) The medical director shall require that all radiology, imaging or nuclear medicine services be performed only upon written order of a licensed physician or by another licensed health professional if that health professional is acting within their scope of practice as defined by applicable laws and rules of the licensing board. Nothing herein shall be construed to expand or restrict such laws and rules pertaining to the practice of various health professions. The request and all results must be recorded in the patient's medical record;

**Interpretive Guideline**

Review medical records to determine that radiology services are provided only on the order of practitioners with clinical privileges. Any other practitioners that order radiology services must be approved by the governing body, medical staff and conform to applicable State law.  
- verify that all results are recorded in the patient's medical record;

**ST - H0155 - RADIOLOGY SVCS - Radiation Control**

**Title** RADIOLOGY SVCS - Radiation Control

**Type** Rule

59A-3.242(2)(g), FAC

**Regulation Definition**

(g) The medical director shall document all misadministration of radioactive materials, as those terms are defined by chapter 64E-5, F.A.C.

**Interpretive Guideline**

Chapter 64E-5, F.A.C. (refers to the Bureau of Radiation Control of the Department of Health)  
Interview the medical director and inquire how they would report any mishandling of radioactive materials.

Review and verify that there are Policies for:

Reporting of Exposures, Radiation Levels, Concentrations of Radioactive Material Exceeding the Constraints or Limits, Medical Events and Dose to an Embryo/Fetus or a Nursing Child.

(1) Reportable Events. In addition to the notification required by Rule 64E-5.344, F.A.C., each licensee or registrant shall submit a written report within 30 days after learning of any these occurrences

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 109 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

Review and verify that there are Policies for Operating and Emergency Procedures.

**ST - H0156 - RADIOLOGY SVCS - Quality Control Program**

**Title** RADIOLOGY SVCS - Quality Control Program

**Type** Rule

59A-3.242(2)(h), FAC

**Regulation Definition**

(h) The medical director shall maintain and document in writing a quality control program designed to minimize the unnecessary duplication of radiographic studies, to minimize exposure time of patients and personnel, and to maximize the quality of diagnostic information and therapy provided.

**Interpretive Guideline**

- The hospital must have a quality assurance program regarding patient radiology records.
- Review the Radiology Department Policy and Procedures as they pertain to quality control

**ST - H0160 - RESPIRATORY THERAPY - Policy/Procedure**

**Title** RESPIRATORY THERAPY - Policy/Procedure

**Type** Rule

59A-3.242(3), FAC

**Regulation Definition**

(3) Respiratory Therapy. Each hospital shall have written policies and procedures describing the scope of respiratory services provided to patients of the hospital. This document shall contain written guidelines for the transfer or referral of patients requiring respiratory care services not provided at the hospital.

**Interpretive Guideline**

- The scope of diagnostic and/or therapeutic respiratory services offered by the hospital should be defined in writing, and approved by the Medical staff.

Review Respiratory Therapy policies and procedures. Is there a policy and procedure for each respiratory service provided at the hospital? Do the policies specify how transfer or referral will occur?

- Interview the respiratory therapy director and/or respiratory therapists about duties and respiratory services performed. What services are provided in the hospital? What services are contracted out?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 110 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0161 - RESPIRATORY THERAPY - Safety/Quality**

**Title** RESPIRATORY THERAPY - Safety/Quality

**Type** Rule

59A-3.242(3)(a), FAC

**Regulation Definition**

(a) When respiratory care services are provided outside the hospital, the hospital shall ensure by contract or other enforceable mechanism that such services meet all safety requirements and quality control measures required by the hospital.

**Interpretive Guideline**

-Review the contract for respiratory therapy services not provided at the hospital.  
-Interview the respiratory therapy director regarding how the hospital ensures that contracted services conform to the hospital's safety standards and professional standards of care?  
What quality control measures does the hospital require of contracted respiratory services?

**ST - H0162 - RESPIRATORY THERAPY - Physician Director**

**Title** RESPIRATORY THERAPY - Physician Director

**Type** Rule

59A-3.242(3)(b), FAC

**Regulation Definition**

(b) Respiratory care services provided within a hospital shall have medical direction provided by a physician member of the organized medical staff with special interest and knowledge in the management of acute and chronic respiratory problems. The physician director shall be responsible for the overall direction of respiratory services, for conducting a review of the quality, safety and appropriateness of respiratory care services quarterly, and shall be available for any required respiratory care consultation.

**Interpretive Guideline**

Skip this if all respiratory care services are contracted.

- Review the director's credentialing file for educational qualifications and job requirements. The time spent directing the department must be appropriate to the scope and complexity of the services provided.  
- How is the director available for respiratory care consultation?  
- Ask for documentation of the director's quarterly review of the services.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 111 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0163 - RESPIRATORY THERAPY - Supervision**

**Title** RESPIRATORY THERAPY - Supervision

**Type** Rule

59A-3.242(3)(c), FAC

**Regulation Definition**

(c) Respiratory care services in a hospital may be supervised by a technical director who is registered or certified by the National Board of Respiratory Care Inc., or has the documented equivalent education, training and experience. Other respiratory care personnel shall provide respiratory care commensurate with their documented training, experience, and competence.

**Interpretive Guideline**

- Is there a respiratory care services supervisor?
- What certification and/or training is required to be the supervisor?
- Review a sample of personnel files for respiratory care staff to ensure they meet the requirements specified by the medical staff and State Licensure requirements.

Florida law requires that Respiratory Therapists be licensed through the Florida Department of Health

**ST - H0164 - RESPIRATORY THERAPY - Student Training**

**Title** RESPIRATORY THERAPY - Student Training

**Type** Rule

59A-3.242(3)(d), FAC

**Regulation Definition**

(d) The formal training of respiratory therapy students shall be carried out only in programs accredited by appropriate professional educational organizations. Individuals in student status shall be directly supervised when engaged in patient care activities.

**Interpretive Guideline**

Does the hospital have an agreement with an accredited organization for training respiratory therapy students? If so, does the agreement require direct supervision when the students are engaged in patient care activities?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 112 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0165 - RESPIRATORY THERAPY - Education/Training/Exp**

**Title** RESPIRATORY THERAPY - Education/Training/Exp

**Type** Rule

59A-3.242(3)(e), FAC

**Regulation Definition**

(e) The education, training and experience of personnel who provide respiratory care services shall be documented, and shall be related to each individual's level of participation in the provision of respiratory care services.

**Interpretive Guideline**

- Does the hospital have written policies to address each type of respiratory care service provided?
- Review treatment logs to identify staff providing the service and verify their qualifications.
- Review job descriptions, training, and licenses in personnel files. If specialized training or experience is required to perform specific duties, is this training documented in their personnel file?

**ST - H0166 - RESPIRATORY THERAPY - Hazardous Procedures**

**Title** RESPIRATORY THERAPY - Hazardous Procedures

**Type** Rule

59A-3.242(3)(f), FAC

**Regulation Definition**

(f) Nonphysician respiratory care personnel shall not perform patient procedures associated with a potential hazard, including arterial puncture for obtaining blood samples, unless authorized in writing by the physician director of the respiratory care service acting in accordance with professional staff policy.

**Interpretive Guideline**

- Review respiratory care policies and procedures regarding procedures that non-physician respiratory care personnel may perform. Has the physician director authorized in writing which personnel may perform each procedure? Is this authorization in accordance with policies?
- What are the procedures for obtaining arterial blood gases?
- Interview the director regarding who is authorized to perform ABGs and other potentially hazardous procedures? How does the hospital ensure staff competency?
- Review authorizing documentation from the physician director.
- Respiratory therapy is allowed to have their licensed respiratory personnel perform the ABGs and they can be covered under their own CLIA, or they can be under the main lab's CLIA.



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 113 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0167 - RESPIRATORY THERAPY - In-service Education**

**Title** RESPIRATORY THERAPY - In-service Education

**Type** Rule

59A-3.242(3)(g), FAC

**Regulation Definition**

(g) The physician director shall be responsible for ensuring all personnel providing respiratory care services participate in education programs designed to augment the personnel's knowledge of pertinent new developments in respiratory care services and maintain current competency. Such participation shall occur annually, and shall include instruction in safety, infection control, and cardiopulmonary resuscitation.

**Interpretive Guideline**

- Review the in-service educational programs for respiratory care services personnel. Is there documentation of annual participation by all staff? Are the areas of safety, infection control, and cardiopulmonary resuscitation required?
- How is competence otherwise demonstrated?

**ST - H0168 - RESPIRATORY THERAPY - Patient Care**

**Title** RESPIRATORY THERAPY - Patient Care

**Type** Rule

59A-3.242(3)(h), FAC

**Regulation Definition**

(h) There shall be written policies and procedures specifying the scope and conduct of patient care rendered in the provision of respiratory care services. All policies and procedures must be approved by the physician director, reviewed annually, revised as necessary, dated to indicate the time of last review, and enforced. Respiratory care policies shall include the following:

1. Specification as to who may perform specific procedures and provide instruction, under what circumstances, and under what degree of supervision.

**Interpretive Guideline**

- Is there documentation that these policies are reviewed annually, dated as to the last review and revised as necessary?
- 1: Do the policies specify which types of respiratory therapist (RT) staff can perform which procedures and supervision requirements? (Certified Respiratory Therapists (CRT) and Registered Respiratory Therapists (RRT) are both licensed to function in situations of unsupervised patient contact requiring individual judgment. Respiratory care practitioners (RCP) are licensed, but can only deliver respiratory care services under direct supervision - per Florida Statute 468).
- 2: Interview RT staff regarding their training and understanding.
- 3: Interview RT staff regarding responses to adverse drug reactions and other emergencies.
- 4: From what source are therapeutic gases obtained? Where are gases stored? Observed gas storage areas. Are tanks

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 114 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

2. Assembly and sequential operation of equipment and accessories to implement therapeutic regimens.
3. Steps to be taken in the event of adverse reactions, and other emergencies.
4. Procurement, handling, storage and dispensing of therapeutic gases.
5. Infection control measures, including specifics as to changing and cleansing of equipment.
6. Administration of medications in accordance with the physician's order.

secure?

- 5: Interview RT staff about the changing and cleansing of equipment. Do interviews agree with the policy and procedures and professional standards?

- 6: Where are the medications stored? If any are stored in the Respiratory Therapy department, observe that they are stored correctly at the right temperature and are in date. Interview RT staff regarding medication storage and the process to ensure expired medications are removed.

**ST - H0169 - RESPIRATORY THERAPY - Equipment & Facilities**

**Title** RESPIRATORY THERAPY - Equipment & Facilities

**Type** Rule

59A-3.242(3)(i), FAC

**Regulation Definition**

(i) The respiratory care service shall have equipment and facilities to assure the safe, effective and timely provision of respiratory care service to patients.

1. All equipment shall be calibrated and operated according to manufacturer's specifications, and shall be periodically inspected and maintained.
2. Where piped-in gas is used, an evaluation shall be made prior to use to assure identification of the gas and its delivery within an established safe pressure range.
3. Ventilators used for continuous assistance or controlled breathing shall have operative alarm systems at all times.

**Interpretive Guideline**

Is there available equipment for all respiratory therapy services provided by the hospital? Is the equipment functional?

Inspect logs for equipment calibration, pressure range of piped-in gas, and monitoring of alarm systems of ventilators.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 115 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0170 - RESPIRATORY THERAPY - Orders**

**Title** RESPIRATORY THERAPY - Orders

**Type** Rule

59A-3.242(3)(j), FAC

**Regulation Definition**

(j) Prescriptions for respiratory care shall specify the type, frequency and duration of treatment and, as appropriate, the type and dose of medication, the type of diluent, and the oxygen concentration, and shall be incorporated into the patient's medical record.

**Interpretive Guideline**

Review medical records of patients receiving respiratory services to verify the services are provided only on the order of a physician or physician extender in accordance with State Law. Is the order for respiratory care services specific including medications and oxygen concentration? Are the services provided in accordance with these orders?

**ST - H0171 - SPECIAL CARE UNITS -Distinct/Access/Isolation**

**Title** SPECIAL CARE UNITS -Distinct/Access/Isolation

**Type** Rule

59A-3.244(3), FAC

**Regulation Definition**

(3) Special Care Units. The hospital shall ensure that a special care unit is a physically and functionally distinct entity within the hospital, has controlled access, and has an effective means of isolation for patients suffering from communicable or infectious disease or acute mental disorder.

**Interpretive Guideline**

- Ask if hospital has any special care units.
- Observe access to these units. Are there isolation rooms/areas if needed? Are units physically and functionally distinct?
- Ask the staff the reasons to utilize the isolation rooms? Who is authorized access into the special unit?
- Review the facility's Policy and Procedure to ensure that based on your observation and interviews, the facility is following its own policies and procedures.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 116 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0172 - SPECIAL CARE UNITS - Visual Observation**

**Title** SPECIAL CARE UNITS - Visual Observation

**Type** Rule

59A-3.244(3)(a)1-2, FAC

**Regulation Definition**

- (a) Special care units shall provide:
1. Direct or indirect visual observation by unit staff of all patients from one or more vantage points;
  2. A direct intercommunication or alarm system between the nurse's station and the bedside; and

**Interpretive Guideline**

The Special Care Unit to see if staff have direct or indirect visual observation from 1 or more vantage points (camera, window, etc.)  
Ask staff how they ensure that they observe all of the patients.  
Observe and test the call system between the nursing's station and the bedside.  
Review unit record, does the documentation show the patients are being observed. Read the facility's policies and procedures regarding visual observation of all the patients in the secure unit.

**ST - H0174 - SPECIAL CARE UNITS - Adjustable Beds**

**Title** SPECIAL CARE UNITS - Adjustable Beds

**Type** Rule

59A-3.244(3)(a)3, FAC

**Regulation Definition**

- (a) Special care units shall provide:
3. Beds that are adjustable to positions required by the patient, that are easily movable, and that have a locking or stabilizing mechanism to attain a secure, stationary position. Headboards, when present, shall be removable or adjustable to permit ready access to the patient's head.

**Interpretive Guideline**

Observe: Are beds adjustable, easily movable; do they have a locking system and removable and adjustable headboards? If necessary, have staff demonstrate. Do the beds move when the locks are on?

Interview staff: Have there been any problems with the beds?

Record Review: Review the incident log. Have there been any incidents associated to issues of the patients' beds?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 117 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0175 - SPECIAL CARE UNITS - Physician Advisor**

**Title** SPECIAL CARE UNITS - Physician Advisor

**Type** Rule

59A-3.244(3)(b-d), FAC

**Regulation Definition**

- (b) Each special care unit shall be advised by a physician who is a member of the organized medical staff.
- (c) Each special care unit shall have its relationship to other departments and units of the hospital specified in writing (organizational chart).
- (d) All staff shall participate in annual in-service education programs concerning cardiopulmonary resuscitation and safety and infection control requirements.

**Interpretive Guideline**

Ask who physician adviser is. Review organization chart for relationship to other departments. Review a few personnel files for in-services on CPR, safety, and infection control.

**ST - H0176 - SPECIAL CARE UNITS - Policies/Procedures**

**Title** SPECIAL CARE UNITS - Policies/Procedures

**Type** Rule

59A-3.244(3)(e), FAC

**Regulation Definition**

- (e) Written policies and procedures shall be developed concerning the scope and provision of care in each special care unit. Such policies and procedures shall be reviewed annually, revised as necessary, dated to indicate the time of last review, enforced, and include the following:
  1. Specific criteria for the admission and discharge of patients;
  2. A system for informing the responsible member of the organized medical staff of changes in the patient's condition;
  3. Methods for procurement of equipment and drugs at all

**Interpretive Guideline**

- Ensure policies and procedures have been developed, reviewed annually and revised if needed, and include items 1-6.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 118 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

- times;
4. Specific procedures relating to infection and traffic control;
  5. Specification as to who may perform special procedures, under what circumstances, and under what degree of supervision; and specific policies as to the use of standing orders; and
  6. A protocol for handling emergency conditions related to the breakdown of essential equipment.

**ST - H0177 - SPECIAL CARE UNITS - Trauma Center**

**Title** SPECIAL CARE UNITS - Trauma Center

**Type** Rule

59A-3.244(3)(f), FAC

**Regulation Definition**

(f) No hospital shall hold itself out as a Trauma Center unless it has been verified as a Trauma Center by the Department of Health. Any violation of the Trauma Center provisions shall subject any violator to appropriate remedies provided by section 395.1065, F.S.

**Interpretive Guideline**

Is the hospital designated as a Trauma Center? Check facility files prior to going to the hospital. Are there indications the facility is holding itself out as a Trauma Center when it is not designated as such?

**ST - H0178 - ADULT DIAG CARDIAC CATH PROG - Organized/Staf**

**Title** ADULT DIAG CARDIAC CATH PROG - Organized/Staf

**Type** Rule

59A-3.246(1), FAC

**Regulation Definition**

(1) Adult Diagnostic Cardiac Catheterization Program. All licensed hospitals that establish adult diagnostic cardiac catheterization laboratory services under section 408.0361, F.S., shall operate in compliance with the most recent

**Interpretive Guideline**

- Interview the Cardiac Cath Director for program adherence to standards. If concerned about interview and survey observations, review training records or personnel files.
- Tour cardiac cath unit for patient safety, quality, housekeeping, infection control, and functional safety.
- Review cardiac cath policy and procedures are based on American College of Cardiology/American Heart

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 119 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

guidelines of the American College of Cardiology/American Heart Association regarding the operation of diagnostic cardiac catheterization laboratories. Hospitals are considered to be in compliance with American College of Cardiology/American Heart Association guidelines when they adhere to standards regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety. The applicable guideline is the 2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update. J Am Coll Cardiol 2012; 59:2221-305 (2012 ACC/SCAI Guidelines) which is hereby incorporated by reference and effective at adoption. The copyrighted material is available for public inspection at the Agency for Health Care Administration, Hospital and Outpatient Services Unit, 2727 Mahan Drive, Tallahassee, FL 32308 and the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee, FL 32399. A copy may be obtained from Elsevier Inc, Reprint Department by email at [reprints@elsevier.com](mailto: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.

Association guidelines.

- Review cardiac cath patient safety and integration into hospital quality program.
- Review patient sample of records and patient interviews for quality of cardiac cath program.

**ST - H0179 - ADULT DIAG CARDIAC CATH PROG - Licensure**

**Title** ADULT DIAG CARDIAC CATH PROG - Licensure

**Type** Rule

59A-3.246(1)(a), FAC

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 120 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(a) Licensure.

1. A hospital may apply for 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, confirming the hospital's intent and ability to comply with section 408.0361(1), F.S.

2. Hospitals with adult diagnostic cardiac catheterization services programs must renew their licenses at the time of the hospital licensure renewal, providing the information in section 408.0361(1), F.S. Failure to renew the hospital's license or failure to update the information in section 408.0361(1), F.S., shall cause the license to expire.

**Interpretive Guideline**

Check the hospital's license to verify that Adult Cardiac Catheterization is listed on the license as a licensed program.

**ST - H0180 - ADULT CARDIO SVC-LICENSURE**

**Title** ADULT CARDIO SVC-LICENSURE

**Type** Rule

59A-3.246(3)(a)5-7 & (b)

**Regulation Definition**

(3)(a) Level II Adult Cardiovascular Services.

5. Hospitals are considered to be in compliance with the guidelines in the 2012 ACC/SCAI Guidelines and the 2014

**Interpretive Guideline**



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 121 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

SCAI/ACC/AHA Update when they adhere to standards regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety. Hospitals must also document an ongoing quality improvement plan to ensure that the cardiac catheterization program, the percutaneous coronary intervention program and the cardiac surgical program meet or exceed national quality and outcome benchmarks reported by the American College of Cardiology-National Cardiovascular Data Registry and the Society of Thoracic Surgeons.

6. In addition to the requirements set forth in subparagraph (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;

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 122 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

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

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 123 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

National Database with regard to data reporting.

7. 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 update the information in two through four above shall cause the license to expire.

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

1. Each cardiac surgeon shall be Board certified.

a. New surgeons shall be Board certified within 4 years after completion of their fellowship.

b. Experienced surgeons with greater than 10 years experience shall document that their training and experience preceded the availability of Board certification.

2. 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 the review process described in subparagraph 59A-3.246(4)(b)3., F.A.C.

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

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 124 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

volume, lifetime experience, institutional volume, individual operator's other cardiovascular interventions and quality assessment of the operator's ongoing performance.

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

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

**ST - H0181 - ADULT CARDIO SVCS - LEVEL 2 P&P**

**Title** ADULT CARDIO SVCS - LEVEL 2 P&P

**Type** Rule

59A-3.246(3)(c) FAC

**Regulation Definition**

(3) Level II Adult Cardiovascular Services.

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

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

2. The policy and procedure manual shall document specific

**Interpretive Guideline**

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 125 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

outreach programs directed at Medicaid and charity care patients for Level II adult cardiovascular services.

**ST - H0182 - ADULT DIAG CARDIAC CATH PROG - QI Program**

**Title** ADULT DIAG CARDIAC CATH PROG - QI Program

**Type** Rule

59A-3.246(1)(f) & (i), FAC

**Regulation Definition**

(f) Radiographic Cardiac Imaging Systems. A quality improvement program for radiographic imaging systems shall include 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.

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

**Interpretive Guideline**

- Review the cardiac cath quality improvement program for:  
Radiographic image quality, individual physician procedure volume, major complications, overall complication rates, patient demographic information, verification of data accuracy, and procedures for confidentiality.
- Determine if the hospital cardiac cath quality improvement program is based on the referenced American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards.
- Review individual physician volume and interview cardiac cath interventionist physicians as needed.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 126 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0183 - ADULT DIAG CARDIAC CATH PROG - Support Equip**

**Title** ADULT DIAG CARDIAC CATH PROG - Support Equip

**Type** Rule

59A-3.246(1)(e), FAC

**Regulation Definition**

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

**Interpretive Guideline**

- Tour each procedure room to verify the presence of a locked crash cart.
- Review the listing of contents on randomly chosen carts.
- Review log and documentation to ensure defibrillator and corresponding equipment are checked for function and operational capacity.

**ST - H0184 - ADULT DIAG CARDIAC CATH PROG - Physical Plant**

**Title** ADULT DIAG CARDIAC CATH PROG - Physical Plant

**Type** Rule

59A-3.246(1)(g) FAC

**Regulation Definition**

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

**Interpretive Guideline**

- Health facility surveyor and life safety code surveyor are to tour the cardiac cath lab.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 127 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0185 - ADULT DIAG CARDIAC CATH PROG - Personnel**

**Title** ADULT DIAG CARDIAC CATH PROG - Personnel

**Type** Rule

59A-3.246(1)(h), FAC

**Regulation Definition**

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

**Interpretive Guideline**

- Request Cardiac Catheterization Procedure Schedule for several months. Verify team composition.
- Interview members of the Cardiac Catheterization Team to assure usual team member composition.

**ST - H0186 - ADULT DIAG CARDIAC CATH PROG - Emergency Svcs**

**Title** ADULT DIAG CARDIAC CATH PROG - Emergency Svcs

**Type** Rule

59A-3.246(1)(j), FAC

**Regulation Definition**

(j) Emergency Services.  
1. All hospitals providing adult diagnostic cardiac catheterization program services, except hospitals licensed as a Level II adult cardiovascular services provider, shall have written transfer agreements developed specifically for diagnostic cardiac catheterization patients with one or more hospitals licensed as a Level II adult cardiovascular services provider. Written agreements must be in place with a ground ambulance service capable of advanced life support and Intra-Aortic Balloon Pump (IABP) transfer. Agreements may include air ambulance service, but must have ground ambulance backup. A transport vehicle must be on-site to begin transport within 20 minutes of a request and have a

**Interpretive Guideline**

- Review protocol for emergency transporting patients to a hospital providing open heart surgery (Level II adult cardiovascular services). Would travel time be sixty minutes or less by emergency vehicle under average travel conditions?
- Review documentation that transfer and transport agreements have been tested and the results indicate a transfer time of no more than 60 minutes from the time the emergency was recognized and the patient arrived at the receiving hospital.
- Who does the facility consider at high risk for diagnostic catheterization complications?
- Do they have a policy for referring high risk patients?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 128 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

transfer time within 60 minutes. Transfer time is defined as the number of minutes between the recognition of an emergency as noted in the hospital's internal log and the patient's arrival at the receiving hospital. Transfer and transport agreements must be reviewed and tested once every 6 months, with appropriate documentation maintained, including the hospital's internal log or emergency medical services data.

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

**ST - H0187 - ADULT DIAG CARDIAC CATH PROG - Mded/Charity**

**Title** ADULT DIAG CARDIAC CATH PROG - Mded/Charity

**Type** Rule

59A-3.246(1)(k), FAC

**Regulation Definition**

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

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

**Interpretive Guideline**

-Review the policy and procedure manual to determine if the hospital has a plan for providing adult diagnostic cardiac catheterization program services to Medicaid and charity care patients.

Do the policies and procedures document specific outreach programs directed at Medicaid and charity care patients?

-Interview the cardiac cath director.



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 129 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0188 - HEALTH INFORMATION MGMT - Process**

**Title** HEALTH INFORMATION MGMT - Process

**Type** Rule

59A-3.270(1), FAC

**Regulation Definition**

- (1) Each hospital must establish processes to obtain, manage, and utilize information to enhance and improve individual and organizational performance in patient care, governance, management, and support processes. Such processes must:
- (a) Be planned and designed to meet the hospital's internal and external information needs;
  - (b) Provide for confidentiality, security and integrity;
  - (c) Provide uniform data definitions and methods for capturing and storing data, including electronic mediums and optical imaging;
  - (d) Provide education and training in information management principles to decision-makers and other hospital personnel who generate, collect, and analyze information;
  - (e) Transmit information in a timely and accurate manner; and
  - (f) Provide for the manipulation, communication and linkage of information.

**Interpretive Guideline**

- Health Information Management (HIM) is the body of knowledge and practice that ensures the availability of health information to facilitate real-time healthcare delivery and critical health-related decision making for multiple purposes across diverse organizations, settings, and disciplines.

Look to see if the HIM department has an established system for ensuring the following:

- How medical record data is created and managed.
  - How medical records are processed after the patient is discharged
  - How discharged medical record data is stored and indexed for prompt retrieval.
  - How records are coded for billing information
  - How medical records are secured from unauthorized access; how patient health information is protected, and how the integrity of the medical record is maintained.
  - How hospital personnel are trained about generating, collecting and analyzing health information.
- Tour the medical record department to observe how medical records are processed, coded, and stored.
- Review the facility policies and procedures regarding the HIM system. Make observations of how staff use the active medical record and conduct interviews of HIM staff to determine that they have an established system.

**ST - H0189 - HEALTH INFORMATION MGMT - Transplant Tracking**

**Title** HEALTH INFORMATION MGMT - Transplant Tracking

**Type** Rule

59A-3.270(2) FAC

**Regulation Definition**

- (2) All hospitals involved in the transplantation of organs or

**Interpretive Guideline**

- Interview the hospital designated organ and tissue requestor to determine if the hospital has a centralized tracking

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 130 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

tissues must maintain a centralized tracking system to record the receipt and disposition of all organs and tissues transplanted within the hospital.

(a) The tracking system must be kept separate from patients' medical records, and must include:

1. The organ or tissue type;
2. The donor identification number;
3. The name and license number of the procurement or distribution center supplying the organ or tissue;
4. Recipient information, including, at a minimum the patient's name and identification number;
5. The name of the physician who performed the transplant;
6. The date the organ or tissue was received by the hospital; and
7. The date the organ or tissue was transplanted.

(b) This information must be provided, on a quarterly basis, to the organ procurement organization or tissue bank that originally provided the organ or tissue.

system.

- Is this tracking system separate from the medical record requirements regarding organ and tissue procurement?
- Verify documentation can be retrieved from this tracking system regarding receipt and observation of all organs and tissues transplanted within the hospital.
- Review the tracking system print out to ensure the data includes the information required by regulations, also, request documentation this information was provided quarterly to the organ procurement organization or tissue bank utilized by the hospital.

**ST - H0190 - HEALTH INFORMATION MGMT - Medical Records**

**Title** HEALTH INFORMATION MGMT - Medical Records

**Type** Rule

59A-3.270(3) FAC; 395.3025(6) FS

**Regulation Definition**

59A-3.270

(3) Each hospital must maintain a current and complete medical record for every patient seeking care or service. The medical record must contain information required for completion of birth, death and stillbirth certificates, and must, contain the following information:

- (a) Identification data;
- (b) Chief complaint or reason for seeking care;
- (c) Present illness;

**Interpretive Guideline**

- Review a sample of patient medical records, including active records one from each nursing unit, 5 discharged patient records within the past 3 months, and ambulatory care records representing each different type of ambulatory care services.
- Review the medical record contains information required for completion of birth, death and still birth certificates, and, at a minimum contain an original or true copy of the information, as applicable.
- Validate applicable medical record information from patient observations and interviews.
- If the medical records are missing applicable information, interview the HIM director and personnel responsible for documenting or obtaining this information
- Review the HIM policies regarding the required content of the patient medical record.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 131 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

- (d) Personal medical history;
- (e) Family medical history;
- (f) Physical examination report;
- (g) Provisional and pre-operative diagnosis;
- (h) Clinical laboratory reports;
- (i) Radiology, diagnostic imaging, and ancillary testing reports;
- (j) Consultation reports;
- (k) Medical and surgical treatment notes and reports;
- (l) Evidence of appropriate informed consent;
- (m) Evidence of medication and dosage administered;
- (n) A copy of the Patient Care Record, in accordance with subsection 64J-1.001(18), F.A.C., if the patient was delivered to the hospital by ambulance;
- (o) Tissue reports;
- (p) Physician, APRN, PA and nurse progress notes;
- (q) Principal diagnosis, secondary diagnoses and procedures when applicable;
- (r) Discharge summary;
- (s) Appropriate social work services reports, if provided;
- (t) Autopsy findings when performed;
- (u) Individualized treatment plan;
- (v) Clinical assessment of the patients needs;
- (w) Certifications of transfer of the patient between hospitals as specified by rule 59A-3.255, F.A.C.; and,
- (x) Routine Inquiry Form regarding request for organ donation in the event of the death of the patient.
- (y) A copy of the Hospital Outpatient Observation Notice or Medicare Outpatient Observation Notice as required by subsection 395.301(3), F.S., if the patient was placed on observation status.

Refer to tag 0230 if there is a problem with medical records and the committee responsible for them.

395.3025(6) Patient records shall contain information required for completion of birth, death, and fetal death certificates.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 132 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0191 - HEALTH INFORMATION MGMT -Operative Procedures**

**Title** HEALTH INFORMATION MGMT -Operative Procedures

**Type** Rule

59A-3.270(4) FAC

**Regulation Definition**

(4) For patients undergoing operative or other invasive procedures the medical record policies must also require:

- (a) The recording of preoperative diagnoses prior to surgery;
- (b) That operative reports be recorded in the health record immediately following surgery or that an operative progress note is entered in the patient record to provide pertinent information; and,
- (c) Postoperative information must include vital signs, level of consciousness, medications, blood components, complications and management of those events, identification of direct providers of care, discharge information from the post-anesthesia care area.

**Interpretive Guideline**

- Review a sample of inpatient surgical records to ensure there is a preoperative diagnosis in the record prior to surgery or an invasive procedure.
- Are the operative reports or an operative progress note recorded immediately following surgery?
- Review the postoperative information includes vital signs, level of consciousness, medications, blood components, complications and management of those events, identification of direct providers of care, and discharge information from the post-anesthesia care area

**ST - H0193 - HEALTH INFORMATION MGMT - Med Records Dept**

**Title** HEALTH INFORMATION MGMT - Med Records Dept

**Type** Rule

59A-3.270(6), FAC

**Regulation Definition**

(6) Each hospital must have a patient information system, medical records department or similarly titled unit with administrative responsibility for medical records. The medical records department must:

- (a) Maintain a system of identification and filing to ensure the

**Interpretive Guideline**

Tour the medical record department to observe how medical records are processed, coded, and stored.  
Observe the staff involved in the process.  
Determine the location(s) where medical records are maintained.  
Verify a medical record is maintained for each person treated or receiving care. The hospital may have a separate record for both inpatients and outpatients.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 133 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

prompt location of a patient's medical record. Patient records may be stored on electronic medium such as optical imaging, computer, or microfilm;

(b) Centralize all appropriate clinical information relating to a patient's hospital stay in the patient's medical record;

(c) Index, and maintain on a current basis, all medical records according to disease, operation and physician.

Interview the Director of Health Information Management. Ask him/her to explain the following:

- How medical record data is created and managed.
- How medical records are identified and filed.
- How medical records are processed after the patient is discharged
- How discharged medical record data is stored and indexed for prompt retrieval.

Review a sample of active and closed medical records for completeness and accuracy in accordance with the hospital policy. Include a sample of outpatient records in order to determine compliance in outpatient departments, services, and locations.

**ST - H0194 - HEALTH INFORMATION MGMT - Confidentiality**

**Title** HEALTH INFORMATION MGMT - Confidentiality

**Type** Rule

59A-3.270(7) FAC; 395.3025(4) &(7b)FS

**Regulation Definition**

59A-3.270(7) Patient records must have a privileged and confidential status and must not be disclosed without the consent of the person to whom they pertain unless disclosed in accordance with section 395.3025(4), F.S.

395.3025(4) Patient records are confidential and must not be disclosed without the consent of the patient or his or her legal representative, but appropriate disclosure may be made without such consent to:

- (a) Licensed facility personnel, attending physicians, or other health care practitioners and providers currently involved in the care or treatment of the patient for use only in connection with the treatment of the patient.
- (b) Licensed facility personnel only for administrative purposes or risk management and quality assurance functions.
- (c) The agency, for purposes of health care cost containment.
- (d) In any civil or criminal action, unless otherwise prohibited by law, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice by the party seeking

**Interpretive Guideline**

- Review the facility HIM policy and procedure for confidentiality of patient records. - Have these policies been implemented and authorized persons allowed access to patient records.
- Tour the patient care areas and observe the hospital's security practices for patient records.
- Interview the HIM director regarding procedures in place to ensure confidentiality of medical records.
- Interview staff to determine if they are aware of the Privacy and Confidentiality requirements regarding patient information and determine if known breeches of confidentiality have occurred
- If the hospital utilizes electronic patient records are appropriate security safeguards in place?
- Review a sample of patient records for a form and/or any documentation to provide confidentiality or disclosure of records.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 134 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

such records to the patient or his or her legal representative.

(e) The agency upon subpoena issued pursuant to s. 456.071, but the records obtained thereby must be used solely for the purpose of the agency and the appropriate professional board in its investigation, prosecution, and appeal of disciplinary proceedings. If the agency requests copies of the records, the facility shall charge no more than its actual copying costs, including reasonable staff time. The records must be sealed and must not be available to the public pursuant to s.

119.07(1) or any other statute providing access to records, nor may they be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency must make available, upon written request by a practitioner against whom probable cause has been found, any such records that form the basis of the determination of probable cause.

(f) The Department of Health or its agent, for the purpose of establishing and maintaining a trauma registry and for the purpose of ensuring that hospitals and trauma centers are in compliance with the standards and rules established under ss. 395.401, 395.4015, 395.4025, 395.404, 395.4045, and 395.405, and for the purpose of monitoring patient outcome at hospitals and trauma centers that provide trauma care services.

(g) The Department of Children and Families, its agent, or its contracted entity, for the purpose of investigations of or services for cases of abuse, neglect, or exploitation of children or vulnerable adults.

(h) A local trauma agency or a regional trauma agency that performs quality assurance activities, a panel or committee assembled to assist a local trauma agency, or a regional trauma agency performing quality assurance activities. Patient records obtained under this paragraph are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

(i) Organ procurement organizations, tissue banks, and eye

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 135 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

banks required to conduct death records reviews pursuant to s. 395.2050.

(j) The Medicaid Fraud Control Unit in the Department of Legal Affairs pursuant to s. 409.920.

(k) The Department of Financial Services, or an agent, employee, or independent contractor of the department who is auditing for unclaimed property pursuant to chapter 717.

(l) A regional poison control center for purposes of treating a poison episode under evaluation, case management of poison cases, or compliance with data collection and reporting requirements of s. 395.1027 and the professional organization that certifies poison control centers in accordance with federal law.

395.3025(7)(b) Absent a specific written release or authorization permitting utilization of patient information for solicitation or marketing the sale of goods or services, any use of that information for those purposes is prohibited.

**ST - H0195 - HEALTH INFORMATION MGMT - Record Copies**

**Title** HEALTH INFORMATION MGMT - Record Copies

**Type** Rule

59A-3.270(8), FAC

**Regulation Definition**

(8) Any licensed facility must, upon request, and only after discharge of the patient, furnish to any patient admitted or treated in the facility, or to any patient's guardian, curator, or personal representative, or to anyone designated by the patient in writing, a true and correct copy of all of the patient's records, including X-rays, which are in the possession of the licensed facility, provided the person requesting such records agrees to pay a reasonable charge for copying the records, pursuant to Section 395.3025, F.S. The per page fee is

**Interpretive Guideline**

- Interview the HIM director as to how discharged patients, or legal representatives are able to access their medical record. Review the HIM policies about this procedure.
- Look to see if these procedures include the exceptions for progress notes and consultation reports of a psychiatric or substance abuse nature concerning the care and treatment performed by the licensed facility.
- Ask about their procedure for a person to examine his/her record to assure that the records are not damaged, destroyed or altered.
- Select a sample of patients who have been discharged for more than 30 days. Request their medical records. Are those records correct and complete?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 136 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

applicable to each page generated during copying of the medical record by the facility or from a copy service providing these services on behalf of the facility. Progress notes and consultation reports of a psychiatric or substance abuse nature concerning the care and treatment performed by the licensed facility are exempted from this requirement. The licensed facility must further allow any such person to examine the original records in its possession, or microfilms or other suitable reproductions of the records stored on electronic mediums, upon such reasonable terms imposed to assure that the records will not be damaged, destroyed, or altered.

(a) The provisions of this section do not apply to any licensed facility whose primary function is to provide psychiatric care or substance abuse treatment to its patients.

(b) Disclosure of the medical records of inmates of any institution, facility or program of the Department of Corrections must be made in conformance with Section 945.10, F.S., and applicable rules adopted thereunder.

**NOTE:**

This tag does not apply to psychiatric care, substance abuse treatment and inmates of the Department of Corrections.

**ST - H0196 - HEALTH INFORMATION MGMT - DC Med Records**

**Title** HEALTH INFORMATION MGMT - DC Med Records

**Type** Rule

59A-3.270(9) FAC; 395.3015 FS

**Regulation Definition**

59A-3.270(9) Each hospital operated by the Department of Corrections must use a problem oriented medical record for each patient, which must be initiated at the time of intake or admission and which must contain all pertinent information required by this section.

395.3015 Patient records; form and content.-Each hospital operated by the agency or by the Department of Corrections shall require the use of a system of problem-oriented medical

**Interpretive Guideline**

Only applies to hospitals operated by the Department of Health and Rehabilitation Services and Department of Corrections.



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 137 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

records for its patients, which system shall include the following elements: basic client data collection; a listing of the patient's problems; the initial plan with diagnostic and therapeutic orders as appropriate for each problem identified; and progress notes, including a discharge summary.

**ST - H0197 - DOC Record Content**

**Title** DOC Record Content

**Type** Rule

59A-3.270(10), FAC

**Regulation Definition**

(10) Each problem oriented medical record maintained by hospitals operated by the Department of Corrections must be standardized within each hospital and must be capable of providing easy comparison of basic information on medical records at all such hospitals. Each problem oriented medical record maintained by these hospitals must contain at least the following information:

- (a) A patient data base which compiles all known facts about the patient which have relevance to his health care, and which in addition to the other requirements of this section contains:
1. Comments and complaints as spoken by the patient or other persons significant in the patient's life, including relatives, friends and caretakers;
  2. A patient profile, including health related habits, social, nutritional and educational information, and a review of physical systems;
  3. Relevant legal documents, including but not limited to status forms, forensic forms, consent forms, authority permits, and Baker Act forms; and
  4. A medical diagnosis listed according to the International Classification of Diseases and a mental illness diagnosis listed according to the Diagnosis and Statistical Manual of Mental

**Interpretive Guideline**

Problem oriented medical record is just a different format of how information is in the record.  
Applies to hospitals operated by the Department of Corrections

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 138 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

Disorders, as relevant to the patient's condition.

(b) A problem list, which is a table of contents to the patient's record, which identifies by number, date and description of the patients problems.

(c) A plan of care which must specify the specific course of action to be taken to address the problem(s) described, including diagnosis, diagnostic and therapeutic orders, treatment, examination, patient education, referral, and other necessary activities.

(d) Progress notes which must document the activity and follow-up undertaken for each problem in a structured format which is dated, titled and numbered according to the problem to which it relates.

**ST - H0198 - DOC Discharge Summary**

**Title** DOC Discharge Summary

**Type** Rule

59A-3.270(11), FAC

**Regulation Definition**

(11) The discharge summary of each problem oriented medical record in hospitals operated by the Department of Corrections must be completed, signed and dated within 15 days following the patient's discharge. The summary must include:

(a) The reason for admission;

(b) A recapitulation of the patient's hospitalization;

(c) A statement of the patient's progress and condition upon discharge;

(d) The facility or person, including the patient himself when relevant, assuming responsibility for the patient after discharge; and,

(e) Recommendations, when necessary, for after care, follow-up, referral or other action necessary to help the patient deal with problems.

**Interpretive Guideline**

- Only applies to hospitals run by the Department of Corrections.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 139 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0199 - SURVEIL/PREVEN/CONTROL OF INFECTION- Program**

**Title** SURVEIL/PREVEN/CONTROL OF INFECTION- Program

**Type** Rule

59A-3.250(1), FAC

**Regulation Definition**

(1) Each hospital shall establish an infection control program involving members of the organized medical staff, the nursing staff, other professional staff as appropriate, and administration. The program shall comply with the requirements in sections 381.0098 and 395.1011, F.S. and shall provide for:

- (a) The surveillance, prevention, and control of infections among patients and personnel;
- (b) The establishment of a system for identifying, reporting, evaluating and maintaining records of infections;
- (c) Ongoing review and evaluation of all septic, isolation and sanitation techniques employed in the hospital; and,
- (d) Development and coordination of training programs in infection control for all hospital personnel.

**Interpretive Guideline**

- Tour the facility for implementation of the infection control program.
- Interview the Infection Control Officer or person assigned to maintain the program.
- Review the Infection Control Program for (a)-(d) components
- How does the facility identify infections (is this a house wide responsibility)?
- Observe care and services offered by nurses, medical, or other direct care staff, or involved in sanitization for appropriate utilization of techniques.
- Observe for isolation, sanitation and hospital staff understanding of infection control Policies and Procedures.
- How does the Infection Control Program provide training programs to all staff?
- Select records of active patients with infection when possible as part of a sample.
- Does the program involve medical staff, nursing, professional staff and administration as appropriate

Refer to tag 0230 for committee requirements for infection control.

**ST - H0200 - SURVEIL/PREVEN/CONTROL OF INFECTION- P&P**

**Title** SURVEIL/PREVEN/CONTROL OF INFECTION- P&P

**Type** Rule

59A-3.250(2), FAC

**Regulation Definition**

(2) Each hospital shall have written policies and procedures reflecting the scope of the infection control program outlined in subsection (1). The written policies and procedures shall be

**Interpretive Guideline**

- Review the Infection Control Policies and Procedures.
- Do the Policies and Procedures define the scope of the program?
- Are the Policies and Procedures reviewed and dated every two years by the Infection Control members?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 140 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

reviewed at least every two years by the infection control program members, dated at the time of each review, revised as necessary, and enforced.

- Review Policies and Procedures for current practice
- Do your observations on the facility tour show enforcement of the Infection Control Policies and Procedures?
- Observe care and practice in various units based on the complexity and scope of services provided.

Refer to tag 0230 for committee requirements for infection control.

**ST - H0201 - SURVEIL/PREVEN/CONTROL OF INFECTION- Content**

**Title** SURVEIL/PREVEN/CONTROL OF INFECTION- Content

**Type** Rule

59A-3.250(3) FAC; 395.1011 FS

**Regulation Definition**

59A-3.250

- (3) The policies and procedures devised by the infection control program shall be approved by the governing board, and shall contain the following:
- (a) Specific policies for the shelf life of all stored sterile items.
  - (b) Specific policies and procedures related to occupational exposure to blood and body fluids.
  - (c) Specific policies and procedures related to admixture and drug reconstitution, and to the manufacture of intravenous and irrigating fluids.
  - (d) Specific policies related to the handling and disposal of biomedical waste as required by chapter 64E-16, F.A.C., OSHA 29 CFR Part 1910.1030, Bloodborne Pathogens.
  - (e) Specific policies related to the selection, storage, handling, use and disposition of disposable items.
  - (f) Specific policies related to decontamination and sterilization activities performed in central services and throughout the hospital, including a requirement that steam gas (ETO) and hot air sterilizers be tested with live bacterial spores at least weekly.
  - (g) Specific policies regarding the indications for universal precautions, body substance isolation, CDC isolation

**Interpretive Guideline**

- Review the Policies and Procedures for the Infection Control Program for the minimum of (a)-(i) the Governing Board approved the program.
- Review a sample of personnel records for Infection Control Training.
- Tour sterile storage areas and check dates for expiration dates of sterilization.
- Tour a sample of Nursing Unit clean storage and check sterile supplies.
- Review Infection Control Policies and Procedures specifically for Exposure to Blood & Body Fluids.
- Interview Infection Control Officer regarding this program.
- Review Policies and Procedures on drug admixtures, reconstituting and additions to IV/Irrigation fluids. Are licensed staff specifically trained to perform this function? Observe staff prepare, and administer injectable, IV's, or aseptic technique.
- Do staff adhere to infection control policies and manufacturers recommendations for medication, admixtures, IV's, and injectables?
- Review Policies and Procedures for Components of Biomedical Waste Program.
- Observe for the specific bagging, collection, storage, and removal (if possible).
- Tour and observe for types of isolation precautions. Are facility precautions in accord with CDC or equivalent guidelines?
- Are the staff performing within the established precaution instructions?
- Observe staff decontaminate and sterilize equipment.
- Observe environment and handling of linen. Observe the storage and collection of soiled linen.
- Observe sanitation and cleanliness (esp. vent, airflow and humidity).
- Interview Infection Control Officer regarding their Reportable Diseases to the Public Health Department.
- Review types of Diseases reported.- Review the Policies and Procedures for the Infection Control Program for the

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 141 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

guidelines, or equivalent and the types of isolation to be used for the prevention of the transmission of infectious diseases.

(h) A requirement that soiled linen is collected in such a manner as to minimize microbial dissemination into the environment.

(i) A requirement that all cases of communicable diseases as set forth in chapter 64D-3, F.A.C., be promptly and properly reported as required by the provisions of that rule.

395.1011 Identification, segregation, and separation of biomedical waste.-Each licensed facility shall comply with the requirements contained in s. 381.0098.

minimum of (a)-(i)

- Did the Governing Board approve the program.

- Interview Infection Control Officer regarding this program for clarity.

**ST - H0202 - SURVEIL/PREVEN/CONTROL OF INFECTION-Meetings**

**Title** SURVEIL/PREVEN/CONTROL OF INFECTION-Meetings

**Type** Rule

59A-3.250(4), FAC

**Regulation Definition**

(4) The individuals involved in the infection control program shall meet at least quarterly, shall maintain written minutes of all meetings, and shall make a report at least annually to the assigned professional staff and the governing board.

**Interpretive Guideline**

- Review quarterly Infection Control Program minutes for one year.

- Annual report to the Governing Board would be evident in the Governing Board minutes.

Refer to tag 0230 for committee requirements for infection control.

**ST - H0203 - SURVEIL/PREVEN/CONTROL OF INFECTION-EmpHlth**

**Title** SURVEIL/PREVEN/CONTROL OF INFECTION-EmpHlth

**Type** Rule

59A-3.250(5), FAC

**Regulation Definition**

(5) Each hospital shall establish an employee health policy to

**Interpretive Guideline**

- Interview Infection Control Officer regarding the employee health policy

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 142 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

minimize the likelihood of transmission of communicable disease by both employees and patients. Such policies shall include work restrictions for an employee whenever it is likely that communicable disease may be transmitted until such time as a medical practitioner certifies that the employee may return to work.

- Interview managers in departments for knowledge of employee restrictions for communicable diseases.
- Are there work restriction policies for employees?
- Does a medical practitioner certify when an employee may return to work?

**ST - H0204 - QUALITY IMPROVEMENT - System**

**Title** QUALITY IMPROVEMENT - System

**Type** Rule

59A-3.271(1), FAC

**Regulation Definition**

(1) General Provisions. Each hospital shall have a planned, systematic, hospital wide approach to the assessment, and improvement of its performance to enhance and improve the quality of health care provided to the public.

(a) Such a system shall be based on the mission and plans of the organization, the needs and expectations of the patients and staff, up-to-date sources of information, and the performance of the processes and their outcomes.

(b) Each system for quality improvement, which shall include utilization review, must be defined in writing, approved by the governing board, and enforced, and shall include:

1. A written delineation of responsibilities for key staff;
2. A policy for all privileged staff, whereby staff members do not initially review their own cases for quality improvement program purposes;
3. A confidentiality policy;
4. Written, measurable criteria and norms;
5. A description of the methods used for identifying problems;
6. A description of the methods used for assessing problems, determining priorities for investigation, and resolving problems;

**Interpretive Guideline**

- Interview the person(s) assigned to quality improvement regarding items 1-8..
- Request the Quality Improvement Plan.
- Does the Plan address all departments and include items 1-8?
- Review examples of where the facility has assessed problems, determined priorities for investigations and resolved problems.
- How has the QI Program improved processes or outcomes?
- Interview staff or department managers about the QI program.
- Does plan prioritize for investigation and problem resolution plan?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 143 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

7. A description of the methods for monitoring activities to assure that desired results are achieved and sustained; and,
8. Documentation of the activities and results of the program.

**ST - H0205 - QUALITY IMPROVEMENT - Data Collection System**

**Title** QUALITY IMPROVEMENT - Data Collection System

**Type** Rule

59A-3.271(2), FAC

**Regulation Definition**

(2) Each hospital shall have in place a systematic process to collect data on process outcomes, priority issues chosen for improvement, and the satisfaction of the patients. Processes measured shall include:

- (a) Appropriate surgical and other invasive procedures;
- (b) Preparation of the patient for the procedure;
- (c) Performance of the procedure and monitoring of the patient;
- (d) Provision of post-procedure care;
- (e) Use of medications including prescription, preparation and dispensing, administration, and monitoring of effects;
- (f) Results of autopsies;
- (g) Risk management activities;
- (h) Quality improvement activities including at least clinical laboratory services, diagnostic imaging services, dietetic services, nuclear medicine services, and radiation oncology services.

**Interpretive Guideline**

- Interview person(s) assigned to Quality Improvement Plan.
- Do they have a Data Collection System for items (a)-(h)?
- How does the facility evaluate the Patient Satisfaction?
- On tour with Manager/Department Heads inquire about their processes which have been selected for improvement.
- How is the Risk Management Program incorporated into the overall QI Program?
- The preparation, surgical procedure, post procedural care and use of medications must be monitored for outcomes and opportunities to improve the processes. Review data and outcomes.
- The QI Program must be specific to the types of patients and population served (i.e. psych/behavior consider safety/observations, general acute facility consider surgical services care).
- Interview the person responsible for the QI Program - inquire about current programs on processes under QI review.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 144 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0206 - QUALITY IMPROVEMENT - Data Assessment Process**

**Title** QUALITY IMPROVEMENT - Data Assessment Process

**Type** Rule

59A-3.271(3), FAC

**Regulation Definition**

(3) Each hospital shall have a process to assess data collected to determine:

- (a) The level and performance of existing activities and procedures,
- (b) Priorities for improvement, and,
- (c) Actions to improve performance.

**Interpretive Guideline**

- Review Quality Improvement data.
- Which processes indicators are selected currently for Quality Improvement?
- What actions have been implemented to improve process/outcomes?

**ST - H0207 - QUALITY IMPROVEMENT -Incorporated Into Proced**

**Title** QUALITY IMPROVEMENT -Incorporated Into Proced

**Type** Rule

59A-3.271(4), FAC

**Regulation Definition**

(4) Each hospital shall have a process to incorporate quality improvement activities in existing hospital processes and procedures.

**Interpretive Guideline**

- Interview QI person for examples of qi activities which have been incorporated into procedures.
- Interview managers and staff about the examples.

**ST - H0208 - GOVERNING BOARD**

**Title** GOVERNING BOARD

**Type** Rule

59A-3.272(1), FAC



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 145 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(1) The licensee shall have a governing board responsible for the conduct of the hospital as a functioning institution.

**Interpretive Guideline**

- Review the facility's governing board minutes to ensure issues discussed have to do with the hospital's function.
- Review the governing board written bylaws, rules and regulations to see how the governing board is organized.

**ST - H0209 - GOVERNING BOARD - Organization**

**Title** GOVERNING BOARD - Organization

**Type** Rule

59A-3.272(2), FAC

**Regulation Definition**

- (2) The governing board shall be organized under written bylaws, rules and regulations which it reviews at least every two years, dates to indicate time of last review, revises as necessary, and enforces. Governing board by-laws shall:
- (a) State the role and purpose of the hospital, including an organizational chart defining the lines of authority. The description of the structure of the hospital shall include full disclosure in writing of the names and addresses of all owners and persons controlling 5 percent or more interest in the hospital. In the case of corporations, holding companies, partnerships, and similar organizations, the names and addresses of officers, directors, and stockholders, both beneficial and of record, when holding 5 percent or more interest, shall be disclosed.
- (b) State the qualifications for governing board membership, and the method of selecting members as well as the terms of appointment or election of members, officers and chairmen of committees.
- (c) Provide for the designation of officers, their duties, and for the organization of the governing board into essential committees with the number and type consistent with the size and scope of the hospital's activities.
- (d) Coordinate through an executive committee or the

**Interpretive Guideline**

- Request documentation showing the governing board written bylaws, rules and regulations are reviewed at least every two years.
- Review the governing board's minutes for one year. Does the governing board meet as often as required by their bylaws, rules and regulations?
- Review the hospital organizational chart.
- Ask to see disclosure documentation of any person, organization, partnership, etc., that has five percent or more interest in the hospital.
- Review the governing board's by laws. What are the required qualifications for governing board memberships?
- What are the duties, terms of appointment, etc. specified in the bylaws for its officers?
- Determine if the organization of the governing board is consistent with the size and scope of the hospital?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 146 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

governing board as a whole, the policies and activities of the facility and special committees established by the governing board.

(e) Specify the frequency of meetings, at regularly stated intervals, the number or percentage of members constituting a quorum, and require that minutes be recorded and made available to all members of the governing board.

**ST - H0210 - GOVERNING BOARD - CEO**

**Title** GOVERNING BOARD - CEO

**Type** Rule

59A-3.272(3), FAC

**Regulation Definition**

(3) The governing board shall establish the position of chief executive officer or other similarly titled position, and define in writing the responsibility, authority and accountability of the chief executive officer for operation and maintenance of the hospital.

**Interpretive Guideline**

- Review the hospital's organization chart. Does the facility have a Chief Executive Officer? If the position is not titled Chief Executive Officer: Interview the Administrator and ask the title of the position that acts as the CEO?
- Review the CEO's record.
- Was this position established by the governing board?
- Are the responsibilities and authority of the CEO clearly established in writing?
- How is the CEO held accountable for the daily operation and maintenance of the hospital?

**ST - H0211 - GOVERNING BOARD - Membership/Privileges**

**Title** GOVERNING BOARD - Membership/Privileges

**Type** Rule

59A-3.272(4)(a-b); FAC, 395.0191(1)& (5)

**Regulation Definition**

59A-3.272  
(4) The governing board shall approve the by-laws, rules and regulations of the organized medical staff, provide for the appointment, reappointment, or dismissal of members of the

**Interpretive Guideline**

- Determine how the governing board determines who is eligible for appointment, what criteria is used.
- Interview the HR Director/CEO and ask what procedure is used to appoint the medical staff privileges? What criteria has the governing board given the HR Director for hiring medical staff? Ensure the requirements do not discriminate based on race, sex, age, or ethnicity.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 147 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

organized medical staff, and provide a procedure for hearings and appeals on all actions concerning appointment, reappointment or dismissal. No action on appointment, reappointment, or dismissal of a member of the organized medical staff shall be taken without prior referral to the organized medical staff for their recommendation, except in emergency cases.

(a) The governing board shall provide that no qualified applicant is denied organized medical staff privileges or clinical privileges solely because the applicant is licensed as a physician, dentist or podiatrist, psychologist, advanced practice registered nurse, or physician assistant.

(b) The governing board shall set standards and procedures to be applied by the hospital and the organized medical staff in considering and acting upon applications for staff membership or professional privileges, including delineation of privileges. Such standards or procedures shall be available for public inspection, and shall not operate to deny staff privileges or clinical privileges in an arbitrary, unreasonable or capricious manner, or on the basis of sex, race, creed, or national origin.

395.0191 Staff membership and clinical privileges.-

(1) No licensed facility, in considering and acting upon an application for staff membership or clinical privileges, shall deny the application of a qualified doctor of medicine licensed under chapter 458, a doctor of osteopathic medicine licensed under chapter 459, a doctor of dentistry licensed under chapter 466, a doctor of podiatric medicine licensed under chapter 461, or a psychologist licensed under chapter 490 for such staff membership or clinical privileges within the scope of his or her respective licensure solely because the applicant is licensed under any of such chapters.

(5) The governing board of each licensed facility shall set standards and procedures to be applied by the licensed facility

- Select a sample of medical staff to verify that the governing board has been the one to appoint the medical staff. Has the HR Director followed the governing board's requirements?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 148 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

and its medical staff in considering and acting upon applications for staff membership or clinical privileges. These standards and procedures shall be available for public inspection.

**ST - H0212 - GOVERNING BOARD- Membership/Privilege AMA/AOA**

**Title** GOVERNING BOARD- Membership/Privilege AMA/AOA

**Type** Rule

59A-3.272(4)(c), FAC; 395.0191(3), FS

**Regulation Definition**

59A-3.272(4)

(c) When the standards and procedures established by the governing board require, as a precondition to obtaining staff membership or professional clinical privileges, the completion of or eligibility in, a program established by the American Medical Association or the Liaison Committee on Graduate Medical Education, the governing board shall also make available staff membership or privileges to physicians who have obtained the completion of or eligibility in, any program which is in the same area of medical specialization established by the American Osteopathic Association.

395.0191

(3) When a licensed facility requires, as a precondition to obtaining staff membership or clinical privileges, the completion of, eligibility in, or graduation from any program or society established by or relating to the American Medical Association or the Liaison Committee on Graduate Medical Education, the licensed facility shall also make available such membership or privileges to physicians who have attained completion of, eligibility in, or graduation from any equivalent program established by or relating to the American Osteopathic Association.

**Interpretive Guideline**

- Interview the HR Director/CEO and ask if the governing board's requirements for providing privileges are based on the American Medical Association requirements. Completion of comparable programs established by the American Osteopathic Association is acceptable.

- Review the medical staff's records to ensure that when the American Medical Association requirements are utilized, then the criterion is met.

American Medical Association: <http://www.ama-assn.org/>

American Osteopathic Association: <http://www.osteopathic.org/Pages/default.aspx>

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 149 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0213 - GOVERNING BOARD- Specialty Designation**

**Title** GOVERNING BOARD- Specialty Designation

**Type** Rule

59A-3.272(4)(d), FAC

**Regulation Definition**

(d) The governing board shall require a delineation of privileges for each member of the organized medical staff. The delineation of privileges shall not be stated simply as a specialty designation, such as "general surgery" or "general medicine" unless such terms are specifically defined elsewhere.

**Interpretive Guideline**

- Review a sample of medical staff records to ensure their specialty designation is defined.

**ST - H0214 - GOVERNING BOARD- Applicant Eligibility**

**Title** GOVERNING BOARD- Applicant Eligibility

**Type** Rule

59A-3.272(4)(e-h), 395.0191(2&4), 395.01

**Regulation Definition**

59A-3.272

(4) (e) The governing board shall require that eligibility for privileges, delineation of privileges, and reappointments, be based on the applicant's background, experience, health, training, demonstrated current competence, adherence to applicable professional ethics, reputation, ability to work with others, ability of the hospital to provide adequate facilities and supportive services for the applicant and his patients, and such other elements as the governing board determines that are not inconsistent with this part.

(f) The governing board shall establish a procedure, within a

**Interpretive Guideline**

- Do these criteria include evaluation of individual character, competence, training and judgment?
- Are there written criteria for staff appointments to the medical staff?
- The governing board must ensure that the hospital's rules and criteria for medical staff memberships and granting of clinical privileges are applied equally to all practitioners.
- Review the governing board's criteria for appointment and documentation of their application.
- What is the time frame for this application process?
- Is there a written process for approval if there is an adverse decision?
- Are there written governing board policies and procedures regarding providing diagnostic laboratory tests and X-rays to licensed chiropractors?
- Review sample of credentialing files for privileges, delineation of privileges and reappointments. Review background checks, health status, training, specialized credentials and disciplinary action.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 150 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

time-limited period, for approving, approving in part, or denying an applicant's request for privileges.

(g) The governing board shall establish a procedure for an applicant for privileges to appeal an adverse decision, and shall establish a time-limited period for rendering a final decision after the appeal.

(h) The governing board shall set standards and procedures which provide for reasonable access by licensed chiropractors to the reports of diagnostic x-rays and laboratory tests of the institutions licensed facilities, subject to the same standards and procedures as other licensed physicians. However, nothing contained in the provisions of this section shall require a licensed facility to grant staff privileges to a chiropractor.

- Review policy and procedure for approving, partial approval or denying and applicant's request for privileges.
- Review procedure for appealing an adverse decision.

395.0191

(2)(a) Each licensed facility shall establish rules and procedures for consideration of an application for clinical privileges submitted by an advanced practice registered nurse licensed under part I of chapter 464, in accordance with the provisions of this section. No licensed facility shall deny such application solely because the applicant is licensed under part I of chapter 464 or because the applicant is not a participant in the Florida Birth-Related Neurological Injury Compensation Plan.

(b) An advanced practice registered nurse who is certified as a registered nurse anesthetist licensed under part I of chapter 464 shall administer anesthesia under the onsite medical direction of a professional licensed under chapter 458, chapter 459, or chapter 466, and in accordance with an established protocol approved by the medical staff. The medical direction shall specifically address the needs of the individual patient.

(c) Each licensed facility shall establish rules and procedures for consideration of an application for clinical privileges submitted by a physician assistant licensed pursuant to s. 458.347 or s. 459.022. Clinical privileges granted to a

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 151 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

physician assistant pursuant to this subsection shall automatically terminate upon termination of staff membership of the physician assistant's supervising physician.

(4) Nothing herein shall restrict in any way the authority of the medical staff of a licensed facility to review for approval or disapproval all applications for appointment and reappointment to all categories of staff and to make recommendations on each applicant to the governing board, including the delineation of privileges to be granted in each case. In making such recommendations and in the delineation of privileges, each applicant shall be considered individually pursuant to criteria for a doctor licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or for an advanced practice registered nurse licensed under part I of chapter 464, or for a psychologist licensed under chapter 490, as applicable. The applicant's eligibility for staff membership or clinical privileges shall be determined by the applicant's background, experience, health, training, and demonstrated competency; the applicant's adherence to applicable professional ethics; the applicant's reputation; and the applicant's ability to work with others and by such other elements as determined by the governing board, consistent with this part.

395.0195

Access of chiropractic physicians to diagnostic reports.-Each hospital shall set standards and procedures which provide for reasonable access by licensed chiropractic physicians to the reports of diagnostic X rays and laboratory tests of licensed facilities, subject to the same standards and procedures as other licensed physicians. However, this section does not require a licensed facility to grant staff privileges to a chiropractic physician.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 152 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0216 - GOVERNING BOARD- Written Notification**

**Title** GOVERNING BOARD- Written Notification

**Type** Rule

59A-3.272(5),FAC; 395.0191(6)FS

**Regulation Definition**

59A-3.272

(5) Within 30 days of receipt of a written request, either by an applicant for staff privileges, or by a member of the organized medical staff whose privileges have been suspended, denied, revoked or curtailed, whether in whole or in part, the licensed facility shall supply the reasons for such action in writing to the requesting applicant or staff member. A denial of staff membership or professional clinical privileges to any applicant shall be submitted, in writing, to the applicant's respective licensing board.

395.0191

(6) Upon the written request of the applicant, any licensed facility that has denied staff membership or clinical privileges to any applicant specified in subsection (1) or subsection (2) shall, within 30 days of such request, provide the applicant with the reasons for such denial in writing. A denial of staff membership or clinical privileges to any applicant shall be submitted, in writing, to the applicant's respective licensing board.

**Interpretive Guideline**

- Review the governing board policy for notifying an applicant for staff privileges or member of the medical staff, who provides a written request of this action, is provided a written response.
- Is this response provided within 30 days?
- If there was a denial of staff memberships or clinical privileges, was the applicant's licensing board notified in writing of this action?



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 153 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0217 - GOVERNING BOARD- Licensee Acting as Gov Body**

**Title** GOVERNING BOARD- Licensee Acting as Gov Body

**Type** Rule

59A-3.272(6), FAC

**Regulation Definition**

(6) Nothing herein shall prohibit the licensee of the facility from acting as the governing board, provided that the articles of incorporation or other written organizational plan describe the manner in which the licensee executes the governing board's responsibility.

**Interpretive Guideline**

- Does this hospital licensee act as this hospital's governing board?
- If so, review the hospital's Articles of Incorporation or other written organizational plan to determine how the licensee executes this responsibility.

**ST - H0218 - MGMT & ADMIN - CEO Appoint By Gov Board**

**Title** MGMT & ADMIN - CEO Appoint By Gov Board

**Type** Rule

59A-3.273(1), FAC

**Regulation Definition**

(1) Each hospital shall be under the direction of a chief executive officer appointed by the governing board, who is responsible for the operation of the hospital in a manner commensurate with the authority conferred by the governing board.

**Interpretive Guideline**

- Verify that the hospital has a Chief Executive Officer appointed by the governing board for the entire hospital.
- Review the governing board requirements for this position.
- Interview the Chief Executive Officer regarding operation of the hospital. Verify management of the entire hospital.
- Is the hospital operated as required by State law and in compliance with the governing board guidelines?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 154 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0219 - MGMT & ADMIN - CEO Regulatory Responsibility**

**Title** MGMT & ADMIN - CEO Regulatory Responsibility

**Type** Rule

59A-3.273(2), FAC

**Regulation Definition**

(2) The chief executive officer shall take all reasonable steps to provide for:

- (a) Compliance with applicable laws and regulations; and,
- (b) The review of and prompt action on reports and recommendations of authorized planning, regulatory, and inspecting agencies.

**Interpretive Guideline**

- Does the Chief Executive Officer insure compliance with all regulations and laws?
- Does the hospital respond promptly to regulatory requirements found out of compliance?
- Review State inspection reports and hospital survey findings for identified problems.
- Tour and interview staff to determine if these identified problems has been corrected.
- Review documentation that reports were sent promptly to Federal, State and Local agencies as required.

**ST - H0220 - MGMT & ADMIN -CEO Organization Responsibility**

**Title** MGMT & ADMIN -CEO Organization Responsibility

**Type** Rule

59A-3.273(3), FAC

**Regulation Definition**

(3) The chief executive officer shall provide for the following:

- (a) Establishment and implementation of organized management and administrative functions, including:
  - 1. Clear lines of responsibility and accountability within and between department heads and administrative staff;
  - 2. Effective communication mechanisms among departments, medical staff, the administration and the governing board;
  - 3. Internal controls;
  - 4. Coordination of services with the identified needs of the patient population;
  - 5. A policy on patient rights and responsibilities;

**Interpretive Guideline**

- The hospital Chief Executive Officer is responsible for implementing organized management with administrative functions. Based on the hospital's organizational chart are the department heads identified and responsible for developing and implementing appropriate hospital policies and procedures for their department?
- Do these policies cover the areas identified in paragraph (a) 1-14 of this regulation?
- Review personnel policies and procedures to ensure they meet the requirements under paragraph (b) of this regulation.
- Review a sample of personnel records to ensure compliance with State regulations.
- Interview the hospital risk management department to ensure compliance with State regulations.
- Review a sample of personnel records to ensure State educational licensee requirements are met regarding human immune deficiency virus education as identified in paragraph (e) of this regulation.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 155 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

6. A mechanism for receiving and responding to complaints concerning patient care;
7. A policy on withholding resuscitative services;
8. Policies and procedures on identification and referral of organ and tissue donors including notification of organ and tissue procurement agencies when organs and tissues become available as specified under rule 59A-3.274, F.A.C.;
9. Policies and procedures for meeting the communication needs of multicultural populations and persons with impaired hearing or speaking skills;
10. Policies and procedures on discharge planning;
11. A policy to assist in accessing educational services for children or adolescents when treatment requires a significant absence from school;
12. Policies and procedures to assure that the treatment, education and developmental needs of neonates, children and adolescents transferred from one setting to another are assessed;
13. Dissemination and enforcement of a policy prohibiting the use of smoking materials in hospital buildings and procedures for exceptions authorized for patients by a PA, APRN or physician's written authorization;
14. A policy regarding the use of restraints and seclusion; and,

See also Comprehensive Emergency Management Plan at CORE Tag Z830.

(b) Personnel policies and practices which address:

1. Non-discriminatory employment practices;
2. Verification of credentials including current licensure and certification;
3. Periodic performance evaluations; and,
4. Provision of employee health services.

(c) Financial policies and procedures;

(d) An internal risk management program which meets the requirements of section 395.0197, F.S., and chapter 59A-10,

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 156 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

F.A.C., and,

(e) Assurance of compliance with educational requirements on human immunodeficiency virus and acquired immune deficiency syndrome pursuant to sections 381.0034 and 381.0035, F.S., and chapter 64D-2, F.A.C.

**ST - H0221 - ANATOMICAL GIFTS, ROUTINE INQ - Donation**

**Title** ANATOMICAL GIFTS, ROUTINE INQ - Donation

**Type** Rule

59A-3.274(1), FAC

**Regulation Definition**

(1) Each Class I and Class II hospital shall establish a mechanism whereby the next of kin of all patients who are deemed medically acceptable and who die in Florida hospitals are given the opportunity to consider the donation of organs, tissues and eyes for transplantation and research.

**Interpretive Guideline**

- Does the hospital have policies and procedures for requesting organ, tissue and eyes of medically suitable donors?
- Are there written protocols to ensure that once the Organ Procurement Organization (OPO) determines medical suitability, the person's family is informed of donation options?
- Is the family informed of the right to decline to donate?

**ST - H0222 - ANATOMICAL GIFTS, ROUTINE INQ - Educ/Training**

**Title** ANATOMICAL GIFTS, ROUTINE INQ - Educ/Training

**Type** Rule

59A-3.274(2)(a)-(f), FAC

**Regulation Definition**

(2) Education and Training of Designee. The hospital administrator or designee making the request of the next of kin for organ, tissue and eye donations shall be trained in the request procedures used in organ and tissue donation. The Organ Procurement Organization (OPO), tissue bank and eye bank shall, in conjunction with their affiliated hospitals,

**Interpretive Guideline**

- Verify that the hospital's governing body has approved the hospital's organ procurement policy.
- Review the hospital's written agreement with the OPO to ensure it is consistent with facility policies and procedures.
- Is the name, address, and phone number of the OPO on file?
- Does the hospital have personnel with sensitivity training for discussing organ and/or tissue donation with the family?
- Review a sample of death records to verify the hospital has implemented organ and/or tissue procurement policies.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 157 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

develop a requester training curriculum that will meet the individual needs of each affiliated hospital. The Agency shall assist, if requested, in the implementation of the requester training curriculum in conjunction with an OPO, tissue bank and eye bank where the OPO, tissue bank and eye bank do not have adequate resources for the implementation of the requester training curriculum within their affiliated hospitals. This training shall include the following minimum basic curriculum:

(a) The criteria used by the affiliated OPO, tissue bank, and eye bank for determining the acceptability of patients as organ, tissue, or eye donors;

(b) The requirements of Florida law to be met in order for a donation to be allowed to proceed including:

1. Explanatory information regarding the family's rights to allow or refuse a donation, to donate specific organs, tissues or eyes and to designate the organs, tissues or eyes for the purpose of transplantation, medical research or instruction, and,

2. The criteria for determining whether a particular death falls within the scope of section 406.11, F.S., necessitating close communication with the Medical Examiner's office, and permission from the Medical Examiner when required;

(c) Necessary basic information regarding the process and procedures related to organ, tissue, and eye donation and transplantation including the following:

1. The procedures and techniques used in the recovery and preservation of organs, tissues and eyes;

2. The success rates of currently accepted transplant procedures;

3. The numbers of patients presently awaiting these procedures; and,

4. The financial procedures and arrangements applicable to the donation of organs, tissues and eyes.

(d) The various approaches which can be used in dealing with

- Interview staff to verify they are aware of the hospital's organ procurement policies and procedures.
- Review the hospital's Routine Inquiry Report.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 158 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

a family in a grief situation and offering them the opportunity of organ, tissue, or eye donation. These approaches shall be based on the criteria of the affiliated OPO, tissue bank, and eye bank, which shall not be inconsistent with these guidelines;

(e) Notification of the affiliated OPO, tissue bank and eye bank; and,

(f) Training regarding the administrative rules and guidelines promulgated by the Agency for the purpose of implementing the Routine Inquiry provisions of the Anatomical Gift Act, in accordance with section 765.522, F.S.

**ST - H0223 - ANATOMICAL GIFTS, ROUTINE INQ - Procedures**

**Title** ANATOMICAL GIFTS, ROUTINE INQ - Procedures

**Type** Rule

59A-3.274(3)(a)-(c), FAC

**Regulation Definition**

(3) Each Class I and Class II hospital or its designee shall, using the criteria of the affiliated OPO, tissue bank, and eye bank, implement the following procedures:

(a) Establish and publish a formal written policy and procedure for the identification and referral of organ, tissue, and eye donors. This policy shall include the procedure to be followed for the determination of brain death.

(b) Identify and designate the personnel or organization which will make the request for organ, tissue, or eye donation. These personnel shall be trained as required in subsection (2), above, and shall be available on a 24-hour "on call" basis to make the initial evaluations of donor suitability, request, and referrals.

(c) The Hospital Administrator or designee shall ensure that the District Medical Examiner is contacted in all medical examiners' cases regarding the wishes of the family as to organ, tissue, and eye donation and to determine whether or

**Interpretive Guideline**

- Does the hospital have written criteria to identify potential organ and tissue donors?
- Is there a written protocol specifying the designated requestor or OPO representative responsible for approaching potential donor families?
- Review training schedules and personnel files to ensure all designated requestors have completed the required training.
- Is there a hospital policy that includes determination of brain death?
- Are Routine Inquiry Forms completed when referral is made to an OPO?
- Is a Routine Inquiry Form completed for medical examiner cases?
- Are the completed forms filed in the patient's medical record?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 159 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

not the medical examiner has released such organs, tissues or eyes for transplantation, medical research or instruction. This contact shall be recorded on the Routine Inquiry Form and placed in the patient's medical record. When completion of the Routine Inquiry Form is designated by the hospital administrator and accepted by the affiliated procurement agency, the contact shall be noted in the records of the affiliated procurement agency. This notation shall indicate that request for donation of organs, tissue or eyes was made.

**ST - H0224 - ANATOMICAL GIFTS, ROUTINE INQ - Referral**

**Title** ANATOMICAL GIFTS, ROUTINE INQ - Referral

**Type** Rule

59A-3.274(3)(d), FAC

**Regulation Definition**

(3) Each Class I and Class II hospital or its designee shall, using the criteria of the affiliated OPO, tissue bank, and eye bank, implement the following procedures:

(d) The hospital administrator or designee shall ensure that all identified potential organ, tissue, or eye donors meeting the criteria of brain death as defined in section 382.009, F.S., or cardiorespiratory death as defined in subsection 59A-3.065(9), F.A.C., shall be referred to the affiliated OPO, tissue bank, or eye bank for evaluation and recovery of the organs, tissues, or eyes to be donated according to the medical standards of the affiliated OPO, tissue bank and eye bank. This referral shall be recorded on the Routine Inquiry Form and placed in the patient's medical record. When completion of the Routine Inquiry Form is designated by the hospital administrator and accepted by the affiliated procurement agency, the referral shall be noted in the records of the affiliated procurement agency.

**Interpretive Guideline**

- Review the hospital's policy and procedures that ensure coordination between facility staff and OPO staff regarding identification of potential donors.
- Does the policy specify that a referral be documented on the Routine Inquiry Form and placed in the patient's medical record?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 160 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0225 - ANATOMICAL GIFTS, ROUTINE INQ - Affiliations**

**Title** ANATOMICAL GIFTS, ROUTINE INQ - Affiliations

**Type** Rule

59A-3.274(3)(e), FAC

**Regulation Definition**

(3) Each Class I and Class II hospital or its designee shall, using the criteria of the affiliated OPO, tissue bank, and eye bank, implement the following procedures:

(e) The hospital shall work with the affiliated OPO, tissue bank, and eye bank to evaluate the patient as a potential organ, tissue, or eye donor in accordance with section 765.522, F.S. The medical acceptability of such organs, tissues, and eyes shall be determined according to the medical standards of the affiliated procurement agency. The hospital administrator may designate personnel of the affiliated OPO, tissue bank, or eye bank who shall make the request for donation. Where non-hospital personnel are designated to make the request for organ, tissue or eye donation, the affiliated OPO, tissue bank, or eye bank shall be given the opportunity to approach the next of kin about donation and shall utilize the following procedure when approaching the next of kin:

1. The affiliated OPO shall be given the opportunity to approach the next of kin about donation of organs in all suitable vascular organ donor cases when the potential donor meets the medical standards of the affiliated OPO. Where the suitable vascular organ donor also meets the medical standards of the affiliated tissue bank or eye bank, and in the absence of a contrary agreement between the affiliated OPO, tissue bank, and eye bank, the affiliated OPO may represent the affiliated tissue bank and eye bank and approach the next of kin about donation in all suitable tissue and eye donor cases.
2. The affiliated tissue bank shall be given the opportunity to

**Interpretive Guideline**

Verify the hospital has an agreement with at least one tissue bank and eye bank. If not, the hospital has an agreement with an OPO that also has the responsibility for tissue and eye donations. The hospital administrator may designate OPO to make the request for organ, tissue and eye donations if hospital staff is not utilized.



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 161 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

approach the next of kin about donation in all suitable tissue donor cases where the potential donor meets the medical standards of the affiliated tissue bank and where the affiliated OPO has not already approached the next of kin for donation of tissues and eyes in all non-suitable vascular organ donor cases. Where the suitable tissue donor also meets the medical standards of the affiliated eye bank, and in the absence of a contrary agreement between the affiliated tissue bank and eye bank, the affiliated tissue bank may represent the affiliated eye bank and approach the next of kin about donation in all suitable eye donor cases.

3. The affiliated eye bank shall be given the opportunity to approach the next of kin about donation in all suitable eye donor cases where the potential donor meets the medical standards of the affiliated eye bank, and where the affiliated OPO or tissue bank has not already approached the next of kin for donation of eyes. Where the suitable eye donor also meets the medical standards of the affiliated tissue bank, and in the absence of a contrary agreement between the affiliated eye bank and tissue bank, the affiliated eye bank may represent the affiliated tissue bank and approach the next of kin about donation in all suitable tissue donor cases.

**ST - H0226 - ANATOMICAL GIFTS, ROUTINE INQ - Timing/Form**

**Title** ANATOMICAL GIFTS, ROUTINE INQ - Timing/Form

**Type** Rule

59A-3.274(3)(f)-(g), FAC

**Regulation Definition**

(3) Each Class I and Class II hospital or its designee shall, using the criteria of the affiliated OPO, tissue bank, and eye bank, implement the following procedures:

(f) The request for organ, tissue, or eye donation shall be made at or near the time of death, and in a manner which is

**Interpretive Guideline**

- Procurement agency protocol for medically suitable donors is written in the affiliated OPO's, tissue banks and eye banks agreements with the hospital.
- Verify that the Routine Inquiry Form indicates why patients were not medically suitable as organ and tissue donors.
- The hospital or affiliated OPO, tissue bank or eye bank contacts the donor registry to determine whether a medically suitable donor has consented to organ and tissue donation.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 162 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

conducive to the discussion of organ, tissue, and eye donation with the grieving next of kin according to the priority specified in section 765.512, F.S.

(g) A Routine Inquiry Form shall be completed upon every patient death occurring within the hospital and shall become a part of each patient's medical record.

1. The form shall document whether the patient was deemed medically suitable for donation of organs, tissues and eyes, and if the patient is not medically suitable for donation, the form shall document the specific reason according to the criteria of the affiliated procurement agency.

2. If the patient is deemed medically acceptable for donation, the form shall document that the patient's appropriate next of kin was approached, as well as the outcome of the patient's expressed wishes, if known, regarding the donation of organs, tissues, and eyes. If the family allows donation, a specific consent form shall be signed or completed by means of telegraphic, recorded telephonic, or other recorded message by the appropriate next of kin as specified in section 765.512, F.S.

3. If a request for donation is deemed to be exempted according to subsection (4) of this section, or the medical standards of the affiliated OPO, tissue bank, and eye bank, the form shall document the specific reason for the lack of a request.

- Verify if the Routine Inquiry Form indicates that the next of kin was approached regarding organ and tissue donation.

**ST - H0227 - ANATOMICAL GIFTS, ROUTINE INQ - Med Rec/Stats**

**Title** ANATOMICAL GIFTS, ROUTINE INQ - Med Rec/Stats

**Type** Rule

59A-3.274(3)(h), FAC; 395.2050 FS

**Regulation Definition**

59A-3.274  
(3) Each Class I and Class II hospital or its designee shall,

**Interpretive Guideline**

- Review a sample of death records to determine if the Routine Inquiry Form was completed and made a part of the patient's medical record.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 163 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

using the criteria of the affiliated OPO, tissue bank, and eye bank, implement the following procedures:

(h) The lack of request and a complete written explanation shall be noted on the Routine Inquiry Form and made a part of the patient's medical record or if designated by the hospital administrator, and accepted by the affiliated procurement agency, in the affiliated procurement agency's records. If the affiliated procurement agency has been designated, the patient's medical record shall document the referral of the potential donor to the affiliated procurement agency. All Routine Inquiry Forms maintained by the affiliated procurement agency shall be complete and include the patient's name and medical record number. These records shall be made available to the hospital during normal working hours. The referral of the affiliated procurement agency shall be documented in the patient's medical record. This documentation shall include the name of the procurement agency and time and date of the referral. This referral shall be documented in the patient's death record.

- Is statistical data regarding this form forwarded to AHCA on a quarterly basis?
- Summary Data Form to AHCA quarterly as required?
- Verify whether the Routine Inquiry Forms are completed and made part of donor records. If a request is not made of the next of kin of a medically suitable donor, verify the Routine Inquiry Form is completed and forwarded to AHCA for data analysis.
- Verify that the statistical data is forwarded to AHCA on a quarterly basis.

395.2050 Routine inquiry for organ and tissue donation; certification for procurement activities; death records review.-

(1) Every general hospital, and every specialty hospital that offers the range of medical services offered by a general hospital but only to a portion of the population restricted by age or gender, licensed under this chapter shall comply with the requirements of s. 765.522 pertaining to requests for organ or tissue donation.

(2) Every hospital licensed under this chapter that is engaged in the procurement of organs, tissues, or eyes shall comply with the certification requirements of ss. 765.541-765.546.

(3) Each organ procurement organization designated by the federal Health Care Financing Administration and licensed by the state shall conduct an annual death records review in the organ procurement organization's affiliated donor hospitals.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 164 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

The organ procurement organization shall enlist the services of every Florida licensed tissue bank and eye bank affiliated with or providing service to the donor hospital and operating in the same service area to participate in the death records review.

**ST - H0228 - ANATOMICAL GIFTS, ROUTINE INQ - Exemptions**

**Title** ANATOMICAL GIFTS, ROUTINE INQ - Exemptions

**Type** Rule

59A-3.274(4)(a), FAC

**Regulation Definition**

(4) Request Exemptions.

(a) The appropriate next of kin as defined by section 765.512, F.S., of patients deemed medically acceptable by the medical standards of the affiliated OPO, tissue bank and eye bank, and dying in the hospital shall be asked about organ, tissue, and eye donation except as follows:

1. There is on record notification of prior objection by the individual, or the appropriate next of kin as defined by section 765.512, F.S., or
2. The appropriate next of kin cannot be found after a reasonable search; or
3. No positive identification of the potential donor has been found; or
4. The medical examiner has denied permission; or
5. The hospital or designee, in accordance with a request for the affiliated procurement agency, has agreed to delay the request until the family has left the hospital.

**Interpretive Guideline**

- Does the hospital have an exception policy that excludes asking a patient about organ, tissue or eye donation in certain cases even though the patient was deemed medically acceptable?
- Interview the hospital designated requestors to ensure that this policy has been implemented.

**Agency for Health Care Administration  
ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 165 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0229 - ORGANIZED MEDICAL STAFF**

**Title** ORGANIZED MEDICAL STAFF

**Type** Rule

59A-3.275(1), FAC

**Regulation Definition**

(1) Each hospital shall have an organized medical staff organized under written by-laws approved by the governing board and responsible to the governing board of the hospital for the quality of all health care provided to patients in the facility and for the ethical and professional practices of its members.

**Interpretive Guideline**

- Review the facility's written by-laws regarding medical staff organization.
- Determine if the by-laws were approved by the facility's governing board meeting minutes.
- Review governing board minutes for written evidence the facility is reporting quality of healthcare issues to the governing board and medical staff being held accountable for ensuring quality healthcare to the patients.

**ST - H0230 - ORGANIZED MEDICAL STAFF - Committees**

**Title** ORGANIZED MEDICAL STAFF - Committees

**Type** Rule

59A-3.275(2), FAC

**Regulation Definition**

(2) Each hospital's organized medical staff shall determine its appropriate committee structure and shall provide that the following required committee functions are carried out with sufficient periodicity to assure their objectives being achieved by separate committee, combined committees, or committee of the whole:

- (a) Coordination of the activities and general policies of the various departments.
- (b) Interim decision making for the organized medical staff between staff meetings, under such limitations as shall be set by the organized medical staff.

**Interpretive Guideline**

- Determine the committee structure.
- Ask for proof the facility meets the requirements in a-j with the committees they have and the committee meets to accomplish its goals.
- Review by-laws as needed to determine compliance
- Refer to the following tags if there are problems with the committees:
  - Tag 0190 for Medical Records
  - Tags 0199-0203 for Infection Control.
  - Tags 0211 and 0212 for privileges at hospital.
  - Tags 0204 - 0207 for quality improvement.
  - Tags 0081 - 0098 for pharmacy related tags.
  - Tag 0176 for policy and procedures on admission and discharge.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 166 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(c) Follow-up and appropriate disposition of all reports dealing with the various staff functions.

Tag 0154 for radiology.

Tag 0160 for respiratory policy.

(d) Review of all applications for appointment and reappointment to all categories of staff, and recommendations on each to the governing board, including delineation of privileges to be granted in each case, and right of hearing and appearance. Except in emergency cases, recommendations to the governing board for withdrawal of any privileges of a member of the organized medical staff or dismissal from the organized medical staff will be made only after a thorough investigation by the organized medical staff or a committee thereof, with the subject member being given the right of hearing before the organized medical staff or a committee thereof, if requested within a reasonable time as specified in the hospital's by-laws.

(e) Medical records currently maintained describing the condition, treatment, and progress of patient in sufficient completeness to assure transferable comprehension of the case at any time.

(f) Clinical evaluation of the quality of medical care provided to all categories of patients on the basis of documented evidence.

(g) Review of hospital admissions with respect to need for admission, length of stay, discharge practices and evaluation of the services ordered and provided.

(h) Surveillance of hospital infection potentials and cases and the promotion of a preventive and corrective program designed to minimize these hazards.

(i) Surveillance of pharmacy and therapeutic policies and practices within the institution.

(j) Hospital tests may be ordered only by the attending physician, or by another licensed health professional if that licensed health professional is acting within his scope of practice as defined by applicable laws and rules of the agency. Nothing herein shall be construed to expand or restrict such laws and rules pertaining to the practice of the various health professions.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 167 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0231 - MAINTENANCE - Preventive Plan**

**Title** MAINTENANCE - Preventive Plan

**Type** Rule

59A-3.276(1), FAC

**Regulation Definition**

(1) Each hospital shall develop, implement, and maintain a written preventive maintenance plan, in conjunction with the policies and procedures developed by the infection control committee, to ensure that the facility is maintained in accordance with the following:

- (a) The interior and exterior of buildings shall be in good repair, free of hazards, and painted as needed.
- (b) All patient care equipment shall be maintained in a clean, properly calibrated, and safe operating condition;
- (c) All plumbing fixtures shall be maintained in good repair to assure proper functioning, and provided with back flow prevention devices, when required, to prevent contamination from entering the water supply;
- (d) All mechanical and electrical equipment shall be maintained in working order, and shall be accessible for cleaning and inspection;
- (e) Loose, cracked, or peeling wallpaper or paint shall be promptly replaced or repaired to provide a satisfactory finish;
- (f) All furniture and furnishings, including mattresses, pillows, and other bedding; window coverings; including curtains, blinds, shades, and screens; and cubicle curtains or privacy screens, shall be maintained in good repair; and,
- (g) The grounds and buildings shall be maintained in a safe and sanitary condition and kept free from refuse, litter, and vermin breeding or harborage areas.

**Interpretive Guideline**

- Review the facility written preventative maintenance plan.
- Were the policies and procedures developed in conjunction with the hospital infection control program? (Refer to tag 0200 for IC policy and procedure)
- Is the physical plant and environment maintained in a manner to ensure the safety and well-being of patients? (For any problems or questions with items a-g, contact life safety)

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 168 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0232 - MAINTENANCE - Sufficient Personnel**

**Title** MAINTENANCE - Sufficient Personnel

**Type** Rule

59A-3.276(2), FAC

**Regulation Definition**

(2) Each hospital shall employ or otherwise arrange for sufficient personnel to implement and maintain its preventative maintenance program.

**Interpretive Guideline**

- Review staffing documentation to confirm that there is adequate staff to implement and maintain the preventative maintenance program.
- Interview staff regarding the maintenance program.

**ST - H0233 - FUNCTIONAL SAFETY - Hospital Safety Committee**

**Title** FUNCTIONAL SAFETY - Hospital Safety Committee

**Type** Rule

59A-3.277(1), FAC

**Regulation Definition**

(1) Each hospital shall have a hospital safety committee to adopt, implement and monitor a comprehensive, hospital wide safety program. The committee's functions and responsibilities may be assumed by another hospital committee. The committee shall adopt written policies and procedures to enhance the safety of the hospital, its personnel and patients. Such policies shall include but not be limited to the following:

- (a) A method of coordination of the safety policies of the various hospital units, departments and committees;
- (b) An incident reporting system;
- (c) A method of conveying safety-related information to all hospital employees; and,
- (d) Conduct of a hazardous surveillance program at specifically defined intervals.

**Interpretive Guideline**

- Has a hospital wide safety program been adopted and implemented?
- Interview staff to verify their awareness of the safety program and that it has been implemented.
- Interview patients regarding safety and security issues (e.g. proper identification before medication or procedure).
- Refer to tags 410-412 for incident reporting system requirement details.
- Refer to tags 425-426 for patient safety plan.
- For the hazardous surveillance program (drills), see also tag 0007.



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 169 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0234 - FUNCTIONAL SAFETY-Patient Identification Syst**

**Title** FUNCTIONAL SAFETY-Patient Identification Syst

**Type** Rule

59A-3.277(2), FAC

**Regulation Definition**

(2) In addition to other requirements, each hospital shall provide a complete system for patient identification within the hospital, including a system for all emergency room cases, including DOA, and disasters.

**Interpretive Guideline**

- Review the hospital safety policy regarding patient identification for all patient care areas.
- Tour and observe if the patient identification policy is consistently implemented.
- Interview:
  - staff in the surgical departments, Obstetrics, anesthesia etc regarding patient identification procedures.
  - floor staff on patient identification procedures. (Upon admission, medication pass, prior to a procedure).
  - patients regarding proper identification especially before medications or procedures.
- In the emergency room review who, how and at what point the patient is identified/ID bands are placed.
- See also 'Patient Safety Plan' requirements at 395.1012(1) F.S. (H0425) and Patient Safety Officer and Committee at 395.1012(2), F.S. (H0426).

**ST - H0235 - REHAB, PSYCH & SUBST ABUSE -Pt Eval/Assess/Tx**

**Title** REHAB, PSYCH & SUBST ABUSE -Pt Eval/Assess/Tx

**Type** Rule

59A-3.278(1), FAC

**Regulation Definition**

(1) All rehabilitation, psychiatric, and substance abuse programs provided by hospitals shall provide to the patient:

- (a) An evaluation upon referral;
- (b) Establishment of goals;
- (c) Development of a plan of treatment, including discharge planning, in coordination with the referring individual and rehabilitation staff, and after discussion with the patient and family;

**Interpretive Guideline**

- Review the hospital's Policies and Procedures for Rehab Psych and Substance Abuse to determine the scope of services.
- Review a sample of patient records for documentation of patient referral and admission treatment goals.
- Check for treatment plan and assessment documentation.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 170 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

- (d) Regular and frequent assessment, performed on an interdisciplinary basis, of the patient's condition and progress, and of the results of treatment;
- (e) Maintenance of treatment and progress records; and,
- (f) At least a quarterly assessment of the quality and appropriateness of the care provided.

**ST - H0236 - REHAB, PSYCH & SUBST ABUSE - Contracted**

**Title** REHAB, PSYCH & SUBST ABUSE - Contracted

**Type** Rule

59A-3.278(2), FAC

**Regulation Definition**

(2) When any rehabilitation activity, psychiatric or substance abuse treatment is provided from outside the hospital, the source shall be available whenever needed for patient care, meet all safety requirements, abide by all pertinent rules and regulations of the hospital and medical staff, and document the quality assurance measures to be implemented.

**Interpretive Guideline**

- Is treatment provided by outside providers?
- If service is contracted, review the contract or agreement to ensure all hospital regulations and medical staff requirements are met.
- Does the hospital have a quality assurance program for this service?

**ST - H0237 - REHAB, PSYCH & SUBST ABUSE - Scope of Svcs**

**Title** REHAB, PSYCH & SUBST ABUSE - Scope of Svcs

**Type** Rule

59A-3.278(3), FAC

**Regulation Definition**

(3) The scope of services offered, and the relationship of the rehabilitation, psychiatric or substance abuse program to other hospital units, as well as all supervisory relationships within the program, shall be defined in writing. Responsibility for the performance of clinical services also shall be clearly defined.

**Interpretive Guideline**

- Review the department's written policies and procedures and are they reviewed annually as required? Ask for additional documentation as needed to meet requirements of this tag.
- Interview the staff and supervisors to verify the current policies and procedures have been implemented.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 171 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

Delegation of authority within the program shall be specified in job descriptions and in organizational plans. Written policies and procedures to guide the operation of the rehabilitation program shall be developed and reviewed at least annually, revised as necessary, dated to indicate the time of last revision, and enforced.

**ST - H0238 - REHAB, PSYCH & SUBST ABUSE - Plan of Care**

**Title** REHAB, PSYCH & SUBST ABUSE - Plan of Care

**Type** Rule

59A-3.278(4), FAC

**Regulation Definition**

(4) There shall be a current written plan of care for each patient receiving rehabilitative, psychiatric or substance abuse services. The plan shall state the diagnosis, and problem list when appropriate, pertinent to the rehabilitation or treatment process; precautions necessitated by the patient's general medical condition or other factors; the short-term and long-term goals of the treatment program; and require monthly or more frequent review of the patient's progress. The medical record and the written plan shall evidence a team approach, with participation of the professional and administrative staffs, the patient, and, as appropriate, the patient's family. The medical record shall document the written instructions given to the patient and the family concerning appropriate care after discharge from the hospital.

**Interpretive Guideline**

- Review a sample of patient records to verify interdisciplinary participation and includes patient and family input, if appropriate.
- Are there measurable long-term and short-term goals?
- Is there frequent review and reports of the patient's progress?
- Does the plan include discharge planning?
- For discharged patient records, were written instructions concerning care after discharge given to the patient and/or family?

**Agency for Health Care Administration  
ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 172 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0239 - REHAB, PSYCH & SUBST ABUSE - Sep Notes/Logs**

**Title** REHAB, PSYCH & SUBST ABUSE - Sep Notes/Logs

**Type** Rule

59A-3.278(5), FAC

**Regulation Definition**

(5) The rehabilitation, psychiatric or substance abuse program must have notes and log records that are separately identified from the other admission and discharge records in the hospital in which it is located, and are separately retrievable.

**Interpretive Guideline**

- Are the logs and notes separately identified from the hospital admission and discharge records?
- Can records be retrieved separately from other hospital records?

**ST - H0240 - REHAB, PSYCH & SUBST ABUSE - Distinct Beds**

**Title** REHAB, PSYCH & SUBST ABUSE - Distinct Beds

**Type** Rule

59A-3.278(6), FAC

**Regulation Definition**

(6) The beds assigned to the program must be physically separate from and not commingled with beds not included in the unit. Rehabilitation, psychiatric or substance abuse programs and beds may be located on the same floor as other programs or beds.

**Interpretive Guideline**

Tour the units, look for types of patients in the unit.  
Interview: Ask staff if any unit beds commingled are or have been used for patients without a rehab, psych or substance abuse.  
Record Review: Based on observation, review the unit's policies and procedures and/or patient records for appropriate placement in the unit beds.

**ST - H0241 - REHAB, PSYCH & SUBST ABUSE-Physician In Charge**

**Title** REHAB, PSYCH & SUBST ABUSE-Physician In Charge

**Type** Rule

59A-3.278(7), FAC

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 173 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(7) In addition to meeting the requirements of subsections (1) through (6) of this section, rehabilitation programs provided by hospitals must place responsibility for the medical direction of the rehabilitation program on a physician member of the organized medical staff who, on the basis of training, experience and interest, is knowledgeable in the rehabilitation services offered. Unless otherwise permitted by law, rehabilitation services shall be initiated by a physician. The written request for services shall include reference to the diagnosis or problems for which treatment is planned.

**Interpretive Guideline**

- Interview: Unit staff and ask who refers patients to rehabilitation services?
- Review the credential file for the physician in charge of the Rehab Psych and Substance Abuse program to ensure this person is licensed and credentialed.
- Review samples of clinical records to verify documentation of physician's orders, diagnosis and treatment plan.

**ST - H0242 - REHAB, PSYCH & SUBST ABUSE - Stds of Practice**

**Title** REHAB, PSYCH & SUBST ABUSE - Stds of Practice

**Type** Rule

59A-3.278(8), FAC

**Regulation Definition**

(8) In addition to meeting the requirements of subsections (1)-(6) of this section, psychiatric, or substance abuse rehabilitation programs provided by hospitals shall meet at least the following additional standards:

(a) The program, unit, service or similarly titled part shall treat only those patients whose primary reason for admission was a diagnosis contained in the third edition of the American Psychiatric Association Diagnostic and Statistical Manual.

(b) The program, unit, service or similarly titled part shall have medical direction by an appropriately qualified practitioner, including a physician who is certified by the American Board of Psychiatry and Neurology or is eligible for examination by the Board or similar specialty board recognized by the American Osteopathic Association, a clinical psychologist, or a licensed physician with

**Interpretive Guideline**

- Interview the Medical Director and Psychiatric Nurse to determine the Acceptable Standard of Practice the unit is utilizing. Review the practice being utilized and determine if unit practices comply with those standards.
- Review sampled patients' records to confirm only patients with an appropriate psychiatric diagnosis are treated in this program.
- Review the credential file for the physicians, nurse and staff of the Rehab Psych and Substance Abuse program to ensure they are licensed and credentialed.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 174 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

postgraduate training and experience in the diagnosis and treatment of nervous and mental disorders.

(c) The program, unit, service or similarly titled part shall furnish, through qualified personnel, psychological services, social work services, psychiatric nursing, occupational therapy, and recreational therapy, as appropriate to the needs of the patient.

(d) The program, unit, service or similarly titled part shall have a charge nurse who is a registered professional nurse qualified in psychiatric or mental health nursing.

**ST - H0243 - REHAB, PSYCH & SUBST ABUSE - Pt Rights**

**Title** REHAB, PSYCH & SUBST ABUSE - Pt Rights

**Type** Rule

395.003(5)(a)-(b), FS

**Regulation Definition**

(5)(a) Adherence to patient rights, standards of care, and examination and placement procedures provided under part I of chapter 394 shall be a condition of licensure for hospitals providing voluntary or involuntary medical or psychiatric observation, evaluation, diagnosis, or treatment.

(b) Any hospital that provides psychiatric treatment to persons under 18 years of age who have emotional disturbances shall comply with the procedures pertaining to the rights of patients prescribed in part I of chapter 394.

**Interpretive Guideline**

- Observe the patients on the unit; does it appear that the facility is honoring the patients' rights?
- Interview patients on this unit, are there any concerns regarding patients' rights voiced by the patients?
- Review patients' records for facility's failure to honor patient's rights
- Interview staff regarding any concerns regarding patients' rights.
- Review the facilities grievance log; has anyone filed a grievance regarding the facility's failure to honor patients' rights?
- Review the facility's P&P regarding patient's rights. Is there provision for any person under the age of 18 being admitted to the facility?
- For patient's rights concerns, refer to Baker Act tags in this reg set.

**ST - H0244 - REHAB, PSYCH & SUBST ABUSE-Specialty Supv/Adm**

**Title** REHAB, PSYCH & SUBST ABUSE-Specialty Supv/Adm

**Type** Rule

59A-3.278(9), FAC

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 175 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(9) In addition to the medical direction required in subsection (7), overall supervision and administration of the following specialty rehabilitation programs may be provided by staff with the following credentials:

(a) Physical Therapy - A qualified physical therapist who shall be a graduate of a physical therapy program approved by a nationally recognized accrediting body or have documented equivalent training or experience, shall meet any current requirements for licensure or registration, and shall be currently competent in the field.

(b) Occupational Therapy - A qualified occupational therapist who shall be a graduate of an occupational therapy program approved by a nationally recognized accrediting body; or shall currently hold certification by the American Occupational Therapy Association as an Occupational Therapist, Registered; or shall have documented equivalent training or experience; and shall meet all current requirements for licensure under chapter 468, part IV, F.S.

(c) Speech Pathology and Audiology - A qualified speech-language pathologist or audiologist who shall hold the Certificate of Clinical Competence or a Statement of Equivalence in either speech pathology or audiology issued by the American Speech-Language-Hearing Association, or have documented equivalent training or experience; and shall meet all current requirements for licensure under chapter 468, part II, F.S.

(d) Rehabilitation Nursing - A professionally qualified licensed registered nurse who shall have documented training in rehabilitation nursing and at least one year of rehabilitation nursing experience.

(e) Vocational or Educational Rehabilitation - A qualified individual who shall be a graduate of vocational rehabilitation program at the graduate level, or have documented equivalent training or experience.

(f) Comprehensive Medical Rehabilitation - A qualified

**Interpretive Guideline**

- Observe the unit, what specialty services are provided?
- Review current and recently discharged patient records for these specialty services within the unit.
- If services have been provided, review personnel files for required documentation based on rule.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 176 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

physician who shall be a member of the organized professional staff and who is certified, or eligible for examination, either by the American Board of Physical Medicine and Rehabilitation or by a specialty related to rehabilitation.

**ST - H0245 - REHAB, PSYCH & SUBST ABUSE - CON**

**Title** REHAB, PSYCH & SUBST ABUSE - CON

**Type** Rule

59A-3.278(10), FAC

**Regulation Definition**

(10) Nothing in this section shall be construed to prevent a hospital from providing rehabilitation, psychiatric or substance abuse programs to its patients. However, no hospital shall have rehabilitation, psychiatric, intensive residential treatment program, or substance abuse beds unless it has obtained a valid certificate of need as required by section 408.031 through 408.045, F.S., and meets the requirements of this section.

**Interpretive Guideline**

- Review the hospital license for services/programs provided.
- If rehab, psych. intensive residential treatment and substance abuse are not listed but are provided, ask administrator for certificate of need.
- If facility does not have a certificate of need and services are being provided, contact field office for additional direction.

**ST - H0252 - INTENSIVE RES TX PROG - Composition of Staff**

**Title** INTENSIVE RES TX PROG - Composition of Staff

**Type** Rule

59A-3.302(1), FAC

**Regulation Definition**

(1) Composition. The composition of the staff shall be determined by the needs of the patients being served and the goals of the facility, and shall have available a sufficient number of mental health professionals, health care workers,

**Interpretive Guideline**

- Review the facility's Staffing Policy and Procedures. Does the facility staff the unit based on the number of patients or by the acuity of the patients on the unit.
- Observe the unit to determine if the staff is answering the call lights in a timely manner. Are the patients' needs being met?



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 177 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

program staff and administrative personnel to meet these goals.

- Review the facility's staffing schedule
- Interview the staff and administration about meeting the patients' needs.
- Interview the patients; are their needs being met?

**ST - H0253 - INTENSIVE RES TX PROG - Staff Qualifications**

**Title** INTENSIVE RES TX PROG - Staff Qualifications

**Type** Rule

59A-3.302(1)(a)-(f), FAC

**Regulation Definition**

- (a) The administrator of the facility shall have a master's degree in administration or be of a professional discipline related to child and adolescent mental health and have at least three (3) years administrative experience. A person with a baccalaureate degree may also qualify for administrator with seven (7) years experience of child and adolescent mental health care with no less than three (3) years administrative experience.
- (b) The clinical director shall be at least board eligible in psychiatry with the American Board of Psychiatry with experience in child and adolescent mental health.
- (c) If the clinical director is not full-time, then there shall be a full-time service coordinator who is a mental health professional with at least a master's degree who is experienced in child and adolescent mental health and is responsible for the coordination of treatment aspects of the program.
- (d) Mental health professionals shall include psychiatrists, psychologists, and social workers. These persons, if not on a full-time basis, must be on a continuing consulting basis. The authority and participation of such mental health professionals shall be such that they are able to assume responsibility for supervising and reviewing the needs of the patients and the services being provided. Such individuals shall participate in specific functions, e.g., assessment, treatment planning,

**Interpretive Guideline**

- Review a sample of staff records for the different staff listed in the rule and credentials are up-to-date
- Review the schedule for any requirement of staff including consultants for requirements in the rule.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 178 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

treatment plan and individual case reviews, and program planning and policy and procedure development and review.

(e) Other professional and paraprofessional staff shall include physicians, registered nurses, educators and 24-hour a day mental assistants. Also included on a regular staff basis, or as consultants on a continuing basis, shall be activity staff and vocational counselors; and,

(f) Consultation shall be available as needed from dietitians, speech, hearing and language specialists, or other specialists.

**ST - H0254 - INTENSIVE RES TX PROG -Organization/Personnel**

**Title** INTENSIVE RES TX PROG -Organization/Personnel

**Type** Rule

59A-3.302(2)-(4), FAC

**Regulation Definition**

(2) Organization. The program shall have an organizational plan which clearly explains the responsibilities of the staff.

This plan shall also include:

- (a) Lines of authority, accountability and communication;
- (b) Committee structure and reporting or dissemination of material; and,
- (c) Established requirements regarding the frequency of attendance at general and departmental/service or team/unit meetings.

(3) Policies and Records. Personnel policies and practices shall be designed, established and maintained to promote the objectives of the program and to insure that there are personnel to support a high quality of patient care.

- (a) Each program shall have a written personnel practice plan covering the following areas: job classification; pay plan; personnel selection; probation or work-test period; tenure of office; dismissal; salary increases; procedure for health

**Interpretive Guideline**

- Review the facility's organization plan. Does it include the required information?
- Review sample of personnel files for compliance with requirement in rule.
- Review any policy and procedures regarding updates and changes to personnel requirements. Interview a few employees and see how they are notified of changes in the facility's policies.
- Interview the person responsible for education and see how often the training programs/plans are reviewed, approved, implemented and documented.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 179 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

evaluations; holidays; leave policies; training programs; work evaluation procedures; additional employment benefits; and personnel records. Each new employee shall be given a copy of personnel practices when hired and documentation of receipt shall be maintained in the employee's personnel file. A procedure shall be established for notifying employees of changes in established policies.

(b) There shall be clear job descriptions for all personnel. Each description shall contain the position title, immediate supervisor, responsibilities and authority. These shall also be used as a basis for periodic evaluations by the supervisor.

(c) Accurate and complete personnel records shall be maintained on each employee. Content shall be established to include the following:

1. Current background information, including the application, references and any accompanying documentation sufficient to justify the initial and continued employment of the individual and the position for which he was employed. Applicants for the positions requiring a licensed person shall be employed only after the facility has obtained verification of their licenses. Where accreditation is a requirement, this shall also be verified. Evidence of renewal of license as required by the licensing agent shall be maintained in the employee's personnel record;
2. Current information relative to work performance evaluation;
3. Records of pre-employment health examinations and subsequent health services rendered to employees, as are necessary to ensure that all facility employees are physically and emotionally able to perform their duties;
4. Medical reports that verify the absence of active communicable disease in facility employees; and,
5. Record of any continuing education or staff development programs completed.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 180 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(4) Staff Development. The program must provide opportunities and motivation for continuing education or training to enable each member to add to his knowledge and skills and thus improve the quality of services offered. This must be documented in the employee personnel file. Programs shall be facility-based with a designated person or committee who is responsible, on a continuing basis, for planning and insuring that Plans are implemented. The facility shall also make use of educational programs outside the facility such as workshops, and seminars.

**ST - H0255 - INTENSIVE RES TX PROG-Therapeutic Environment**

**Title** INTENSIVE RES TX PROG-Therapeutic Environment

**Type** Rule

59A-3.303(1), FAC

**Regulation Definition**

(1) General Requirements. The facility shall plan and provide an environment that is therapeutic to, and supportive of, all the patients in regard to their disturbances, their healthy development and their changing needs. The therapeutic environment shall take into consideration the architecture of the facility, indoor and outdoor activity areas, furnishings, equipment, decorations and all other factors that involve the interpersonal and physical environment.

**Interpretive Guideline**

- Tour the unit to ensure there is a therapeutic environment.

**ST - H0256 - INTENSIVE RES TX PROG - Physical Plant Safety**

**Title** INTENSIVE RES TX PROG - Physical Plant Safety

**Type** Rule

59A-3.303(2), FAC

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 181 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(2) Facilities shall:

- (a) Be designed to meet the needs of the age group of the patients and the objectives of the program;
- (b) Provide adequate and appropriate space and equipment for all of the programs of the facility and the various functions within the facility;
- (c) Provide sufficient space and equipment to ensure housekeeping and maintenance programs capable of keeping the building and equipment clean and in good repair; and,
- (d) Provide buildings and grounds of the special hospital that shall be maintained, repaired and cleaned so that they are not hazardous to the health and safety of the patients and staff.
  - 1. Floors, walls, ceilings, windows, doors and all appurtenances of the structures shall be of sound construction, properly maintained, easily cleanable and shall be kept clean.
  - 2. All areas of the facility other than closets or cabinets shall be well lighted. Dormitories, toilets and dayrooms shall have light sources capable of providing adequate illumination to permit observation, cleaning, maintenance and reading. Light fixtures shall be kept clean and maintained.
  - 3. All housing facilities shall be kept free of offensive odors with adequate ventilation.
    - a. If natural ventilation is utilized, the opened window area for ventilation purposes shall be equal to one-tenth of the floor space in the residential area.
    - b. When mechanical ventilation or cooling systems are employed, the system shall be kept clean and properly maintained. Intake air ducts shall be designed and installed so that dust or filters can be readily removed. In residence areas and isolation rooms without natural ventilation, mechanical ventilation systems shall provide a minimum of 10 cubic feet of fresh or filtered recirculated air per minute for each patient occupying the area.
    - c. All toilet rooms shall be provided with direct openings to the outside or provided with mechanical ventilation to the

**Interpretive Guideline**

- Tour the unit/hospital to ensure items a-k are being met.
- Interview the housekeeping staff and maintenance director about items a-k.
- Interview sample patients/residents; do they have enough space/privacy on the units/hospital?
- Review the facility's maintenance policies and procedures for items a-k.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 182 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

outside.

d. Facilities which utilize permanent heating units shall maintain a minimum temperature of 65 degrees F at a point 20 inches above the floor in sleeping areas. Facilities, such as outdoor programs, which cannot provide permanent heating units, shall ensure that patients are provided with items which will provide adequate warmth during sleep. These shall include items such as portable catalytic heaters and sleeping bags, extra blankets and clothing designed to ensure comfortable sleep in cold weather.

(e) Provide both indoor and outdoor areas where patients can gather for appropriate activities. The grounds on which the facility is located shall provide adequate space to carry out the stated goals of the program; for outdoor activity areas that are appropriate for the ages and clinical needs of children; and provide an appropriate transitional area between the facility and the surrounding neighborhood which is consistent with the goals of the facility, and compatible with existing zoning ordinances.

(f) Provide sleeping areas that shall promote comfort and dignity and provide space and privacy for residents.

1. There shall be no more than eight patients in a sleeping room unless written justification on the basis of the program requirements has been submitted to and approved by the licensing agency.

2. Beddings, Clothing and Personal Items. Beds and beddings shall be kept in good repair and cleaned regularly. Used mattress and pillow covers shall be laundered before being issued. Sheets and personal clothing shall be washed at least weekly and blankets washed or dry cleaned at least quarterly. Sheets and blankets shall be stored in a clean, dry place between laundering and issue.

3. Each patient shall have his own bed consisting of a level bedstead and a clean mattress in good condition.

4. All mattresses shall have fire retardant mattress covers or

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 183 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

protectors. Water repellent mattress covers shall be available if needed.

(g) Provide individual and separate accessible storage areas for each resident's clothing and personal possessions.

(h) Provide laundry and/or dry cleaning facilities. Where laundry facilities are provided, they shall be adequate to ensure an ample quantity of clean clothing, bed linens and towels. Laundry facilities shall be of sound construction and shall be kept clean and in good repair. Laundry rooms shall be well lighted and properly ventilated. Clothes dryers and dry cleaning machines shall be vented to the exterior. If laundry facilities are not available, sheets and blankets shall be sent to commercial laundries.

(i) Provide privacy for personal hygiene.

1. All toilets shall have secured seats and be kept clean and in good working order, and all toilets shall be partitioned for privacy.

2. Bathrooms shall be cleaned thoroughly each day.

3. Bathrooms shall be conveniently located to the sleeping areas.

(j) Provide for the personal hygiene for all patients.

1. A written policy shall be maintained on file at the facility.

2. Toothbrushes, toothpaste, soap, and other items of personal hygiene shall be provided by the facility if not provided by the patients.

3. Shatterproof mirrors shall be furnished in each bathroom.

(k) Maintain food service facilities in accordance with the regulations described in chapter 64E-11, F.A.C.

**ST - H0257 - INTENSIVE RES TX PROG - Construction/Maintena**

**Title** INTENSIVE RES TX PROG - Construction/Maintena

**Type** Rule

59A-3.303(3), FAC

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 184 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(3) The facility shall be constructed and maintained in a manner that protects the lives and insures the physical safety of patients, staff and visitors. The center will comply with all relevant federal, state and local building codes, fire, health, safety laws and ordinances and regulations as specified below. Current inspection reports shall be retained in the facility's files for Agency review.

(a) It is the responsibility of the program to arrange for the necessary inspections and to comply within the time frame with any resulting recommendations noted in the inspection reports.

(b) The grounds and all buildings on the grounds shall be maintained in a safe and sanitary condition, as required in Chapter 386, F.S. (Particular Conditions Affecting Public Health).

(c) Water Supply. Water supplies shall be adequate to serve the demands of the facility and shall be constructed, operated and maintained in accordance with requirements of chapter 64E-8, F.A.C.

1. Drinking water shall be accessible to all clients. When drinking fountains are available, the jet of the fountain shall issue from a nozzle of non-oxidizing impervious material set at an angle from the vertical. The nozzle and every other opening in the water pipe or conductor leading to the nozzle shall be above the edge of the bowl so that such nozzle or opening will not be flooded in case a drain from the bowl of the fountain becomes clogged. The end of the nozzle shall be protected by non-oxidizing guards to prevent persons using the fountain from coming into contact with the nozzle. Vertical or bubbler drinking fountains shall be replaced with approved type water fountains or be disconnected. When no approved drinking fountains are available, clients shall be provided with single service cups which shall be stored and dispensed in a manner to prevent contamination. Common drinking cups are prohibited.

**Interpretive Guideline**

- Tour facility and observe for items a-g.
- Interview the follow people about items a-g as appropriate.
  - Staff
  - Patients/residents
  - Administrator/Clinical Director
  - maintenance
- Review any related policy and procedure to ensure compliance.
- If concerns are observed, surveyor may consult with field office or Life Safety Code surveyor.



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 185 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

2. Hot and cold running water under pressure and at safe temperatures (not to exceed 120 degrees F for washing and bathing to prevent scalding) shall be provided at regular washing and bathing areas.

(d) Sanitary System, Facilities and Fixtures.

1. All sewage and liquid waste shall be disposed of in accordance with chapter 64E-6, F.A.C.

2. All plumbing shall be in compliance with the requirements of the Florida Building Code, Plumbing as adopted by the Florida Building Commission and described in rule chapter 61G20-1, F.A.C., or the plumbing code legally applicable to the area where the facility is located.

3. For facilities with nine or more patients, curbed areas with floor drains shall be available in convenient locations throughout the facility for the proper disposal of cleaning water and to facilitate cleaning.

(e) Garbage and Rubbish. All garbage, trash and rubbish from residential areas shall be collected daily and taken to storage facilities. Garbage shall be removed from storage facilities at least twice per week. Wet garbage shall be collected and stored in impervious, leak proof, fly tight containers pending disposal. All containers, storage areas and surrounding premises shall be kept clean and free of vermin. If public or contract garbage collection service is available, the facility shall subscribe to these services unless the volume makes on-site disposal feasible. If garbage and trash are disposed on premises, the method of disposal shall not create sanitary nuisance conditions and shall comply with provisions of rule 64E-12.010, F.A.C.

(f) Outdoor Areas. Outdoor areas shall be kept free of litter and trash and be well drained. If swimming pools are available in facilities with nine or more clients, such pools shall comply with requirements of chapter 64E-9, F.A.C., and shall be supervised at all times when they are in use. Indoor and outdoor recreational areas shall be provided with safeguards

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 186 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

designed for the needs of the residents.

(g) Insect and Rodent Control. Facilities shall be kept free of all insects and rodents. All outside openings shall be effectively sealed or screened to prevent entry of insects or rodents. All pesticides used to control insects or rodents shall be applied in accordance with instructions on the registered product label. Persons applying restricted use pesticides shall be certified by the Department of Agriculture. Facilities not having certified pest control operators shall utilize commercial licensed pest control companies.

**ST - H0258 - INTENSIVE RES TX PROG - Fire Safety**

**Title** INTENSIVE RES TX PROG - Fire Safety

**Type** Rule

59A-3.303(4)-(5), FAC

**Regulation Definition**

- (4) All facilities shall be required to meet the uniform fire safety standards for special hospitals as established by the State Fire Marshal pursuant to section 633.206, F.S.
- (a) All staff shall be instructed in the use of fire extinguishers.
- (b) All fire extinguishers shall be inspected as regulated by local requirements and shall be serviced as required.
- (c) All fire safety systems shall be kept in good operating condition.
- (d) Fire safety systems shall be inspected regularly as regulated by local requirements, and records of such inspections shall be kept on file.
- (5) The special hospital shall provide for safety inspections by a facility personnel committee.
- (a) Personnel responsible for safety evaluation shall receive appropriate training.
- (b) Safety inspections shall be done on a monthly basis, shall

**Interpretive Guideline**

- Tour facility for items 4-5.
  - Review policy and procedures related to fire safety.
- Refer any concerns to life safety.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 187 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

be made into a written report, and shall be maintained on file at the facility.

(c) Special safety measures shall be provided for areas of the facility that may present an unusual hazard to patients, staff or visitors. Poisonous or toxic compounds are to be stored apart from food and other areas that would constitute a hazard to the residents.

**ST - H0260 - INTENSIVE RES TX PROG - Intake & Admission**

**Title** INTENSIVE RES TX PROG - Intake & Admission

**Type** Rule

59A-3.310(1)(a)-(g), FAC

**Regulation Definition**

Services shall be designed to meet the needs of the emotionally disturbed patient and must conform to stated purposes and objectives of the program.

(1) Intake and Admission. Every IRTF shall develop written policies and procedures governing the facilities intake and admissions process.

(a) Acceptance of a child or adolescent for inpatient treatment shall be based on the assessment, arrived at by the multidisciplinary clinical staff involved and clearly explained to the patient and the family. Whether the family voluntarily requests services or the patient is referred by the court, the special hospital shall involve the family's participation to the fullest extent possible. Discharge planning shall begin at the time of intake and admission.

(b) Acceptance of the child or adolescent for treatment shall be based on the determination that the child or adolescent requires treatment of a comprehensive and intensive nature and is likely to benefit by the programs that the facility has to offer.

(c) Admission shall be in keeping with stated policies of the

**Interpretive Guideline**

- Tour the facility observing any items a-g available to you.
- Review policy and procedures relating to items a-g.
- Interview staff at all levels for clarification and understanding of items a-g.
- Review a sample of current and discharged patients' records for compliance with a-g.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 188 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

special hospital and shall be limited to those patients for whom the special hospital is qualified by staff, program and equipment to give adequate care.

(d) Staff members who will be working with the patient, but who did not participate in the initial assessment shall be oriented regarding the patient and the patient's anticipated admission prior to meeting the patient. When the patient is to be assigned to a group, the other patients in the group shall be prepared for the arrival of the new member. There shall be a specific staff member assigned to the new patient to observe him and help with the unit orientation period.

(e) The admission procedure shall include documentation concerning:

1. Responsibility for and amount of financial support;
2. Responsibility for medical and dental care, including consent for medical and surgical care and treatment;
3. Arrangements for appropriate family participation in the program, phone calls and visits when indicated;
4. Arrangements for clothing, allowances and gifts; and
5. Arrangements regarding the patient's leaving the facility with or without medical consent.

(f) Decisions for admission shall be based on the initial assessment of the patient made by the appropriate multidisciplinary clinical staff. This assessment must be documented on the record of treatment on admission.

(g) The admission order must be written by a staff or consultant physician.

**ST - H0268 - INTENSIVE RES TX PROG - Pharmaceutical Svcs**

**Title** INTENSIVE RES TX PROG - Pharmaceutical Svcs

**Type** Rule

59A-3.310(7) FAC

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 189 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(7) Pharmaceutical Services. Pharmaceutical services, if provided, shall be maintained and delivered as described in the applicable sections of chapters 465 and 893, F.S.

**Interpretive Guideline**

- During facility tour, observe for the proper storage of medication on the unit. Are all medications kept secure?
- Observe medication pass to ensure proper delivery of medication.
- Interview clinical director/administrator on how pharmaceutical services are monitored for compliance with requirements.

**ST - H0269 - INTENSIVE RES TX PROG - Lab & Path Svcs**

**Title** INTENSIVE RES TX PROG - Lab & Path Svcs

**Type** Rule

59A-3.310(8), FAC

**Regulation Definition**

(8) Laboratory and Pathology Services.  
(a) The facility shall provide clinical and pathology services within the institution, or by contractual arrangement with a laboratory commensurate with the facility's needs and which is registered under the provisions of chapter 483, F.S.  
1. Provision shall be made for the availability of emergency laboratory services 24 hours a day, 7 days a week, including holidays.  
2. All laboratory tests shall be ordered by a licensed practitioner in accordance with section 483.041(7), F.S.  
3. All laboratory reports shall be filed in the patient's medical record.  
4. The facility shall have written policies and procedures governing the collection, preservation and transportation of specimens to assure adequate stability of specimens.  
(b) Where the facility depends on an outside laboratory for services, there shall be a written contract detailing the conditions, procedures and availability of work performed. The contract shall be reviewed and approved by the medical staff, administrator and the governing board.

**Interpretive Guideline**

- Interview appropriate staff for items a-b.
- Review the governing board minutes, policies and procedures and contracts, as needed for items a-b.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 190 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0270 - INTENSIVE RES TX PROG - Patient Rights**

**Title** INTENSIVE RES TX PROG - Patient Rights

**Type** Rule

59A-3.310(9)(a)-(b)1-5, FAC

**Regulation Definition**

(9) Patients' Rights. Every effort shall be made to safeguard the legal and civil rights of patients and to make certain that they are kept informed of their rights, including the right to legal counsel and all other requirements of due process.

(a) Individual dignity and human rights are guaranteed to all clients of mental health facilities in Florida by the Florida Mental Health Act, known as the "Baker Act," chapter 394, F.S.

(b) Each facility shall be administered in a manner that protects the client's rights, his life, and his physical safety while under treatment.

1. The special hospital's space and furnishings should be designed and planned to enable the staff to respect the patient's right to privacy and, at the same time, provide adequate supervision according to the development and clinical needs of the patients. Provisions for an individual patient's rights regarding privacy shall be made explicit to the patient and family. A written policy concerning patient's rights shall be provided to the patient of authentic research or studies, or innovations of client's record.

2. The special hospital center's policies shall allow patient visitation and communication with all members of the family and other visitors as clinically indicated and when such visits are consistent with the facility's program. When therapeutic considerations recommended by the responsible licensed psychologist or physician necessitate restriction of communication or visits, as set forth in the programs policies

**Interpretive Guideline**

- During tour of the facility, observe for items a-b being met.
- Interview all levels of staff for compliance with and for clarification/understanding of items a-b - Interview the patient/family regarding items a-b.
- Review the facility's policy and procedure regarding residents' rights.
- Review the facility's Admission packet. Are the facility's visiting hours, residents' rights, any restrictions, correspondence, and telephone use addressed in the admissions packet?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 191 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

and procedures, these restrictions shall be evaluated at least weekly by the clinical staff for their continuing effectiveness. These restrictions shall be documented and signed by the responsible psychologist or physician and be placed in the patient's record. The special hospital shall make known to the patient, the family and referring agency its policies regarding visiting privileges on and off the premises, correspondence and telephone calls. These policies shall be stated in writing and shall be provided to the patient and family and updated when change in policy occurs. When limitations on such visits, calls or other communications are indicated by practical reason, e.g., the expense of travel or telephone calls, such limitations shall be determined with participation of the patient's family or guardian.

3. Patients shall be allowed to request an attorney through their parents or guardians. This shall be established as written policy, and the policy shall be provided to families and patients.

4. Patient's opinions and recommendations shall be considered in the development and continued evaluation of the therapeutic program. The special hospital shall have written policies to carry out appropriate procedures for receiving and responding to patient communications concerning the total program.

5. The special hospital shall have written policies regarding methods used for control of patients' behavior. Such written policies shall be provided to the appropriate staff and to the patient and his family. Only staff members responsible for the care and treatment of patients shall be allowed to handle discipline. Patients shall not be subject to cruel, severe, unusual or unnecessary punishment. Patients shall not be subjected to remarks which ridicule them or their families, or others.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 192 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0271 - INTENSIVE RES TX PROG-Restraint/Seclusion/Oth**

**Title** INTENSIVE RES TX PROG-Restraint/Seclusion/Oth

**Type** Rule

59A-3.310(9)(b)6-10, F.A.C.

**Regulation Definition**

(9)(b) Each facility shall be administered in a manner that protects the client's rights, his life, and his physical safety while under treatment.

6. Protective restraint consists of any apparatus or condition which interferes with the free movement of the patient. Only in an emergency shall physical holding be employed unless there are physician's orders for a mechanical restraint. Physical holding or mechanical restraints, such as canvas jackets or cuffs, shall be used only when necessary to protect the patient from injury to himself or others. Use of mechanical restraints reflect a psychiatric emergency and must be ordered by the responsible staff/consultant physician, be administered by trained staff and be documented in the patient's clinical records. The need for the type of restraint used and the length of time it was employed and condition of the patient shall be recorded in the patient's record. An order for a mechanical restraint shall designate the type of restraint to be used, the circumstance under which it is to be used and the duration of its use. A patient in a mechanical restraint shall have access to a staff member at all times during the period of restraint.

7. The facility shall have written policies and procedures which govern the use of seclusion. The use of seclusion shall require clinical justification and shall be employed only to prevent a patient from injuring himself or others, or to prevent serious disruption of the therapeutic environment. Seclusion shall not be employed as punishment or for the convenience of staff. A written order from a physician shall be required for the

**Interpretive Guideline**

- During tour of the facility, observe for items 6-10 being met.
- Interview all levels of staff for compliance with and for clarification/understanding of items 6-10
- Interview the patient/family regarding items 6-10.
- Review the facility's policy and procedure regarding restraints/seclusion.
  
- Review sample patient records for written orders as states in 6-10.



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 193 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

use of seclusion for longer than one hour. Written orders for seclusion shall be limited to twenty-four (24) hours. The written approval of the medical director or the director of psychiatrist services shall be required when seclusion is utilized for more than twenty-four (24) hours. Staff who implement written orders for seclusion shall have documented training in the proper use of the procedures. Appropriate staff shall observe and visually monitor the patient in seclusion every fifteen (15) minutes, documenting the patient's condition and identifying the time of observation. A log shall be maintained which will record on a quarter- hour basis the observation of the patient in seclusion, and will also indicate when the patient was taken to the bathroom, when and where meals were served, when other professional staff visited, etc., and shall be signed by the observer. The need or reason for seclusion shall be made clear to the patient and shall be recorded in the patient's clinical record. The length of time in seclusion shall also be recorded in the clinical record, as well as the condition of the patient. A continuing log shall be maintained by the facility that will indicate by name the patients placed in seclusion, date, time, specified reason for seclusion and length of time in seclusion. In an emergency, orders may be given by a physician over the telephone to a registered professional nurse. Telephone orders must be reviewed within twenty-four (24) hours by the director of psychiatric services.

8. The special hospital shall not exploit a patient or require a patient to make public statements to acknowledge his gratitude to the treatment center.

9. Patients shall not be required to perform at public gatherings.

10. The special hospital shall not use identifiable patients' pictures without written consent. The signed consent form shall be on file at the facility before any such pictures are used. A signed consent form must indicate how pictures shall be used and a copy shall be placed in the patient's clinical record.

**Agency for Health Care Administration  
ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 194 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0272 - INTENSIVE RES TX PROG - Clinical Record Std**

**Title** INTENSIVE RES TX PROG - Clinical Record Std

**Type** Rule

59A-3.310(10)(a)-(b), FAC

**Regulation Definition**

(10) Records. The form and detail of the clinical records may vary but shall minimally conform to the following standards :

(a) Content. All clinical records shall contain all pertinent clinical information and each record shall include:

1. Identification data and consent forms; when these are not obtainable, reason shall be noted;
2. Source of referral;
3. Reason for referral, example, chief complaint, presenting problem;
4. Record of the complete assessment;
5. Initial formulation and diagnosis based upon the assessment;
6. Written treatment plan;
7. Medication history and record of all medications prescribed;
8. Record of all medication administered by facility staff, including type of medication, dosages, frequency of administration, persons who administered each dose, and route of administration;
9. Documentation of course of treatment and all evaluations and examinations, including those from other facilities, for example, emergency rooms or general hospitals;
10. Periodic treatment summaries; updated at least every 90 days;
11. All consultation reports;
12. All other appropriate information obtained from outside sources pertaining to the patient;

**Interpretive Guideline**

- Select a few records of patients in order to ensure the items a(1-14) and b are in the file.
- Interview staff about compliance with implementation of a-b and for clarification of missing information in record.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 195 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

13. Discharge or termination summary report; and,  
14. Plans for follow-up and documentation of its implementation.

(b) Identification data and consent form shall include the patient's name, address, home telephone number, date of birth, sex, next of kin, school and what grade, date of initial contact or admission to the program, legal status and legal document, and other identifying data as indicated.

**ST - H0273 - INTENSIVE RES TX PROG - Progress Notes**

**Title** INTENSIVE RES TX PROG - Progress Notes

**Type** Rule

59A-3.310(10)(c) FAC

**Regulation Definition**

(10) Records. The form and detail of the clinical records may vary but shall minimally conform to the following standards :

(c) Progress Notes. Progress notes shall include regular notations at least weekly by staff members, consultation reports and signed entries by authorized identified staff.

Progress notes by the clinical staff shall:

1. Document a chronological picture of the patient's clinical course;
2. Document all treatment rendered to the patient;
3. Document the implementation of the treatment plan;
4. Describe each change in each of the patient's conditions;
5. Describe responses to and outcome of treatment; and,
6. Describe the responses of the patient and the family or significant others to significant inter-current events.

**Interpretive Guideline**

Reviewing patients' records to ensure Progress Notes have regular notations and include items 1-6.

**Agency for Health Care Administration  
ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 196 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0274 - INTENSIVE RES TX PROG - Discharge Summary**

**Title** INTENSIVE RES TX PROG - Discharge Summary

**Type** Rule

59A-3.310(10)(d) FAC

**Regulation Definition**

(10) Records. The form and detail of the clinical records may vary but shall minimally conform to the following standards :

(d) Discharge Summary. The discharge summary shall include the initial formulation and diagnosis, clinical resume, final formulation and final primary and secondary diagnoses, the psychiatric and physical categories. The final formulation shall reflect the general observations and understanding of the patient's condition during appraisal of the fundamental needs of the patients. Records of discharged patients shall be completed following discharge within a reasonable length of time, and not to exceed 15 days. In the event of death, a summation statement shall be added to the record either as a final progress note or as a separate resume. This final note shall take the form of a discharge summary and shall include circumstances leading to death. All discharge summaries must be signed by a staff or consultant physician.

**Interpretive Guideline**

Select some closed records for review. Ensure there is a discharge summary diagnosis; The discharge has occurred within 15 days and the discharge summary has been signed by a staff or consultant physician.

**ST - H0275 - INTENSIVE RES TX PROG-Recording/Documentation**

**Title** INTENSIVE RES TX PROG-Recording/Documentation

**Type** Rule

59A-3.310(10)(e) FAC

**Regulation Definition**

(10) Records. The form and detail of the clinical records may

**Interpretive Guideline**

- Review patients' records ensure all symbols/abbreviations have been approved by the clinical staff.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 197 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

vary but shall minimally conform to the following standards:  
(e) Recording. Entries in the clinical records shall be made by staff having pertinent information regarding the patient, consistent with the facility policies, and authors shall fully sign and date each entry. When mental health trainees are involved in patient care, documented evidence shall be in the clinical records to substantiate the active participation of supervisory clinical staff. Symbols and abbreviations shall be used only when they have been approved by the clinical staff and when there is an explanatory notation. Final diagnosis, both psychiatric and physical, shall be recorded in full, and without the use of either symbols or abbreviations.

- Review closed records ensure there is a final psychiatric and physical diagnosis recorded. In reviewing open and close records, are all orders and entries dated and timed?
- Review the facility's policies and procedures. Do the records' entries abide by the facility's own policies and procedures.

**ST - H0276 - INTENSIVE RES TX PROG - Records P&P**

**Title** INTENSIVE RES TX PROG - Records P&P

**Type** Rule

59A-3.310(10)(f)-(g) FAC

**Regulation Definition**

(10) Records. The form and detail of the clinical records may vary but shall minimally conform to the following standards:  
(f) Policies and Procedures. The facility shall have written policies and procedures regarding clinical records which shall provide that:

1. Clinical records shall be confidential, current and accurate;
2. The clinical record is the property of the facility and is maintained for the benefit of the patient, the staff and the facility;
3. The facility is responsible for safeguarding the information in the record against loss, defacement, tampering or use by unauthorized persons;
4. The facility shall protect the confidentiality of clinical information and communication between staff members and patients;

**Interpretive Guideline**

- Review the facility's confidentiality policy and procedure to ensure they include items f-g
- Interview appropriate staff for items f-g.
- Review employees' records. Is there evidence of new employee and continued training in patient confidentiality? Interview the person responsible for training. When are new employees trained in patient confidentiality? How often does training occur for current staff?
- Observe where the patients' records are being stored. Are the records safeguarded or left open for others to see.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

*Printed 08/07/2024*

Page 198 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

5. Except as required by law, the written consent of the patient, family, or other legally responsible parties, is required for the release of clinical record information;
6. Records may be removed from the facility's jurisdiction and safekeeping only according to the policies of the facility or as required by law; and,
7. That all staff shall receive training, as part of new staff orientation and with periodic update, regarding the effective maintenance of confidentiality of the clinical record. It shall be emphasized that confidentiality refers as well to discussions regarding patients inside and outside the facility. Verbal confidentiality shall be discussed as part of all employee training.

(g) Maintenance of Records. Each facility shall provide for a master filing system which shall include a comprehensive record on each patient's involvement in every program aspect.

1. Appropriate records shall be kept on the unit where the patient is being treated or be directly and readily accessible to the clinical staff caring for the patient;
2. The facility shall maintain a system of identification and coding to facilitate the prompt location of the patient's clinical records;
3. There shall be policies regarding the permanent storage, disposal or destruction of the clinical records of disclosure of confidential information later in life;
4. The clinical record services required by the facilities shall be directed, staffed and equipped to facilitate the accurate processing, checking, indexing, filing, retrieval and review of all clinical records. The clinical records service shall be the responsibility of an individual who has demonstrated competence and training or experience in clinical record administrative work. Other personnel shall be employed as needed, in order to effect the functions assigned to the clinical record services;

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 199 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

5. There shall be adequate space, equipment and supplies, compatible with the needs of the clinical record service, to enable the personnel to function effectively and to maintain clinical records so that they are readily accessible.

**ST - H0278 - INTENSIVE RES TX PROG -Eval/Indiv Case Review**

**Title** INTENSIVE RES TX PROG -Eval/Indiv Case Review

**Type** Rule

59A-3.310(11), FAC

**Regulation Definition**

(11) Program and Patient Evaluation. The staff shall work towards enhancing the quality of patient care through specified, documented, implemented and ongoing the designing professions having as their purpose processes of clinical care evaluation studies and utilization review mechanisms.

(a) Individual Case Review.

1. There shall be regular staff meetings or unit meetings to review and monitor the progress of the individual child or adolescent patient. Each patient's case shall be reviewed within a month after admission and at least monthly during residential treatment. This shall be documented. This meeting may also be used for review and revision of treatment plans.

2. The facility shall provide for a follow-up review on each discharged patient to determine effectiveness of treatment and disposition.

(b) Program Evaluation.

1. Clinical Care Evaluation Studies. There shall be evidence of ongoing studies to define standards of care consistent with the goals of the program effectiveness of the program, and to identify gaps and inefficiencies in service. Evaluation shall include follow-up studies. Studies shall consist of the following elements:

**Interpretive Guideline**

- Interview staff as needed to address items a-b.
- Review any supporting documentation related to evaluations as listed in items a-b.
- Review facility documentation/policy and procedures for Utilization Review meetings or clinical records.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 200 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

- a. Selection of an appropriate design;
  - b. Specification of information to be included;
  - c. Collection of data;
  - d. An analysis of data with conclusions and recommendations;
  - e. Transmissions of findings; and,
  - f. Follow-up on recommendations.
2. Utilization Review. Each facility shall have a plan for and carry out utilization review. The review shall cover the appropriateness of admission to services, the provision of certain patterns of services, and duration of services. There shall be documentation of utilization review meetings either in minutes or in individual clinical records. The improvement of patient care, shall receive special consideration following a request and documentation of the proposed project by the individual sponsor.

**ST - H0281 - INTENSIVE RES TX PROG - Assessment**

**Title** INTENSIVE RES TX PROG - Assessment

**Type** Rule

59A-3.310(2)(a)1, FAC

**Regulation Definition**

(2) Assessment and Treatment Planning Including Discharge. Every IRTF shall develop written policies and procedures to ensure an initial assessment of the patient's physical, psychological and social status, appropriate to the patient's developmental age, is completed to determine the need and type of care or treatment required, and the need for further assessment. These policies and procedures shall include the assessment process as well as treatment planning including discharge planning, and include methods for involving family members or significant others (i.e., guardians, counselors, friends) in assessment, treatment, discharge, and follow-up care plans.

**Interpretive Guideline**

- Interview staff as needed to address items a-m
- Review any supporting documentation related to the assessment items a-m.
- Review plans for coordination of overall treatment plan.



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 201 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(a) Assessment. The facility is responsible for a complete assessment of the patient, some of which may be required just prior to admission, by professionals acceptable to the facility's staff. The complete assessment shall include:

1. Physical. Subparagraphs a., b. and c. must be completed by a physician, APRN or PA on the staff of the facility prior to admission or within 24 hours after admission.
  - a. Complete medical history, including history of medications;
  - b. General physical examinations;
  - c. Neurological assessment;
  - d. Motor development and functioning;
  - e. Dental assessment;
  - f. Speech, hearing and language assessment;
  - g. Vision assessment;
  - h. Review of immunization status;
  - i. Laboratory workup including routine blood work and analysis;
  - j. Chest x-ray and/or tuberculin test;
  - k. Serology; and,
  - l. Urinalysis.
- m. If any of the physical health assessments indicate the need for further testing or definitive treatment, arrangements shall be made to carry out or obtain the necessary evaluations or treatment by clinicians, physicians, APRNs or PAs trained as applicable, and plans for these treatments shall be coordinated with the patient's overall treatment plan.

**ST - H0283 - INTENSIVE RES TX PROG - Psych Assess**

**Title** INTENSIVE RES TX PROG - Psych Assess

**Type** Rule

59A-3.310(2)(a)2, FAC

**Regulation Definition**

(a) Assessment. The facility is responsible for a complete

**Interpretive Guideline**

- Review the facility's policies and procedures on assessments.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 202 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

assessment of the patient, some of which may be required just prior to admission, by professionals acceptable to the facility's staff. The complete assessment shall include:

2. Psychiatric/Psychological.

a. The assessment includes direct psychiatric evaluation and behavioral appraisal, evaluation of sensory, motor functioning, a mental status examination appropriate to the age of the patient and a psychodynamic appraisal. A psychiatric history, including history of any previous treatment for mental, emotional or behavioral disturbances shall be obtained, including the nature, duration and results of the treatment, and the reason for termination.

b. The psychological assessment includes appropriate testing.

- Review the patient's record for the assessment documentation as described in a-b.
- Interview staff for clarification on documentation, as needed.

**ST - H0284 - INTENSIVE RES TX PROG -Develop/Social Assess**

**Title** INTENSIVE RES TX PROG -Develop/Social Assess

**Type** Rule

59A-3.310(2)(a)3, FAC

**Regulation Definition**

(a) Assessment. The facility is responsible for a complete assessment of the patient, some of which may be required just prior to admission, by professionals acceptable to the facility's staff. The complete assessment shall include:

3. Developmental/Social.

a. The developmental history of the patient includes the prenatal period and from birth until present, the rate of progress, developmental milestones, developmental problems, and past experiences that may have affected the development. The assessment shall include an evaluation of the patient's strengths as well as problems. Consideration shall be given to the healthy developmental aspects of the patient, as well as to the pathological aspects, and the effects that each has on the other shall be assessed. There shall be an assessment of the

**Interpretive Guideline**

- Review the facility's policies and procedures on assessments.
- Review the patient's record for the assessment documentation and includes a-b as described.
- Interview staff for clarification on documentation, as needed.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 203 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

patient's current age, appropriate developmental needs, which shall include a detailed appraisal of his peer and group relationships and activities.

b. The social assessment includes evaluation of the patient's relationships within the structure of the family and with the community at large, and evaluation of the characteristics of the social, peer group, and institutional settings from which the patient comes. Consideration shall be given to the patient's family circumstances, including the constellation of the family group, their current living situation, and all social, religious, ethnic, cultural, financial, emotional and health factors. Other factors that shall be considered are past events and current problems that have affected the patient and family; potential of the family's members meeting the patient's needs; and their accessibility to help in the treatment and rehabilitation of the patient. The expectations of the family regarding the patient's treatment, the degree to which they expect to be involved, and their expectations as to the length of time and type of treatment required shall be assessed.

**ST - H0285 - INTENSIVE RES TX PROG - Nursing Assess**

**Title** INTENSIVE RES TX PROG - Nursing Assess

**Type** Rule

59A-3.310(2)(a)4, FAC

**Regulation Definition**

(a) Assessment. The facility is responsible for a complete assessment of the patient, some of which may be required just prior to admission, by professionals acceptable to the facility's staff. The complete assessment shall include:

4. Nursing. The nursing assessment shall be performed by a person, who at a minimum, is duly licensed in the State of Florida to practice as a registered nurse and shall include the evaluation of:

**Interpretive Guideline**

- Review the facility's policies and procedures on assessments.
- Review the patient's record for the assessment documentation and includes a-f.
- Interview staff for clarification on documentation, as needed.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 204 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

- a. Self-care capabilities including bathing, sleeping, eating;
- b. Hygienic practices such as routine dental and physical care and establishment of healthy toilet habits;
- c. Dietary habits including a balanced diet and appropriate fluid and calorie intake;
- d. Response to physical diseases (e.g., acceptance by the patient of a chronic illness as manifested by his compliance with prescribed treatment);
- e. Responses to physical handicaps (e.g., the use of prostheses for coping patterns used by the visually handicapped); and,
- f. Responses to medications (e.g., allergies or dependence).

**ST - H0286 - INTENSIVE RES TX PROG -Educ/Vocational Assess**

**Title** INTENSIVE RES TX PROG -Educ/Vocational Assess

**Type** Rule

59A-3.310(2)(a)5, FAC

**Regulation Definition**

(a) Assessment. The facility is responsible for a complete assessment of the patient, some of which may be required just prior to admission, by professionals acceptable to the facility's staff. The complete assessment shall include:

5. Educational/Vocational. The patient's current educational/vocational needs in functioning, including deficits and strengths, shall be assessed. Potential educational impairment and current and future educational vocational potential shall be evaluated using, as indicated, specific educational testing and special educators or others.

**Interpretive Guideline**

- Review the facility's policies and procedures on assessments.
- Review the patient's record for the assessment documentation.
- Interview staff for clarification on documentation, as needed.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 205 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0287 - INTENSIVE RES TX PROG - Recreational Assess**

**Title** INTENSIVE RES TX PROG - Recreational Assess

**Type** Rule

59A-3.310(2)(a)6, FAC

**Regulation Definition**

(a) Assessment. The facility is responsible for a complete assessment of the patient, some of which may be required just prior to admission, by professionals acceptable to the facility's staff. The complete assessment shall include:  
6. Recreational. The patient's work and play experiences, activities, interests and skills shall be evaluated in relation to planning appropriate recreational activities.

**Interpretive Guideline**

- Review the facility's policies and procedures on assessments.
- Review the patient's record for the assessment documentation.
- Interview staff for clarification on documentation, as needed.

**ST - H0288 - INTENSIVE RES TX PROG - Treatment Planning**

**Title** INTENSIVE RES TX PROG - Treatment Planning

**Type** Rule

59A-3.310(2)(b) FAC

**Regulation Definition**

(b) Treatment Planning. An initial treatment plan shall be formulated, written and interpreted to the staff and patient within 72 hours of admission. The comprehensive treatment plan shall be developed for each child by a multidisciplinary staff, within 14 days of admission. This plan must be reviewed at least monthly, or more frequently if the objectives of the program indicate. Review shall be noted in the record. A psychiatrist as well as multidisciplinary professional staff must participate in the preparation of the plan and any major revisions.

**Interpretive Guideline**

- Review the facility's policies and procedures on assessments.
- Review documentation for treatment consents.
- Review the patient's record for the assessment and treatment plan documentation.
- Interview staff for clarification on documentation, as needed.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 206 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

1. The treatment plan shall be based on the assessment and shall include clinical consideration of the physical, developmental, psychological, chronological age, family, education, social and recreational needs. The reason for admission shall be specified as shall specific treatment goals, stated in measurable terms, including a projected time frame, treatment modalities to be used, staff who are responsible for coordinating and carrying out the treatment, and expected length of stay and designation of the person or agency to whom the child will be discharged.
2. The degree of the family's involvement (parent or parent surrogates) shall be defined in the treatment planning program.
3. Collaboration with resources and significant others shall be included in treatment planning, when the treatment team determines it will not interfere with the child's treatment.
4. Procedures that place the patient at physical risk or pain shall require special justification. The rationale for their use shall be clearly set forth in the treatment plan and shall reflect the prior involvement and specific review of the treatment plan by a child psychiatrist. When potentially hazardous procedures or modalities are contemplated for treatment, there shall be additional program specific policies governing their use to protect the rights and safety of the patient. The facility shall have specific written policies and procedures governing the use of electroconvulsive therapy or other forms of convulsive therapy. If such procedures are to be used they shall be carried out in a setting with emergency equipment available and shall be administered only by medical personnel who have been trained in the use of such equipment. Policies and procedures shall insure that:
  - a. Electroconvulsive therapy or other forms of convulsive therapy shall not be administered to any patient unless, prior to the initiation of treatment, two child psychiatrists with training or experience in the treatment of adolescents, who are not affiliated with the treating facility, have examined the

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 207 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

patient, consulted with the responsible child psychiatrist and have written and signed reports which show concurrence with the administration of such treatment. Such reviews shall be carried out only by American Board of Psychiatry certified or American Board of Psychiatry eligible child psychiatrists;

b. All signed consultation reports, either recommending or opposing the administration of such treatment, shall be made a part of the patient's clinical record;

c. Written informed consent of members of the family authorized to give consent, and where appropriate the patient's consent shall be obtained and made a part of the patient's clinical records. The person who is giving such consent may withdraw consent at any time;

d. Lobotomies or other surgical procedures for intervention or alterations of a mental, emotional or behavioral disorder shall not be performed on patients.

**ST - H0289 - INTENSIVE RES TX PROG - Discharge Planning**

**Title** INTENSIVE RES TX PROG - Discharge Planning

**Type** Rule

59A-3.310(2)(c), FAC

**Regulation Definition**

(c) Discharge. Discharge planning begins at the time of admission. A discharge date shall be projected in the treatment plan. Discharges shall be signed by a staff physician of the facility. A discharge summary shall be included in the records. Discharge planning shall include input from the multidisciplinary staff and will include family participation.

1. Discharge planning shall include a period of time for transition into the community (e.g., home visits gradually lengthened) for those patients who have been in the program for six months or longer. There must be a written plan for follow-up services, either by the facility or by another agency.

**Interpretive Guideline**

- Review the facility's policies and procedures on assessments.
- Review the patient's record for the discharge documentation.
- Interview staff for clarification on documentation, as needed.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 208 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0290 - INTENSIVE RES TX PROG - Staff Coverage**

**Title** INTENSIVE RES TX PROG - Staff Coverage

**Type** Rule

59A-3.310(3), FAC

**Regulation Definition**

(3) Staff Coverage. Every IRTF shall develop written policies and procedures to ensure the program is staffed with appropriately trained and qualified individuals to meet the needs of the patients. There shall be a master clinical staffing pattern which provides for adequate clinical staff coverage at all times.

(a) There shall be at least one registered nurse on duty at all times. Services of a registered nurse shall be available for all patients at all times.

(b) A physician shall be on call twenty-four (24) hours a day and accessible to the facility within forty-five (45) minutes.

(c) Special attention shall be given to times which probably indicate the need for increased direct care (e.g., weekends, evenings, during meals, transition contained herein, and substantiated by the results between activities, and waking hours).

(d) Staff interaction shall insure that there is adequate communication of information regarding patients (e.g., between working shifts or change of personnel) with consulting professional staff for routine planning and patient review meetings. These interactions shall be documented in writing.

**Interpretive Guideline**

- Review the facility's staffing patterns and physician call schedules for needs listed in a-d.
- Observe care.
- Interview staff regarding staffing patterns and time frames.



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 209 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0291 - INTENSIVE RES TX PROG - Program Activities**

**Title** INTENSIVE RES TX PROG - Program Activities

**Type** Rule

59A-3.310(4)(a)-(d) FAC

**Regulation Definition**

**Interpretive Guideline**

(4) Program Activities. Every IRTF must develop an organizational chart with a description of each unit or department and its services, goals, policies and procedures, its relationship to other services and departments and how these are to contribute to the priorities and goals of the program, and ways in which the program carries out any community education consultation programs. Program goals of the facility shall include those activities designed to promote the physical and emotional growth and development of the patients, regardless of pathology or age level. There should be positive relationships with general community resources, and the facility staff shall enlist the support of these resources to provide opportunities for patients to participate in normal community activities as they are able. All labeling of vehicles used for transportation of patients shall be such that it does not call unnecessary attention to the patients.

(a) Group Size. The size and composition of each living group shall be therapeutically planned and depend on the age, developmental level, sex and clinical conditions. It shall allow for staff-patient interaction, security, close observation and support.

(b) Routine Activities. Basic routine shall be delineated in a written plan which shall be available to all personnel. The daily program shall be planned to provide a consistent well structured yet flexible framework for daily living and shall be periodically reviewed and revised as the needs of the individual patient or the living group change. Basic daily

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 210 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

routine shall be coordinated with special requirements of the patient's treatment plan.

(c) Social and Recreation Activities. Program of recreational and social activities shall be provided for all patients for daytime, evenings and weekends, to meet the needs of the patients and goals of the program. There shall be documentation of these activities as well as schedules maintained of any planned activities.

(d) Religious Activities. Opportunity shall be provided for all patients to participate in religious services and other religious activities within the framework of their individual and family interests and clinical status. The option to celebrate holidays in the patient's traditional manner shall be provided and encouraged.

**ST - H0292 - INTENSIVE RES TX PROG - Education**

**Title** INTENSIVE RES TX PROG - Education

**Type** Rule

59A-3.310(4)(e-f) FAC

**Regulation Definition**

(e) Education. The facility shall arrange for or provide an educational program for all patients receiving services in that facility.

1. The particular educational needs of each patient shall be considered in both placement and programming.
2. Children or adolescents placed in the special hospital by a public agency or at the expense of a public agency shall receive education consistent with the requirements of Chapter 6A-6, F.A.C., as applicable.

(f) Vocational Programs. The facility shall arrange for, or provide, vocational or prevocational training for patients in the facility for whom it is indicated.

1. If there are plans for work experience developed as part of

**Interpretive Guideline**

- Review Vocational Program treatment plans and staffing to meet the needs

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 211 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

the patient's overall treatment plan, the work shall be in the patient's interest with payment where appropriate, as determined by the treatment facility and the vocational program, and never solely in the interest of the facility's goals or needs.

2. Patients shall not be solely responsible for any major phase or institutional operation or maintenance, such as cooking, laundering, housekeeping, farming or repairing. Patients shall not be considered as substitutes for employed staff.

**ST - H0293 - INTENSIVE RES TX PROG - Nutrition & Standards**

**Title** INTENSIVE RES TX PROG - Nutrition & Standards

**Type** Rule

59A-3.310(4)(g) FAC

**Regulation Definition**

(g) Nutrition and Standards. There shall be a provision of planning and preparation of special diets as needed (e.g., diabetic, bland, high calorie). Menus shall be evaluated by a consultant dietitian relative to nutritional adequacy at least monthly, with observation of food intake and changes seen in the patient.

**Interpretive Guideline**

Review menus and patient records for diet options.  
Interview staff and include dietary or kitchen for nutrition information.  
CROSSREFERENCE with tags 0064-0080 for additional nutrition requirements.

**ST - H0294 - INTENSIVE RES TX PROG - Physical Care**

**Title** INTENSIVE RES TX PROG - Physical Care

**Type** Rule

59A-3.310(5) FAC

**Regulation Definition**

(5) Physical Care. The facility shall have available, either within its own organizational structure or by written

**Interpretive Guideline**

- Interview staff as needed regarding patient illness  
- Review patient records for illness and how they were treated.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 212 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

agreements or contracts with outside health care clinicians or facilities, a full range of services for the treatment of illnesses and the maintenance of general physical health.

**ST - H0295 - INTENSIVE RES TX PROG - Plan for Medical Svcs**

**Title** INTENSIVE RES TX PROG - Plan for Medical Svcs

**Type** Rule

59A-3.310(5)(a)1, FAC

**Regulation Definition**

(a) The facility shall develop a written plan for medical services which delineates the ways the facility obtains or provides all general and specialized medical, surgical, nursing, pharmaceutical and dental services.

1. Insofar as rules 59A-3.300 through 59A-3.310, F.A.C., are intended to establish minimum requirements for intensive residential treatment facilities for children and adolescents that have a primary purpose of treating emotional and mental disorders, such facilities are not required to establish and maintain medical buildings and equipment required of general or specialty hospitals as specified in rules 59A-3.080 through 59A-3.281, F.A.C. Services which require such specialized buildings and equipment may be obtained from outside health care providers by written agreement or contract. This shall not preclude the facility from maintaining a medical services area or building which does not meet the requirements of rules 59A-3.065 through 59A-3.281, F.A.C., for the purpose of isolating patients with contagious diseases, conducting physical examinations, providing preventive medical care services, or providing first aid services.

**Interpretive Guideline**

- Review the written plan as describe.
- Interview staff relating to the plan and how services are provided.
- Review facility license for compliance on services provided.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 213 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0296 - INTENSIVE RES TX PROG - Illness Tx/Hlth Maint**

**Title** INTENSIVE RES TX PROG - Illness Tx/Hlth Maint

**Type** Rule

59A-3.310(5)(b)-(g), FAC

**Regulation Definition**

(b) Patients who are physically ill may be cared for on the grounds of the facility if medically feasible as determined by a physician, ARNP or PA. If medical isolation is necessary, there shall be sufficient and qualified staff available to provide care and attention.

(c) Provisions shall be made in writing for patients from the facility to receive care from outside health care providers and hospital facilities, in the event of serious illness which the facility cannot properly handle. Such determinations shall be made by a licensed physician.

(d) Every patient shall have a complete physical examination annually and more frequently if indicated. This examination shall be as inclusive as the initial examination. Efforts shall be made by the institution to have physical defects of the patients corrected through proper medical care. Immunization shall be kept current (DT, polio, measles, mumps, M-M-R).

(e) Each member of the program staff shall be trained to recognize common symptoms of the illnesses of patients, and to note any marked dysfunctions of patients.

(f) Staff shall have knowledge of basic health needs and health problems of patients, such as mental health, physical health and nutritional health. Staff shall teach attitudes and habits conducive to good health through daily routines, examples and discussion, and shall help the patients to understand the principles of health.

(g) Each program shall have a planned program of dental care and dental health which shall be consistently followed. Each

**Interpretive Guideline**

- Review the facility's policy and procedure regarding obtaining medical services, isolation and infectious disease?
- Interview staff regarding items b-g, if needed.
- Observe for ill patients and isolation areas.
- Review the patients' record for items b-g.
- Review employee records for items e-f.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 214 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

patient shall receive a dental examination by a qualified dentist and prophylaxis at least once a year. Reports of all examinations and treatment shall be included in the patient's clinical record.

**ST - H0297 - INTENSIVE RES TX PROG - Emergency Svcs**

**Title** INTENSIVE RES TX PROG - Emergency Svcs

**Type** Rule

59A-3.310(6) FAC

**Regulation Definition**

- (6) Emergency Services. All clinical staff shall have training in matters related to handling emergency situations.
- (a) Policies and procedures shall be written regarding handling and reporting of emergencies and these shall be reviewed at least yearly thereafter by all staff.
- (b) There shall be a physician on call twenty-four (24) hours a day; his/her name and where he/she can be reached shall be clearly posted in accessible places for program staff.
- (c) All staff providing direct patient care must maintain current first aid certificate.
- (d) An emergency medication kit shall be made available and shall be constituted to meet the needs of the facility. The emergency medication kit shall contain items selected by the staff or consultant medical doctor and staff or consultant pharmacist which shall be maintained and safeguarded in accordance with federal and state laws and regulations pertaining to the specific drug items included.
- (e) There shall be an adequate number of first aid kits available to program staff at all times. Contents of the first aid kits shall be selected by the staff or consultant medical personnel and shall include items designed to meet the needs of the facility.
- (f) The program shall have written policies and procedures of

**Interpretive Guideline**

- Review policies, procedures and plans listed in items a-h.
- Interview staff as needed for items a-h.
- Review patient records for emergency services and appropriate notifications.
- Review staff records for first aid certification.
- Observe for appropriate written and posted plans.
- Observe for first aid kits and emergency medication kits.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 215 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

obtaining emergency diagnosis and treatment of dental problems. The program shall have written agreement with a licensed dentist(s) who is a consultant or a member of the staff for emergency dental care.

(g) The facility shall have a written plan to facilitate emergency hospitalization in a licensed medical facility. The facility shall make available a written agreement from a licensed hospital verifying that routine and emergency hospitalization will be provided.

(h) The special hospital shall have a written plan for providing emergency medical and psychiatric care.

1. There shall be a written posted plan which shall clearly specify who is available and authorized to provide necessary emergency psychiatric or medical care, or to arrange for referral or transfer to another facility to include ambulance arrangements, when necessary.

2. There shall be a written plan regarding emergency notification to the parents or legal guardian. This plan and arrangements shall be discussed with all families or guardians of patients upon admission.

**ST - H0300 - INSPECTION REPORTS**

**Title** INSPECTION REPORTS

**Type** Rule

395.0162 F.S.

**Regulation Definition**

(1) Each licensed facility shall maintain as public information, available upon request, records of all inspection reports pertaining to that facility. Copies of such reports shall be retained in its records for not less than 5 years from the date the reports are filed and issued.

(2) Any records, reports, or documents which are confidential and exempt from s. 119.07(1) shall not be distributed or made

**Interpretive Guideline**

Review policy about public record requests and confidentiality.

Review any documentation supporting the policy.

Interview staff as needed for clarification on items 1-3.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 216 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

available for purposes of compliance with this section unless or until such confidential status expires.

(3) A licensed facility shall, upon the request of any person who has completed a written application with intent to be admitted to such facility, any person who is a patient of such facility, or any relative, spouse, guardian, or surrogate of any such person, furnish to the requester a copy of the last inspection report filed with or issued by the agency pertaining to the licensed facility, as provided in subsection (1), provided the person requesting such report agrees to pay a reasonable charge to cover copying costs, not to exceed \$1 per page.

**ST - H0301 - DISCIPLINE ACTION REPORT TO AGENCY**

**Title** DISCIPLINE ACTION REPORT TO AGENCY

**Type** Rule

395.0193(4) F.S.

**Regulation Definition**

(4) Pursuant to ss. 458.337 and 459.016, any disciplinary actions taken under subsection (3) shall be reported in writing to the Division of Health Quality Assurance of the agency within 30 working days after its initial occurrence, regardless of the pendency of appeals to the governing board of the hospital. The notification shall identify the disciplined practitioner, the action taken, and the reason for such action. All final disciplinary actions taken under subsection (3), if different from those which were reported to the agency within 30 days after the initial occurrence, shall be reported within 10 working days to the Division of Health Quality Assurance of the agency in writing and shall specify the disciplinary action taken and the specific grounds therefor. The division shall review each report and determine whether it potentially involved conduct by the licensee that is subject to disciplinary action, in which case s. 456.073 shall apply. The reports are

**Interpretive Guideline**

- Review any documentation about reporting actions to the agency.
- Interview staff about reporting process.
- Review governing board documentation for any reports.



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 217 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

not subject to inspection under s. 119.07(1) even if the division's investigation results in a finding of probable cause.

**ST - H0302 - Rebates Prohibited**

**Title** Rebates Prohibited

**Type** Rule

395.0185(1) FS

**Regulation Definition**

395.0185 Rebates prohibited; penalties.-  
(1) It is unlawful for any person to pay or receive any commission, bonus, kickback, or rebate or engage in any split-fee arrangement, in any form whatsoever, with any physician, surgeon, organization, or person, either directly or indirectly, for patients referred to a licensed facility.

**Interpretive Guideline**

Any payment or benefit provided by a hospital or hospital representative to a case manager, discharge planner or facility-based staff member or 3rd party vendor from whom the hospital receives referrals, violates this unless the hospital can provide documentation to the surveyor that it does not.

**ST - H0310 - Stroke Center Advertising Restrictions**

**Title** Stroke Center Advertising Restrictions

**Type** Rule

395.3039

**Regulation Definition**

395.3039 Advertising restrictions.-A person may not advertise to the public, by way of any medium whatsoever, that a hospital is a state-listed stroke center unless the hospital has submitted documentation to the agency verifying that it is certified and meets the criteria as required in s. 395.3038.

**Interpretive Guideline**

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 218 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0311 - PATIENT RECORDS, PENALTIES FOR ALTERATION**

**Title** PATIENT RECORDS, PENALTIES FOR ALTERATION

**Type** Rule

395.302 F.S.

**Regulation Definition**

(1) Any person who fraudulently alters, defaces, or falsifies any medical record, or causes or procures any of these offenses to be committed, commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

**Interpretive Guideline**

Statutory Only Citation 395.302, F.S.

- Review a sample of patient medical records for evidence of the records being altered.

NOTE: If any concerns arise, referral to Department of Health may be needed.

**ST - H0312 - PEER REVIEW**

**Title** PEER REVIEW

**Type** Rule

395.0193(2) F.S.

**Regulation Definition**

(2) Each licensed facility, as a condition of licensure, shall provide for peer review of physicians who deliver health care services at the facility. Each licensed facility shall develop written, binding procedures by which such peer review shall be conducted. Such procedures shall include:

- (a) Mechanism for choosing the membership of the body or bodies that conduct peer review.
- (b) Adoption of rules of order for the peer review process.
- (c) Fair review of the case with the physician involved.
- (d) Mechanism to identify and avoid conflict of interest on the part of the peer review panel members.
- (e) Recording of agendas and minutes which do not contain

**Interpretive Guideline**

Statutory Only Citation 395.0193(2), FS

- Review policy/procedure/guideline for peer review for items a-g.

- Interview medical director or governing board about peer review.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 219 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

confidential material, for review by the Division of Health Quality Assurance of the agency.

(f) Review, at least annually, of the peer review procedures by the governing board of the licensed facility.

(g) Focus of the peer review process on review of professional practices at the facility to reduce morbidity and mortality and to improve patient care.

**ST - H0313 - TREATMENT, SEXUAL ASSAULT VICTIMS**

**Title** TREATMENT, SEXUAL ASSAULT VICTIMS

**Type** Rule

395.1021 F.S.

**Regulation Definition**

Any licensed facility which provides emergency room services shall arrange for the rendering of appropriate medical attention and treatment of victims of sexual assault through:

(1) Such gynecological, psychological, and medical services as are needed by the victim.

(2) The gathering of forensic medical evidence required for investigation and prosecution from a victim who has reported a sexual battery to a law enforcement agency or who requests that such evidence be gathered for a possible future report.

(3) The training of medical support personnel competent to provide the medical services and treatment as described in subsections (1) and (2).

Such licensed facility shall also arrange for the protection of the victim's anonymity while complying with the laws of this state and may encourage the victim to notify law enforcement personnel and to cooperate with them in apprehending the suspect.

**Interpretive Guideline**

Statutory Only Citation

- Review Program for the Treatment of Sexual Assault Victims.

Interview staff assigned to the program for their knowledge of the treatment, support and protection of Sexually Assaulted Victims.

- Review personnel records of staff assigned to this program for the specialized training in the Treatment of Sexually Assaulted Victims.

- Review policies and interview emergency room and nursing staff:

- How does the staff work closely with law enforcement in the gathering of evidence required for investigation, for reporting and apprehending?

- How is the victims' anonymity maintained?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 220 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0314 - INFECTIOUS DISEASES, NOTIFICATION**

**Title** INFECTIOUS DISEASES, NOTIFICATION

**Type** Rule

395.1025 FS

**Regulation Definition**

Notwithstanding the provisions in s. 381.004, if, while treating or transporting an ill or injured patient to a licensed facility, an emergency medical technician, paramedic, or other person comes into direct contact with the patient who is subsequently diagnosed as having an infectious disease, it shall be the duty of the licensed facility receiving the patient to notify the emergency medical technician, paramedic, or his or her emergency medical transportation service employer, or other person of the individual's exposure to the patient within 48 hours, or sooner, of confirmation of the patient's diagnosis and to advise him or her of the appropriate treatment, if any. Notification made pursuant to this section shall be done in a manner which will protect the confidentiality of such patient information and shall not include any patient's name.

**Interpretive Guideline**

Statutory Only Citation

- Request Program for Notification of Infections Disease Exposure to Emergency Medical Transport Personnel.
- Interview Emergency Department Director or Designee and Infectious Control Nurse/Designee about this process.

**ST - H0316 - Urgent Care Ctrs- Publishing, Posting Charges**

**Title** Urgent Care Ctrs- Publishing, Posting Charges

**Type** Rule

395.107 FS

**Regulation Definition**

- (1) For purposes of this section, the term "facility" means:
- (a) An urgent care center as defined in s. 395.002; or
  - (b) A diagnostic-imaging center operated by a hospital

**Interpretive Guideline**

- Tour urgent care centers and diagnostic-imaging centers under the hospital license for schedule of charges postings.
- Review signage parameters for compliance.
- Interview staff for clarification when needed.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 221 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

licensed under this chapter which is not located on the hospital's premises.

(2) A facility must publish and post a schedule of charges for the medical services offered to patients.

(3) The schedule of charges must describe the medical services in language comprehensible to a layperson. The schedule must include the prices charged to an uninsured person paying for such services by cash, check, credit card, or debit card. The schedule must be posted in a conspicuous place in the reception area and must include, but is not limited to, the 50 services most frequently provided. The schedule may group services by three price levels, listing services in each price level. The posting may be a sign, which must be at least 15 square feet in size, or may be through an electronic messaging board. If a facility is affiliated with a licensed hospital under this chapter, the schedule must include text that notifies the insured patients whether the charges for medical services received at the center will be the same as, or more than, charges for medical services received at the affiliated hospital. The text notifying the patient of the schedule of charges shall be in a font size equal to or greater than the font size used for prices and must be in a contrasting color. The text that notifies the insured patients whether the charges for medical services received at the center will be the same as, or more than, charges for medical services received at the affiliated hospital shall be included in all media and Internet advertisements for the center and in language comprehensible to a layperson.

(4) The posted text describing the medical services must fill at least 12 square feet of the posting. A facility may use an electronic device or messaging board to post the schedule of charges. Such a device must be at least 3 square feet, and patients must be able to access the schedule during all hours of operation of the facility.

(5) A facility that is operated and used exclusively for

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 222 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

employees and the dependents of employees of the business that owns or contracts for the facility is exempt from this section.

(6) The failure of a facility to publish and post a schedule of charges as required by this section shall result in a fine of not more than \$1,000, per day, until the schedule is published and posted.

**ST - H0317 - PRIMARY STROKE CENTERS**

**Title** PRIMARY STROKE CENTERS

**Type** Rule

59A-3.246(4)(a-d) FAC; 395.3038(2)(b)1

**Regulation Definition**

59A-3.246(4) Stroke centers.

(a) Licensure. A hospital may apply for designation as an acute stroke ready center, primary 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 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) Screening. Organized medical staff shall establish specific procedures for screening patients that recognize that numerous

**Interpretive Guideline**

- Review attestation and current designation.
- Observe all areas of the hospital which comprise the primary stroke center.
- Interview the Professional responsible for the Primary stroke center program.
- Refer to <[http://www.jointcommission.org/certification/primary\\_stroke\\_centers.aspx](http://www.jointcommission.org/certification/primary_stroke_centers.aspx)> for requirements for certification.
- Interview physicians and clinical professionals providing stroke center care and services for standard knowledge, stroke team response times/measures, and quality improvement measures.
- Review stroke center staff personnel and training records for education and competency.
- Observe care and services to patients who are in the Primary Stroke Center areas, and sample review patient medical records.
- Interview patients and families for care and services.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 223 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

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) 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;

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 224 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

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



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

*Printed 08/07/2024*

Page 225 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

echocardiography;

d. Administration of intravenous thrombolytic;

e. Reversal of anticoagulation; and

f. Neurologist services, available in person or via telemedicine.

6. The following services may be available on-site or via a transfer agreement:

a. Neurosurgical services within 2 hours of being deemed clinically necessary;

b. Physical, occupational, or speech therapy; and

c. Neurovascular interventions for aneurysms, stenting of carotid arteries, carotid endarterectomy, and endovascular therapy.

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.

395.3038 State-listed stroke centers; notification of hospitals.-

(2)(b)1. This subsection does not apply if the hospital is unable to provide stroke treatment services for a period of time not to exceed 2 months. The hospital shall immediately notify all local emergency medical services providers when the temporary unavailability of stroke treatment services begins and when the services resume.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 226 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0318 - COMPREHENSIVE STROKE CENTERS**

**Title** COMPREHENSIVE STROKE CENTERS

**Type** Rule

59A-3.246(4)(e) FAC

**Regulation Definition**

(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,

**Interpretive Guideline**

- Observe all areas of the hospital which are designated a part of the Comprehensive Stroke Center.
  - Interview the professional responsible for the stroke center.
  - Interview the stroke center medical director.
  - Interview Neurosurgeons, Interventionists, and physicians in the ED.
  - Interview nursing staff in the ED, ICU and Neuro units who provide care and services for patients with stroke.
  - Review quality improvement program for standards and measure performance.
- Review personnel and training records of stroke center personnel for education, training, and competence.
- Interview patients and families for care and services.
  - Review a sample of patient medical records for stroke care and services.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 227 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

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

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 228 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

- 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

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 229 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

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

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 230 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

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

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 231 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

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.

**ST - H0401 - INTERNAL RISK MANAGEMENT PROGRAM**

**Title** INTERNAL RISK MANAGEMENT PROGRAM

**Type** Rule

395.0197(1), F.S.

**Regulation Definition**

(1) Every licensed facility shall, as a part of its administrative functions, establish an internal risk management program that includes all of the following components:

**Interpretive Guideline**

Follow survey process outline in the current risk management documents.

**ST - H0402 - RM Prog - Investigation & Analysis**

**Title** RM Prog - Investigation & Analysis

**Type** Rule

395.0197(1)(a), F.S.

**Regulation Definition**

(a) The investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents to patients.

**Interpretive Guideline**

- Does the plan establish the incident categories?
- Are the incidents specific to this facility?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 232 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0403 - RM Prog -Develop of Measures to Minimize Risk**

**Title** RM Prog -Develop of Measures to Minimize Risk

**Type** Rule

395.0197(1)(b), F.S.

**Regulation Definition**

(b) The development of appropriate measures to minimize the risk of adverse incidents to patients, including, but not limited to:

**Interpretive Guideline**

Follow survey process outline in the current risk management documents.

**ST - H0404 - Approp Measure - Education & Training**

**Title** Approp Measure - Education & Training

**Type** Rule

395.0197(1)(b)1, F.S.; 59A-10.0055(1) FS

**Regulation Definition**

395.0197(1)

(b) The development of appropriate measures to minimize the risk of adverse incidents to patients, including, but not limited to:

1. Risk management and risk prevention education and training of all nonphysician personnel as follows:
  - a. Such education and training of all nonphysician personnel as part of their initial orientation; and
  - b. At least 1 hour of such education and training annually for all personnel of the licensed facility working in clinical areas and providing patient care, except those persons licensed as health care practitioners who are required to complete continuing education coursework pursuant to chapter 456 or the respective practice act.

**Interpretive Guideline**

Follow survey process outline in the current risk management documents.



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 233 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

59A-10.0055

(1) Incident Reporting. An incident reporting system shall be established for each facility. Procedures shall be detailed in writing and disseminated to all employees of the facility. All new employees, within 30 days of employment, shall be instructed about the operation of the system and responsibilities of it. At least annually all nonphysician personnel of the facility working in clinical areas and providing patient care shall receive 1 hour risk management and risk prevention education and training including the importance of accurate and timely incident reporting.

**ST - H0405 - Approp Measure - Recovery Room Prohibition**

**Title** Approp Measure - Recovery Room Prohibition

**Type** Rule

395.0197(1)(b)2, F.S.

**Regulation Definition**

(b) The development of appropriate measures to minimize the risk of adverse incidents to patients, including, but not limited to:

2. A prohibition, except when emergency circumstances require otherwise, against a staff member of the licensed facility attending a patient in the recovery room, unless the staff member is authorized to attend the patient in the recovery room and is in the company of at least one other person. However, a licensed facility is exempt from the two-person requirement if it has:
  - a. Live visual observation;
  - b. Electronic observation; or
  - c. Any other reasonable measure taken to ensure patient protection and privacy.

**Interpretive Guideline**

Follow survey process outline in the current risk management documents.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 234 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0406 - Approp Measure - Surgical Proc Prohibition**

**Title** Approp Measure - Surgical Proc Prohibition

**Type** Rule

395.0197(1)(b)3, F.S.

**Regulation Definition**

(b) The development of appropriate measures to minimize the risk of adverse incidents to patients, including, but not limited to:

3. A prohibition against an unlicensed person from assisting or participating in any surgical procedure unless the facility has authorized the person to do so following a competency assessment, and such assistance or participation is done under the direct and immediate supervision of a licensed physician and is not otherwise an activity that may only be performed by a licensed health care practitioner.

**Interpretive Guideline**

- Interview surgical staff to ascertain if unlicensed staff participate/assisting in surgical procedures - provisions.
- Identify those unlicensed staff participating in surgical procedures.
- Review the unlicensed staff competencies and competency assessments.
- Review surgical schedules and assignments to determine direct and immediate supervision of an unlicensed person.
- Review competencies for Private or Contractual Scrub individuals.

**ST - H0407 - Approp Measure - Ongoing Eval of Proc/Systems**

**Title** Approp Measure - Ongoing Eval of Proc/Systems

**Type** Rule

395.0197(1)(b)4, F.S.

**Regulation Definition**

(b) The development of appropriate measures to minimize the risk of adverse incidents to patients, including, but not limited to:

4. Development, implementation, and ongoing evaluation of procedures, protocols, and systems to accurately identify

**Interpretive Guideline**

- After the review of adverse incidents for the past year, review the plan/policy document to address identity of patient/procedures.
- Verify the system in place to prevent/minimize wrong patient, wrong surgical procedure, wrong site, or a surgical procedure unrelated.
- If an incident breaches protocol, is it reviewed to minimize risk to other patients?
- How does the facility monitor compliance with the protocols for quality program purposes?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 235 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

patients, planned procedures, and the correct site of the planned procedure so as to minimize the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition.

-Review documentation to determine the facility compliance for development, implementation and ongoing evaluation process to prevent occurrences

**ST - H0408 - RM Prog - Pt Grievance Analysis**

**Title** RM Prog - Pt Grievance Analysis

**Type** Rule

395.0197(1)(c), F.S.

**Regulation Definition**

(c) The analysis of patient grievances that relate to patient care and the quality of medical services.

**Interpretive Guideline**

- Review a sample of grievances relating to patient care and medical services.
- Review grievance analysis report relating to patient care and medical services.
- Review evidence that issues related to quality of care/medical care are analyzed including outcomes. Were corrective measures placed into facility-wide systems?
- Verify a plan to prevent re-occurrences.
- Interview Risk Manager to confirm grievance information.

**ST - H0409 - RM Prog - Pt Notification of Adv Incidents**

**Title** RM Prog - Pt Notification of Adv Incidents

**Type** Rule

395.0197 (1)(d), 395.1051 F.S.

**Regulation Definition**

395.0197(1)(d) A system for informing a patient or an individual identified pursuant to s. 765.401(1) that the patient was the subject of an adverse incident, as defined in subsection (5). Such notice shall be given by an appropriately trained person designated by the licensed facility as soon as

**Interpretive Guideline**

- Review the Policy and Procedures developed to enable patient notification (or the patient's healthcare surrogate) of all adverse incidents.
- Interview Risk Manager as needed to clarify compliance.
- Review sample of adverse incidents to verify the trained person is the person notifying patients/surrogate of the adverse incident.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 236 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

practicable to allow the patient an opportunity to minimize damage or injury.

395.1051 Duty to notify patients.-An appropriately trained person designated by each licensed facility shall inform each patient, or an individual identified pursuant to s. 765.401(1), in person about adverse incidents that result in serious harm to the patient. Notification of outcomes of care that result in harm to the patient under this section shall not constitute an acknowledgment or admission of liability, nor can it be introduced as evidence.

**ST - H0410 - RM Prog - Incident Reporting System**

**Title** RM Prog - Incident Reporting System

**Type** Rule

395.0197(1)(e) FS; 59A-10.0055(2)(a-b)

**Regulation Definition**

395.0197(1)(e) The development and implementation of an incident reporting system based upon the affirmative duty of all health care providers and all agents and employees of the licensed health care facility to report adverse incidents to the risk manager, or to his or her designee, within 3 business days after their occurrence.

59A-10.0055

(2) Incident Reports. The incident reporting system shall include the prompt, within 3 calendar days, reporting of incidents to the risk manager, or his designee. Reports shall be on a form developed by the facility for the purpose and shall contain at least the following information:

- (a) The patient's name, locating information, admission diagnosis, admission date, age and sex;
- (b) A clear and concise description of the incident including

**Interpretive Guideline**

- Review the Policy and Procedures for incident reporting to determine facility time frame (no more than 3 days)
- Review a sample of Incident/Occurrence Reports to determine incidents are reported within three (3) business days to the Risk Manager or to the Risk Manager Designee and form contains all information as required in F.A.C.
- If there is a Risk Manager Designee, verify the facility documentation identifying the staff member in the Risk Management Designee position.
- Interview a sample of staff to determine if:
  - The facility has a developed an incident reporting system
  - The facility has a method for reporting incidents within 3 business days of the date of occurrence
  - The staff is able to identify the Risk Manager or Risk Manager Designee

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 237 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

time, date, exact location; and elements as needed for the annual report based on ICD-10-CM;

**ST - H0412 - INCIDENT REPORTING SYSTEM - Reports**

**Title** INCIDENT REPORTING SYSTEM - Reports

**Type** Rule

59A-10.0055(2)(c)-(e), FAC

**Regulation Definition**

- (c) Whether or not a physician was called; and if so, a brief statement of said physician's recommendations as to medical treatment, if any;
- (d) A listing of all persons then known to be involved directly in the incident, including witnesses, along with locating information for each;
- (e) The name, signature and position of the person completing the reports, along with date and time that the report was completed.

**Interpretive Guideline**

- Follow survey process outline in the current risk management documents.
- Review a sample of incident/occurrence reports to verify
  - Was the physician is notified? If so, is the documentation included in the form.
  - Review the patient(s) medical records to verify record shows the incident.
  - Determine compliance with the incident form requirements.
  - Witness locating information should be documented on the form.

**ST - H0413 - RESP OF GOVERNING BOARD AND RISK MANAGER**

**Title** RESP OF GOVERNING BOARD AND RISK MANAGER

**Type** Rule

395.0197(2), F.S.

**Regulation Definition**

- (2) The internal risk management program is the responsibility of the governing board of the health care facility. Each licensed facility shall hire a risk manager who is responsible for implementation and oversight of the facility's internal risk management program and who demonstrates competence, through education or experience, in all of the following areas:

**Interpretive Guideline**

- Verify there is a Risk Manager.  
Review the Risk Mangers' job description for his/her responsibilities.  
Verify the number of current facilities for which the Risk Manager currently has responsibility.  
How does the facility/Governing board ensure competency?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 238 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

- (a) Applicable standards of health care risk management.
- (b) Applicable federal, state, and local health and safety laws and rules.
- (c) General risk management administration.
- (d) Patient care.
- (e) Medical care.
- (f) Personal and social care.
- (g) Accident prevention.
- (h) Departmental organization and management.
- (i) Community interrelationships.
- (j) Medical terminology.

**ST - H0414 - RISK MANAGER ACCESS TO RECORDS**

**Title** RISK MANAGER ACCESS TO RECORDS

**Type** Rule

395.0197(4), F.S.

**Regulation Definition**

(4) ... Each internal risk management program shall include the use of incident reports to be filed with an individual of responsibility who is competent in risk management techniques in the employ of each licensed facility, such as an insurance coordinator, or who is retained by the licensed facility as a consultant. The individual responsible for the risk management program shall have free access to all medical records of the licensed facility. The incident reports are part of the workpapers of the attorney defending the licensed facility in litigation relating to the licensed facility and are subject to discovery, but are not admissible as evidence in court. A person filing an incident report is not subject to civil suit by virtue of such incident report.

**Interpretive Guideline**

- Interview the Risk Manager and the Administrator.
- Review the Risk Manager's job description.
- Review the Policy and Procedures to confirm access to medical records is addressed.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 239 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0415 - DEVELOPMENT OF CORRECTIVE PROCEDURES**

**Title** DEVELOPMENT OF CORRECTIVE PROCEDURES

**Type** Rule

395.0197(4), F.S.

**Regulation Definition**

(4) ... As a part of each internal risk management program, the incident reports shall be used to develop categories of incidents which identify problem areas. Once identified, procedures shall be adjusted to correct the problem areas.

**Interpretive Guideline**

- Ask the Risk Manager how they have determined what incidents to track and trend?
- Review tracking and trending reports based on findings and reported concerns.
- Review documentation for Policy and Procedure adjustments, category development and facility corrective actions/interventions of identified problem areas.
- Verify the issues are tracked and trended. Are these specific to facility problems and issues regarding patient, staff and facility safety.

**ST - H0416 - 15 DAY REPORTS**

**Title** 15 DAY REPORTS

**Type** Rule

395.0197(5 & 7) FS

**Regulation Definition**

395.0197  
(5) For purposes of reporting to the agency pursuant to this section, the term "adverse incident" means an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred, and which:

(a) Results in one of the following injuries:

1. Death;
2. Brain or spinal damage;
3. Permanent disfigurement;

**Interpretive Guideline**

- Interview the Risk Manager regarding reporting Code 15 events.
- Review the facility's Policy and Procedures regarding reporting an adverse incident. Is the Risk Manager following the facility's Policy and Procedures when a Code 15 reportable incident occurs?
- Request a list of any discharged patient that was re-admitted into the facility within days of being discharge.
- Review a few re-admitted patients' records to determine if any were admitted for the previous treatment or surgical procedure.
- Request a list of patients who have expired in the facility in the past year.
- Review those deaths, which resulted in an autopsy being conducted. What was the outcome?
- Review to determine if anyone was transferred to a higher level of care
- Did the Risk Manager file the Code 15 within 15 calendar days?
- Review the consent form, signed by the patient prior to surgery, was the incident outcome listed as one of the

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 240 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

4. Fracture or dislocation of bones or joints;
  5. A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility;
  6. Any condition that required specialized medical attention or surgical intervention resulting from nonemergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or
  7. Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;
- (b) Was the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;
- (c) Required the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or
- (d) Was a procedure to remove unplanned foreign objects remaining from a surgical procedure.

specific risk of the surgical procedure.

- If the Risk Manager was unable to submit an adverse incident within 15 calendar days, did the Risk Manager request an extension from AHCA? Review the extension request.
- How is it determined an incident meets the definition of an "adverse incident" to be reported to the Agency?
- Are the interventions in place. Are those interventions enabling the risk/ quality and staff process to mitigate these types of occurrences for patient safety and error reduction?
- If interventions are in place-ask to see that safety process, evaluation and findings. Are they successful- if not what steps has the facility taken to rectify?

(7) Any of the following adverse incidents, whether occurring in the licensed facility or arising from health care prior to admission in the licensed facility, shall be reported by the facility to the agency within 15 calendar days after its occurrence:

- (a) The death of a patient;
- (b) Brain or spinal damage to a patient;
- (c) The performance of a surgical procedure on the wrong patient;
- (d) The performance of a wrong-site surgical procedure;
- (e) The performance of a wrong surgical procedure;
- (f) The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis



**Agency for Health Care Administration  
ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 241 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

or medical condition;

- (g) The surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage is not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or
- (h) The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure.

The agency may grant extensions to this reporting requirement for more than 15 days upon justification submitted in writing by the facility administrator to the agency. The agency may require an additional, final report. These reports shall not be available to the public pursuant to s. 119.07(1) or any other law providing access to public records, nor be discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board, nor shall they be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency or the appropriate regulatory board shall make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause. The agency may investigate, as it deems appropriate, any such incident and prescribe measures that must or may be taken in response to the incident. The agency shall review each incident and determine whether it potentially involved conduct by the health care professional who is subject to disciplinary action, in which case the provisions of s. 456.073 shall apply.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 242 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0417 - SEXUAL MISCONDUCT**

**Title** SEXUAL MISCONDUCT

**Type** Rule

395.0197(9), F.S.

**Regulation Definition**

- (9) The internal risk manager of each licensed facility shall:
- (a) Investigate every allegation of sexual misconduct which is made against a member of the facility's personnel who has direct patient contact, when the allegation is that the sexual misconduct occurred at the facility or on the grounds of the facility.
  - (b) Report every allegation of sexual misconduct to the administrator of the licensed facility.
  - (c) Notify the family or guardian of the victim, if a minor, that an allegation of sexual misconduct has been made and that an investigation is being conducted.
  - (d) Report to the Department of Health every allegation of sexual misconduct, as defined in chapter 456 and the respective practice act, by a licensed health care practitioner that involves a patient.

**Interpretive Guideline**

Review a list of incidents and chose those relating to allegations of sexual misconduct. This is for allegations against facility's personnel.

Review the facility's Policy and Procedures regarding the investigation of an allegation of sexual misconduct. Was the Policy and Procedures followed?

If the allegation was confirmed, what corrective action was implemented?

Was the family/guardian of victim and the Department of Health notified?

Interview the facility's staff, can they tell you what they would do if someone accused an employee of sexual misconduct? Does it meet the facility's Policy and Procedures?

**ST - H0418 - SEXUAL ABUSE REPORTS**

**Title** SEXUAL ABUSE REPORTS

**Type** Rule

395.0197(10), F.S.

**Regulation Definition**

- (10) Any witness who witnessed or who possesses actual knowledge of the act that is the basis of an allegation of sexual

**Interpretive Guideline**

- Review a list of incidents and chose some incidents regarding allegations of sexual abuse.
- Review the facility's Policy and Procedures regarding the prevention and investigation of sexual abuse.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 243 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

abuse shall:

(a) Notify the local police; and

(b) Notify the hospital risk manager and the administrator.

For purposes of this subsection, "sexual abuse" means acts of a sexual nature committed for the sexual gratification of anyone upon, or in the presence of, a vulnerable adult, without the vulnerable adult's informed consent, or a minor. "Sexual abuse" includes, but is not limited to, the acts defined in s. 794.011(1)(h), fondling, exposure of a vulnerable adult's or minor's sexual organs, or the use of the vulnerable adult or minor to solicit for or engage in prostitution or sexual performance. "Sexual abuse" does not include any act intended for a valid medical purpose or any act which may reasonably be construed to be a normal caregiving action.

- Were the police Risk Manager and Administrator notified?

- Interview facility staff (LPN, RN, CNA, Maintenance, Housekeeping) to determine if they know what to do if someone reports sexual abuse to them.

- Evaluate process success to mitigate reoccurrence and patient safety.

- Check the Patient Safety Committee and Governing Body Agendas to ensure the facility administration, quality, risk, Patient safety are aware with planned interventions.

- Assess the facility for proactive safety culture and awareness process

**ST - H0419 - RISK MANAGER REVIEW OF INCIDENT REPORTS**

**Title** RISK MANAGER REVIEW OF INCIDENT REPORTS

**Type** Rule

59A-10.0055(3), FAC

**Regulation Definition**

(3) Incident Report Review and Analysis. The risk manager shall be responsible for the regular and systematic reviewing of all incident reports including 15-day incident reports for the purpose of identifying trends or patterns as to time, place or persons: and upon emergence of any trend or pattern in incident occurrence shall develop recommendations for corrective actions and risk management prevention education and training. Summary data thus accumulated shall be systematically maintained for 3 years.

**Interpretive Guideline**

Review incident reports for the year and verify Risk Manager is using them to determine patterns and problem areas.  
Are the Code 15 reports included in the trending data?  
Interview the risk manager regarding the method utilized to identify trends, patterns, analysis, and corrective action.  
Review all pertinent documents for verification that the Risk Manager's recommendations were developed and the corrective action(s) implemented.  
Review in-service education documents for programs pertinent to risk management education and training relating to the corrective action(s).  
Verify that the past 3 years of accumulated summary data has been maintained and reviewed.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 244 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0420 - SUMMARY REPORT TO GOVERNING BODY**

**Title** SUMMARY REPORT TO GOVERNING BODY

**Type** Rule

59A-10.055(3)(a), FAC

**Regulation Definition**

(a) At least quarterly or more often as may be required by the governing body, the risk manager shall provide a summary report to the governing body which includes information about activities of risk management as defined herein.

**Interpretive Guideline**

- Interview the Risk Manager and staff about who presents the risk management summary report?
- Review the Governing Body agenda/minutes for risk management reporting of summaries of identified events, safety issues and reporting of current status of corrective action plans including Risk for intervention and follow-up process
- How is the risk management summary report being presented to the Governing Body?

**ST - H0421 - ANNUAL REPORT OF JUDGMENTS**

**Title** ANNUAL REPORT OF JUDGMENTS

**Type** Rule

395.0197(3), F.S.

**Regulation Definition**

(3) . . . Each licensed facility shall annually report to the agency and the Department of Health the name and judgments entered against each health care practitioner for which it assumes liability.

**Interpretive Guideline**

- Review annual documentation of reporting which identifies and summarizes judgments, not actions against practitioners?
- Have these identified practitioners been reported to the Department of Health and Agency for Healthcare Administration?

**ST - H0422 - ANNUAL REPORT SUMMARIZING INCIDENT REPORTS**

**Title** ANNUAL REPORT SUMMARIZING INCIDENT REPORTS

**Type** Rule

395.0197 (6)(a), (c), F.S.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 245 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(6)(a) Each licensed facility subject to this section shall submit an annual report to the agency summarizing the incident reports that have been filed in the facility for that year. The report shall include:

1. The total number of adverse incidents.
2. A listing, by category, of the types of operations, diagnostic or treatment procedures, or other actions causing the injuries, and the number of incidents occurring within each category.
3. A listing, by category, of the types of injuries caused and the number of incidents occurring within each category.
4. A code number using the health care professional's licensure number and a separate code number identifying all other individuals directly involved in adverse incidents to patients, the relationship of the individual to the licensed facility, and the number of incidents in which each individual has been directly involved. Each licensed facility shall maintain names of the health care professionals and individuals identified by code numbers for purposes of this section.
5. A description of all malpractice claims filed against the licensed facility, including the total number of pending and closed claims and the nature of the incident which led to, the persons involved in, and the status and disposition of each claim. Each report shall update status and disposition for all prior reports.

(c) The report submitted to the agency must also contain the name of the risk manager of the licensed facility, a copy of its policy and procedures which govern the measures taken by the facility and its risk manager to reduce the risk of injuries and adverse incidents, and the results of such measures. The annual report is confidential and is not available to the public pursuant to s. 119.07(1) or any other law providing access to public records. The annual report is not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate

**Interpretive Guideline**

- Review the Annual Report(s) submitted to AHCA for items 1 through 5.
- Review a sample of disciplinary actions and outcomes against practitioners and the - reporting of all actions to Department of Health/Medical Quality Assurance.
- Is the policy and procedures document included in the annual report?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 246 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

regulatory board. The annual report is not available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency or the appropriate regulatory board shall make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause.

**ST - H0423 - AGENCY ACCESS TO RECORD**

**Title** AGENCY ACCESS TO RECORD

**Type** Rule

395.0197(13) FS; 59A-10.0055(3) FAC

**Regulation Definition**

395.0197  
(13) The agency shall have access to all licensed facility records necessary to carry out the provisions of this section. The records obtained by the agency under subsection (6), subsection (7), or subsection (9) are not available to the public under s. 119.07(1), nor shall they be discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board, nor shall records obtained pursuant to s. 456.071 be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency or the appropriate regulatory board shall make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause, except that, with respect to medical review committee records, s. 766.101 controls.

**Interpretive Guideline**

- All facility records are to be made available to surveyors upon request.
- Surveyors are to notify their field office managers if a facility refuses access to records.
- The Agency shall have access to all records necessary to carry out the provisions of this section.
- The Agency may request the provider's meeting minutes as pursuant to Subsection 395.0197(13).
- These meeting minutes, however, are confidential and exempt from public records disclosure pursuant to Subsection 395.0197(14).
- Surveyors are to notify their field office managers/supervisors if a facility refuses access to record or if there is a question regarding the need to review meeting minutes to determine compliance
- Document the facility observations, interviews and record review findings on the appropriate survey form.

**NOTE:**

Reviews of the meeting Agenda(s) may provide sufficient information/evidence required to determine Risk Management Program compliance.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 247 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

59A-10.0055(3)

(b) Evidence of the incidents reporting and analysis system and copies of summary reports, incident reports filed within the facility, and evidence of recommended and accomplished corrective actions shall be made available for review to any authorized representative of the Agency upon request during normal working hours.

**ST - H0424 - UNLAWFUL COERCION OF REPORTING OBLIGATION**

**Title** UNLAWFUL COERCION OF REPORTING OBLIGATION

**Type** Rule

395.0197(19), F.S.

**Regulation Definition**

(19) It shall be unlawful for any person to coerce, intimidate, or preclude a risk manager from lawfully executing his or her reporting obligations pursuant to this chapter. Such unlawful action shall be subject to civil monetary penalties not to exceed \$10,000 per violation.

**Interpretive Guideline**

Interview the Risk Manager regarding their ability to report.

**ST - H0425 - PATIENT SAFETY PLAN**

**Title** PATIENT SAFETY PLAN

**Type** Rule

395.1012(1), F.S.

**Regulation Definition**

(1) Each licensed facility must adopt a patient safety plan. A plan adopted to implement the requirements of 42 C.F.R. s. 482.21 shall be deemed to comply with this requirement.

**Interpretive Guideline**

- Review the facility's patient safety plan for compliance with 42 CFR 482.21 (Quality Assurance and Performance Improvement Plan).
- Was the plan implemented? If not, contact field office manager/supervisor for further guidance.
- Does the facility utilize information gathered to demonstrate compliance with 42 CFR 482.21 (Quality Assurance and Performance Improvement Plan)?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 248 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

and Performance Improvement Plan).

**ST - H0426 - PATIENT SAFETY OFFICER AND COMMITTEE**

**Title** PATIENT SAFETY OFFICER AND COMMITTEE

**Type** Rule

395.1012(2), F.S.

**Regulation Definition**

(2) Each licensed facility shall appoint a patient safety officer and a patient safety committee, which shall include at least one person who is neither employed by nor practicing in the facility, for the purpose of promoting the health and safety of patients, reviewing and evaluating the quality of patient safety measures used by the facility, and assisting in the implementation of the facility patient safety plan.

**Interpretive Guideline**

- Determine if the facility has appointed a Patient Safety Officer and a patient safety committee.
- Interview the Patient Safety Officer regarding roles and responsibilities.
- Review the composition of the Patient Safety Committee.
- Determine the eligibility of the committee member not employed by the facility, not a contracted employee of the facility, nor in practice at the facility.
- Review facility documentation of the Patient Safety Committee activities such as agenda/minutes, reports, QA/PI projects and outcomes, Patient Safety Initiatives, etc.
- Review the process by which the committee reviews and evaluates the quality of patient safety measures implemented by the facility.
- Review the process by which the committee assists in the implementation of the facility's Patient Safety Plan.
- Is the facility documentation presented during the survey sufficient to determine compliance?

**NOTE:**

- Reviews of the meeting Agenda(s) may provide sufficient information/evidence required to determine Risk Management Program compliance.
- Determine Patient Safety Program for effective processes.

**ST - H0427 - Patient Safety**

**Title** Patient Safety

**Type** Rule

395.1012(3), F.S.; 59A-3.270(13)



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 249 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

395.1012(3)(a) Each hospital shall provide to any patient or patient's representative identified pursuant to s. 765.401(1) upon scheduling of nonemergency care, or to any other stabilized patient or patient's representative identified pursuant to s. 765.401(1) within 24 hours of the patient being stabilized or at the time of discharge, whichever comes first, written information on a form created by the agency which contains the following information available for the hospital for the most recent year and the statewide average for all hospitals related to the following quality measures:

1. The rate of hospital-acquired infections;
2. The overall rating of the Hospital Consumer Assessment of Healthcare Providers and Systems survey; and
3. The 15-day readmission rate.

(b) A hospital shall also provide to any person, upon request, the written information specified in paragraph (a).

(c) The information required by this subsection must be presented in a manner that is easily understandable and accessible to the patient and must also include an explanation of the quality measures and the relationship between patient safety and the hospital's data for the quality measures.

59A-3.270(13) Information provided pursuant to Section 395.1012(3)(a), F.S., must be provided on Quality Measures and Patient Safety Information, AHCA Form 3190-2001OL, April 2021, incorporated by reference and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-13013>. The form is available online at <https://www.floridahealthfinder.gov/index.html>.

**Interpretive Guideline**

Review patient charts to verify this information was provided for nonemergency care patients.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 250 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0428 - PATIENT ACCESS & SPECIALTY PROVIDERS**

**Title** PATIENT ACCESS & SPECIALTY PROVIDERS

**Type** Rule

395.1052, F.S.

**Regulation Definition**

Patient access to primary care and specialty providers; notification.-A hospital shall:

- (1) Notify each patient's primary care provider, if any, within 24 hours after the patient's admission to the hospital.
- (2) Inform the patient immediately upon admission that he or she may request to have the hospital's treating physician consult with the patient's primary care provider or specialist provider, if any, when developing the patient's plan of care. Upon the patient's request, the hospital's treating physician shall make reasonable efforts to consult with the patient's primary care provider or specialist provider when developing the patient's plan of care.
- (3) Notify the patient's primary care provider, if any, of the patient's discharge from the hospital within 24 hours after the discharge.
- (4) Provide the discharge summary and any related information or records to the patient's primary care provider, if any, within 14 days after the patient's discharge summary has been completed.

**Interpretive Guideline**

Interview patients, if possible, to determine if they received notification. Review patient medical charts to verify compliance with required time frames.

**ST - H0429 - Patient safety**

**Title** Patient safety

**Type** Rule

395.1012(4)

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 251 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(4) Each licensed facility must, at least biennially, conduct a patient safety culture survey using the applicable Survey on Patient Safety Culture developed by the federal Agency for Healthcare Research and Quality. Each facility shall conduct the survey anonymously to encourage completion of the survey by staff working in or employed by the facility. Each facility may contract to administer the survey. Each facility shall biennially submit the survey data to the agency in a format specified by rule, which must include the survey participation rate. Each facility may develop an internal action plan between conducting surveys to identify measures to improve the survey and submit the plan to the agency.

**Interpretive Guideline**

**ST - H0500 - Definitions**

**Title** Definitions

**Type** Memo Tag

395.002 FS; 59A-3.065&.246(1)(b)&.429(1)

**Regulation Definition**

395.002 Definitions.-As used in this chapter:

- (1) "Accrediting organizations" means national accreditation organizations that are approved by the Centers for Medicare and Medicaid Services and whose standards incorporate comparable licensure regulations required by the state.
- (2) "Agency" means the Agency for Health Care Administration.
- (3) "Ambulatory surgical center" means a facility, the primary purpose of which is to provide elective surgical care, in which the patient is admitted to and discharged from such facility within 24 hours, and which is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy, an office maintained by a physician

**Interpretive Guideline**

For treatment of surrendered infant - Infant is defined as a child who a licensed physician reasonably believes is approximately 30 days old or younger. Please refer to 383.50.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 252 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

for the practice of medicine, or an office maintained for the practice of dentistry may not be construed to be an ambulatory surgical center, provided that any facility or office which is certified or seeks certification as a Medicare ambulatory surgical center shall be licensed as an ambulatory surgical center pursuant to s. 395.003.

(4) "Biomedical waste" means any solid or liquid waste as defined in s. 381.0098(2)(a).

(5) "Clinical privileges" means the privileges granted to a physician or other licensed health care practitioner to render patient care services in a hospital, but does not include the privilege of admitting patients.

(6) "Department" means the Department of Health.

(7) "Director" means any member of the official board of directors as reported in the organization's annual corporate report to the Florida Department of State, or, if no such report is made, any member of the operating board of directors. The term excludes members of separate, restricted boards that serve only in an advisory capacity to the operating board.

(8) "Emergency medical condition" means:

(a) A medical condition manifesting itself by acute symptoms of sufficient severity, which may include severe pain, such that the absence of immediate medical attention could reasonably be expected to result in any of the following:

1. Serious jeopardy to patient health, including a pregnant woman or fetus.
2. Serious impairment to bodily functions.
3. Serious dysfunction of any bodily organ or part.

(b) With respect to a pregnant woman:

1. That there is inadequate time to effect safe transfer to another hospital prior to delivery;
2. That a transfer may pose a threat to the health and safety of the patient or fetus; or
3. That there is evidence of the onset and persistence of uterine contractions or rupture of the membranes.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 253 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(9) "Emergency services and care" means medical screening, examination, and evaluation by a physician, or, to the extent permitted by applicable law, by other appropriate personnel under the supervision of a physician, to determine if an emergency medical condition exists and, if it does, the care, treatment, or surgery by a physician necessary to relieve or eliminate the emergency medical condition, within the service capability of the facility.

(10) "Hospital-based off-campus emergency department" means a facility that:

- (a) Provides emergency services and care;
- (b) Is owned and operated by a licensed hospital and operates under the license of the hospital; and
- (c) Is located on separate premises from the hospital.

(11) "General hospital" means any facility which meets the provisions of subsection (13) and which regularly makes its facilities and services available to the general population.

(12) "Governmental unit" means the state or any county, municipality, or other political subdivision, or any department, division, board, or other agency of any of the foregoing.

(13) "Hospital" means any establishment that:

- (a) Offers services more intensive than those required for room, board, personal services, and general nursing care, and offers facilities and beds for use beyond 24 hours by individuals requiring diagnosis, treatment, or care for illness, injury, deformity, infirmity, abnormality, disease, or pregnancy; and
- (b) Regularly makes available at least clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, or other definitive medical treatment of similar extent, except that a critical access hospital, as defined in s. 408.07, shall not be required to make available treatment facilities for surgery, obstetrical care, or similar services as long as it maintains its critical access hospital designation and shall be required to make such

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 254 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

facilities available only if it ceases to be designated as a critical access hospital.

However, the provisions of this chapter do not apply to any institution conducted by or for the adherents of any well-recognized church or religious denomination that depends exclusively upon prayer or spiritual means to heal, care for, or treat any person. For purposes of local zoning matters, the term "hospital" includes a medical office building located on the same premises as a hospital facility, provided the land on which the medical office building is constructed is zoned for use as a hospital; provided the premises were zoned for hospital purposes on January 1, 1992.

(14) "Hospital bed" means a hospital accommodation which is ready for immediate occupancy, or is capable of being made ready for occupancy within 48 hours, excluding provision of staffing, and which conforms to minimum space, equipment, and furnishings standards as specified by rule of the agency for the provision of services specified in this section to a single patient.

(15) "Initial denial determination" means a determination by a private review agent that the health care services furnished or proposed to be furnished to a patient are inappropriate, not medically necessary, or not reasonable.

(16) "Intensive residential treatment programs for children and adolescents" means a specialty hospital accredited by an accrediting organization as defined in subsection (1) which provides 24-hour care and which has the primary functions of diagnosis and treatment of patients under the age of 18 having psychiatric disorders in order to restore such patients to an optimal level of functioning.

(17) "Licensed facility" means a hospital or ambulatory surgical center licensed in accordance with this chapter.

(18) "Lifesafety" means the control and prevention of fire and other life-threatening conditions on a premises for the purpose of preserving human life.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 255 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(19) "Managing employee" means the administrator or other similarly titled individual who is responsible for the daily operation of the facility.

(20) "Medical staff" means physicians licensed under chapter 458 or chapter 459 with privileges in a licensed facility, as well as other licensed health care practitioners with clinical privileges as approved by a licensed facility's governing board.

(21) "Medically necessary transfer" means a transfer made necessary because the patient is in immediate need of treatment for an emergency medical condition for which the facility lacks service capability or is at service capacity.

(22) "Person" means any individual, partnership, corporation, association, or governmental unit.

(23) "Premises" means those buildings, beds, and equipment located at the address of the licensed facility and all other buildings, beds, and equipment for the provision of hospital or ambulatory surgical care located in such reasonable proximity to the address of the licensed facility as to appear to the public to be under the dominion and control of the licensee. For any licensee that is a teaching hospital as defined in s. 408.07, reasonable proximity includes any buildings, beds, services, programs, and equipment under the dominion and control of the licensee that are located at a site with a main address that is within 1 mile of the main address of the licensed facility; and all such buildings, beds, and equipment may, at the request of a licensee or applicant, be included on the facility license as a single premises.

(24) "Private review agent" means any person or entity which performs utilization review services for third-party payors on a contractual basis for outpatient or inpatient services. However, the term shall not include full-time employees, personnel, or staff of health insurers, health maintenance organizations, or hospitals, or wholly owned subsidiaries thereof or affiliates under common ownership, when performing utilization review

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 256 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

for their respective hospitals, health maintenance organizations, or insureds of the same insurance group. For this purpose, health insurers, health maintenance organizations, and hospitals, or wholly owned subsidiaries thereof or affiliates under common ownership, include such entities engaged as administrators of self-insurance as defined in s. 624.031.

(25) "Service capability" means all services offered by the facility where identification of services offered is evidenced by the appearance of the service in a patient's medical record or itemized bill.

(26) "At service capacity" means the temporary inability of a hospital to provide a service which is within the service capability of the hospital, due to maximum use of the service at the time of the request for the service.

(27) "Specialty bed" means a bed, other than a general bed, designated on the face of the hospital license for a dedicated use.

(28) "Specialty hospital" means any facility which meets the provisions of subsection (13), and which regularly makes available either:

- (a) The range of medical services offered by general hospitals, but restricted to a defined age or gender group of the population;
- (b) A restricted range of services appropriate to the diagnosis, care, and treatment of patients with specific categories of medical or psychiatric illnesses or disorders; or
- (c) Intensive residential treatment programs for children and adolescents as defined in subsection (15).

(29) "Stabilized" means, with respect to an emergency medical condition, that no material deterioration of the condition is likely, within reasonable medical probability, to result from the transfer of the patient from a hospital.

(30) "Urgent care center" means a facility or clinic that provides immediate but not emergent ambulatory medical care



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 257 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

to patients. The term includes:

- (a) An offsite facility of a facility licensed under this chapter, or a joint venture between a facility licensed under this chapter and a provider licensed under chapter 458 or chapter 459, that does not require a patient to make an appointment and is presented to the general public in any manner as a facility where immediate but not emergent medical care is provided.
- (b) A clinic organization that is licensed under part X of chapter 400, maintains three or more locations using the same or a similar name, does not require a patient to make an appointment, and holds itself out to the general public in any manner as a facility or clinic where immediate but not emergent medical care is provided.
- (31) "Utilization review" means a system for reviewing the medical necessity or appropriateness in the allocation of health care resources of hospital services given or proposed to be given to a patient or group of patients.
- (32) "Utilization review plan" means a description of the policies and procedures governing utilization review activities performed by a private review agent.
- (33) "Validation inspection" means an inspection of the premises of a licensed facility by the agency to assess whether a review by an accrediting organization has adequately evaluated the licensed facility according to minimum state standards.

59A-3.065 Definitions.

In addition to definitions contained in chapters 395 and 408, part II, F.S., the following definitions shall apply specifically to hospitals, as used in rules 59A-3.065-.310, F.A.C.:

- (1) "Advanced Practice Registered Nurse" or "APRN" means a person licensed in the State of Florida under the provisions of chapter 464, F.S. to practice professional nursing and certified in advanced or specialized nursing practice.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 258 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(2) "Agency" means the Agency for Health Care Administration (AHCA).

(3) "Ambulatory care" means the delivery of care pertaining to non-emergency, adult, adolescent, and pediatric outpatient encounters, whether performed through the clinical departments of the hospital or an organized ambulatory program which is included as a component of the licensed hospital, regardless of the physical location of such services.

(4) "At or near the Time of Death" means that point in time in the care of the patient at which the procedures have begun for the determination and certification of brain death as defined under the provisions of section 382.009, F.S., or cardiorespiratory (cardiac) death as defined under the provisions of rule 59A-3.065, F.A.C.

(5) "Brain Death" means the determination of death under provisions of section 382.009, F.S., where there is irreversible cessation of the functioning of the entire brain, including the brain stem.

(6) "Cardiorespiratory Death" means the cessation of life which is manifested by the loss or absence of spontaneous heart beat and breathing.

(7) "Child abuse or neglect" means harm, pursuant to section 39.01(32), F.S., or threatened harm to a child's physical or mental health or welfare by the acts or omissions of a parent, adult household member, or other person responsible for the child's welfare, or, for purposes of reporting requirements, by any person.

(8) "Continuous" means available at all times without cessation, breaks or interruption.

(9) "Dentist" means a doctor of dentistry legally authorized to practice under chapter 466, F.S.

(10) "Designee or Requester" means a person or organization identified, designated, and delegated by the hospital administrator to carry out the provisions of this chapter and the responsibilities mandated by section 765.522, F.S., and to

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 259 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

make the request to the patient or next of kin for the donation of organs, tissues and eyes.

(11) "Diagnostic imaging" means those ionizing and non-ionizing radiological procedures, including but not limited to x-rays, and computerized tomographic scanning, requiring the supervision and expertise of a physician with appropriate training or experience.

(12) "District Medical Examiner" means a physician who fills a position defined according to the provisions of section 406.06, F.S.

(13) "Donation" means the free and voluntary gift of one or more organs, tissues or eyes for the purpose of medical research or transplant surgery.

(14) "Donor" means a person from whom organs, tissues or eyes have been surgically removed for the purpose of transplantation.

(15) "Emergency Medical Technician (EMT)" means any person who is certified as an EMT pursuant to chapter 401, F.S.

(16) "Eye bank" means a public or private entity which is involved in the retrieval, processing or distribution of human eye tissue for transplantation and certified pursuant to section 765.541, F.S. Funeral homes or direct disposers engaged solely in the retrieval of eye tissue are not considered an eye bank for these purposes.

(17) "Facilities" means those objects, including physical plant, equipment and supplies, necessary for providing required services.

(18) "General hospital" as defined in section 395.002(10), F.S., means any facility which meets the provisions of subsection (29) and which regularly makes its facilities and services available to the general population.

(19) "Governing board" means the individual, agency, group or corporation appointed, elected, or otherwise designated, in which the ultimate responsibility and authority for the conduct

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 260 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

of the hospital is vested.

(20) "Health professional" means a person specifically licensed to practice a health profession, or a person specifically trained to practice one or more aspects of a health profession by a school or program officially recognized by this State or accredited by a national accrediting organization.

(21) "Inpatient beds" means accommodations with supporting services for patients who are admitted by physician order with the expectation that the patient would stay in excess of 24 hours and occupy a bed.

(22) "Intensive residential treatment programs for children and adolescents" or "intensive residential treatment facilities" or "IRTF" means a specialty hospital restricted to providing intensive residential treatment programs for children and adolescents as defined in section 395.002(15), F.S.

(23) "Licensed practical nurse" means one who is currently licensed in the state of Florida to practice practical nursing as defined in chapter 464, F.S.

(24) "Long term care hospital" means a general hospital which:

(a) Meets the provisions of section 395.002(12), F.S.;

(b) Has an average length of inpatient stay greater than 25 days for all hospital beds; and,

(c) Meets the provisions of subsection 59C-1.002(28), F.A.C.

(25) "Medical Examiner's Case" means any death occurring in the State and which is defined according to the provisions of section 406.11, F.S.

(26) "Nursing services" means those services pertaining to the curative, restorative, and preventive aspects of nursing care that are performed or supervised by a registered professional nurse under the direction of a physician.

(27) "On duty" means personnel within the hospital, appropriately dressed, continuously alert and responsive to patient needs.

(28) "Operating room suite" means a room, or set of

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 261 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

physically contiguous rooms located on the same floor, used primarily for the purpose of performing operations and other physically invasive procedures on patients, as well as rooms for surgical supply and disinfecting.

(29) "Organ" means a body part such as a heart, kidney, pancreas, liver, or lung that requires vascular reanastomosis.

(30) "Organ Procurement Organization" means a public or private entity designated as an OPO by the Secretary of the U.S. Department of Health and Human Services (HHS) which is engaged in the process of recovering organs for the purposes of transplantation and certified pursuant to section 765.541, F.S.

(31) "Organized medical staff" means a formal organization of physicians and other health professionals approved by the governing board with the delegated responsibility to provide for the quality of all medical care, and other health care as appropriate, provided to patients, for planning for the improvement of that care, and for the ethical conduct and professional practices of its members. Nothing herein shall be construed to preclude a governing board from restricting membership on the organized medical staff to only those disciplines required to be included by Florida law.

(32) "Paramedic" means any person who is certified as a paramedic pursuant to chapter 401, F.S.

(33) "Pharmacist" means one who is licensed under chapter 465, F.S., and engages in the practice of the profession of pharmacy.

(34) "Physician" means a doctor of medicine or osteopathy legally authorized to practice under the provisions of chapter 458 or 459, F.S.

(35) "Physician Assistant" or "PA" means a person who is licensed to perform medical services delegated by the supervising physician pursuant to chapter 458 or 459, F.S.

(36) "Podiatrist" means a person legally authorized to practice podiatry under chapter 461, F.S.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 262 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(37) "Potential Donor" means any person approaching death or who has died in a Florida hospital and is deemed medically acceptable according to the medical standards of the affiliated OPO, tissue bank or eye bank for organ, tissue, or eye donation.

(38) "Premises" means those buildings, beds, and facilities located at the main address of the licensee and all other buildings, beds, and facilities for the provision of hospital care located in such reasonable proximity to the main address of the licensee as to appear to the public to be under the dominion and control of the licensee.

(39) "Provisional accreditation" means a determination by a hospital accrediting organization that substantial standards compliance deficiencies exist in a hospital.

(40) "Provisional license" means a restricted license issued to a hospital which does not meet requirements for a standard license, but is in compliance with the pertinent statutes and rules.

(41) "Psychiatric hospital" means a Class III specialty hospital primarily restricted to treating persons whose sole diagnosis, or in the event of more than one diagnosis, the principal diagnosis, as defined in the Diagnostic and Statistical Manual of Mental Disorders is a psychiatric disorder, as defined in rule 59C-1.040, F.A.C.

(42) "Qualified medical person" means for the purposes of section 395.1041, F.S., the licensed individual responsible for the operation of the emergency services area during the time of a transfer.

(43) "Quality improvement program" means a program of ongoing activities designed to objectively and systematically evaluate the quality of patient care and services, pursue opportunities to improve patient care and services, and resolve identified problems which applies standards of patient care to evaluate the quality of the hospital's performance.

(44) "Registered dietitian" means one who meets the standards

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 263 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

and qualifications established by the Commission on Dietetic Registration of the Academy of Nutrition and Dietetics and is currently registered with the Academy of Nutrition and Dietetics.

(45) "Registered professional nurse" means one who is currently licensed in the State of Florida to practice professional nursing as defined in chapter 464, F.S.

(46) "Rehabilitation hospital" means a Class III specialty hospital in which an organized program of integrated intensive care services is provided by a coordinated multidisciplinary team to patients with severe physical disabilities, as defined under paragraph 59C-1.039(2)(c), F.A.C.

(47) "Routine Inquiry Form" means a reporting document developed by the hospital that is used to indicate that a request for donation of organs, tissues, or eyes was made.

(48) "Rural hospital" means a general hospital which meets the definition of section 395.602(2)(e), F.S.

(49) "Selected Infectious Diseases" means Acquired Immunodeficiency Syndrome; anthrax; syphilis in an infectious stage; diphtheria; disseminated vaccinia; Hansen's disease; hepatitis A; hepatitis B; hepatitis non-A, non-B; Legionnaire's disease; malaria; measles; meningococcal meningitis; plague; poliomyelitis; psittacosis; pulmonary tuberculosis; Q fever; rabies; rubella; typhoid fever.

(50) "Special care unit" means a unit designated to provide acute care services, with a concentration of qualified professional staffing and supportive resources, to patients requiring extraordinary care on a concentrated and continuous 24-hour basis. Special care units include, but are not limited to burn, cardiac, cardiovascular surgery, neonatal, respiratory, renal care provided in the hospital, but not including ambulatory units, spinal injury units, trauma and multipurpose special care units, operating room suite, including medical-surgical intensive care or any combination of the above.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 264 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(51) "Substance abuse hospital" means a Class III specialty hospital primarily restricted to treating persons whose sole diagnosis, or in the event of more than one diagnosis, the principal diagnosis, as defined in the Diagnostic and Statistical Manual of Mental Disorders is a substance abuse disorder defined under paragraph 59C-1.041(2)(u), F.A.C.

(52) "Tissue" means any non-visceral or non-vascularized collection of similar cells and their associated intercellular substances. There are four generally accepted basic body tissues:

- (a) Epithelium (including corneal tissue);
- (b) Connective tissues including blood, bone and cartilage;
- (c) Muscle; and,
- (d) Nerve tissue.

(53) "Tissue Bank" means a public or private entity certified pursuant to section 765.541, F.S., which is involved in at least one of the following activities:

- (a) Procuring, processing, storing or distributing viable or nonviable human tissues to clinicians who are not involved in the procurement process;
- (b) Procuring, processing, and storing human tissues in one institution and making these tissues available to clinicians in other institutions; or
- (c) Procuring, processing, and storing human tissues for individual depositors and releasing these tissues to clinicians at the depositor's request.

(54) "Transplantation" means the surgical grafting or implanting in its entirety or in part one or more tissues or organs taken from another person.

59A-3.246 Licensed Programs.

(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



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 265 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

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.

(c) Therapeutic Procedures. An adult diagnostic cardiac catheterization program established pursuant to section 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.

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

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

59A-3.429 (1) Definitions. As used in this section:

(a) "Telemedicine" means on call and readily available for remote consultation, diagnosis, and treatment by means of audiovisual telecommunications technology.

(b) "Onsite" means on call and readily available for consultation and continuous patient management.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 266 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

383.145 (2)

DEFINITIONS.-As used in this section, the term:

(a) "Audiologist" means a person licensed under part I of chapter 468 to practice audiology.

(b) "Department" means the Department of Health.

(c) "Hearing loss" means a hearing loss of 30 dB HL or greater in the frequency region important for speech recognition and comprehension in one or both ears, approximately 500 through 4,000 hertz.

(d) "Hospital" means a facility as defined in s. 395.002(13) and licensed under chapter 395 and part II of chapter 408.

(e) "Infant" means an age range from 30 days through 12 months.

(f) "Licensed health care provider" means a physician or physician assistant licensed under chapter 458; an osteopathic physician or physician assistant licensed under chapter 459; an advanced practice registered nurse, a registered nurse, or a licensed practical nurse licensed under part I of chapter 464; a midwife licensed under chapter 467; or a speech-language pathologist or an audiologist licensed under part I of chapter 468.

(g) "Management" means the habilitation of the child with hearing loss.

(h) "Newborn" means an age range from birth through 29 days.

(i) "Physician" means a person licensed under chapter 458 to practice medicine or chapter 459 to practice osteopathic medicine.

(j) "Screening" means a test or battery of tests administered to determine the need for an in-depth hearing diagnostic evaluation.

(k) "Toddler" means a child from 12 months to 36 months of age.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 267 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0501 - Physician Notification**

**Title** Physician Notification

**Type** Rule

395.0192 FS

**Regulation Definition**

Duty to notify physicians.-A hospital shall notify each obstetrical physician who has privileges at the hospital at least 120 days before the hospital closes its obstetrical department or ceases to provide obstetrical services.

**Interpretive Guideline**

This act shall take effect July 1, 2016.

Determine if the hospital provides or provided obstetrical services. If the hospital has obstetrical services Interview the person responsible for the obstetrical department to determine any closures or breaks in service in the department. Review the obstetrical admission and discharges to verify any closures or gaps in service. If the hospital experienced a closure or a stop in providing obstetrical services, determine if the obstetrical physicians were notified at least 120 days prior to the closing of the obstetrical department.

Review the hospitals policy and procedures for department closures and obstetrical physician notifications.

If the hospital does not have obstetrical services, determine if the hospital had offered the service in the past and stopped providing the service. Determine if the facility provided appropriate notification to the obstetric physicians at least 120 days prior to closing or ceasing the obstetrical service.

**ST - H0502 - Violations of Emergency Access Reporting**

**Title** Violations of Emergency Access Reporting

**Type** Rule

59A-3.255(6)(h) FAC

**Regulation Definition**

(h) Hospital personnel and physicians shall report any apparent violations of emergency access requirements under section 395.1041, F.S., to the Agency. Reports shall be made within 30 days following the occurrence. Violations include failure to report when on-call or intentionally misrepresenting the patient's condition in cases of medically necessary transfers or in determining the presence or absence of an

**Interpretive Guideline**

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 268 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

emergency medical condition or rendering appropriate emergency services and care, or failure or refusal to sign a certificate of transfer as required by this section.

**ST - H0503 - EMERGENCY SERVICES; DISCRIMINATION; LIABILITY**

**Title** EMERGENCY SERVICES; DISCRIMINATION; LIABILITY

**Type** Rule

395.1041(3)(a)-(c)

**Regulation Definition**

(3) EMERGENCY SERVICES; DISCRIMINATION; LIABILITY OF FACILITY OR HEALTH CARE PERSONNEL.-

(a) Every general hospital which has an emergency department shall provide emergency services and care for any emergency medical condition when:

1. Any person requests emergency services and care; or
2. Emergency services and care are requested on behalf of a person by:
  - a. An emergency medical services provider who is rendering care to or transporting the person; or
  - b. Another hospital, when such hospital is seeking a medically necessary transfer, except as otherwise provided in this section.

(b) Arrangements for transfers must be made between hospital emergency services personnel for each hospital, unless other arrangements between the hospitals exist.

(c) A patient, whether stabilized or not, may be transferred to another hospital which has the requisite service capability or is not at service capacity, if:

1. The patient, or a person who is legally responsible for the patient and acting on the patient's behalf, after being informed

**Interpretive Guideline**

Review emergency room patient, including patient transferred after stabilization to another hospital for compliance with this regulation.

For surrendered infants, physician/hospital liability concerns please refer to H0029

**Agency for Health Care Administration  
ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 269 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

of the hospital's obligation under this section and of the risk of transfer, requests that the transfer be effected;

2. A physician has signed a certification that, based upon the reasonable risks and benefits to the patient, and based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another hospital outweigh the increased risks to the individual's medical condition from effecting the transfer; or

3. A physician is not physically present in the emergency services area at the time an individual is transferred and a qualified medical person signs a certification that a physician, in consultation with personnel, has determined that the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual's medical condition from effecting the transfer. The consulting physician must countersign the certification; provided that this paragraph shall not be construed to require acceptance of a transfer that is not medically necessary.

**ST - H0504 - Price Transparency -Prov Timely/Accurate Info**

**Title** Price Transparency -Prov Timely/Accurate Info

**Type** Rule

395.301(1)(a-b)6, (c)-(d)1; 59A-3.256(2)

**Regulation Definition**

395.301 Price transparency; itemized patient statement or bill; patient admission status notification.-

(1) A facility licensed under this chapter shall provide timely and accurate financial information and quality of service measures to patients and prospective patients of the facility, or to patients' survivors or legal guardians, as appropriate. Such information shall be provided in accordance with this section

**Interpretive Guideline**

Interview the Risk Manager and review facility website contents. Follow survey process outline in the current risk management documents.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 270 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

and rules adopted by the agency pursuant to this chapter and s. 408.05. Licensed facilities operating exclusively as state facilities are exempt from this subsection.

(a) Each licensed facility shall make available to the public on its website information on payments made to that facility for defined bundles of services and procedures. The payment data must be presented and searchable in accordance with, and through a hyperlink to, the system established by the agency and its vendor using the descriptive service bundles developed under s. 408.05

(b) Each licensed facility shall post on its website a consumer-friendly list of standard charges for at least 300 distinct shoppable health care services, or an Internet-based price estimator tool meeting federal standards. If a facility provides fewer than 300 distinct shoppable health care services, it shall make available on its website the standard charges for each service it provides. As used in this paragraph, the term:

1. "Shoppable health care service" means a service that can be scheduled by a healthcare consumer in advance. The term includes, but is not limited to, the services described in s. 627.6387(2)(e) and any services defined in regulations or guidance issued by the United States Department of Health and Human Services.

2. "Standard charge" has the same meaning as that term is defined in regulations or guidance issued by the United States Department of Health and Human Services for purposes of hospital price transparency.

(3)(c). At a minimum, the facility shall provide the estimated average payment received from all payors, excluding Medicaid and Medicare, for the descriptive service bundles available at that facility and the estimated payment range for such bundles. Using plain language, comprehensible to an ordinary layperson, the facility must disclose that the information on average payments and the payment ranges is an

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 271 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

estimate of costs that may be incurred by the patient or prospective patient and that actual costs will be based on the services actually provided to the patient. The facility's website must:

1. Provide information to prospective patients on the facility's financial assistance policy, including the application process, payment plans, and discounts, and the facility's charity care policy and collection procedures.
2. If applicable, notify patients and prospective patients that services may be provided in the health care facility by the facility as well as by other health care providers who may separately bill the patient and that such health care providers may or may not participate with the same health insurers or health maintenance organizations as the facility.
3. Inform patients and prospective patients that they may request from the facility and other health care providers a more personalized estimate of charges and other information, and inform patients that they should contact each health care practitioner who will provide services in the hospital to determine the health insurers and health maintenance organizations with which the health care practitioner participates as a network provider or preferred provider.
4. Provide the names, mailing addresses, and telephone numbers of the health care practitioners and medical practice groups with which it contracts to provide services in the facility and instructions on how to contact the practitioners and groups to determine the health insurers and health maintenance organizations with which they participate as network providers or preferred providers.

(b)1. Upon request, and before providing any nonemergency medical services, each licensed facility shall provide in writing or by electronic means a good faith estimate of reasonably anticipated charges by the facility for the treatment of the patient's or prospective patient's specific condition. The

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 272 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

facility must provide the estimate to the patient or prospective patient within 7 business days after the receipt of the request and is not required to adjust the estimate for any potential insurance coverage. The estimate may be based on the descriptive service bundles developed by the agency under s. 408.05(3)(c) unless the patient or prospective patient requests a more personalized and specific estimate that accounts for the specific condition and characteristics of the patient or prospective patient. The facility shall inform the patient or prospective patient that he or she may contact his or her health insurer or health maintenance organization for additional information concerning cost-sharing responsibilities.

2. In the estimate, the facility shall provide to the patient or prospective patient information on the facility's financial assistance policy, including the application process, payment plans, and discounts and the facility's charity care policy and collection procedures.

3. The estimate shall clearly identify any facility fees and, if applicable, include a statement notifying the patient or prospective patient that a facility fee is included in the estimate, the purpose of the fee, and that the patient may pay less for the procedure or service at another facility or in another health care setting.

4. Upon request, the facility shall notify the patient or prospective patient of any revision to the estimate.

5. In the estimate, the facility must notify the patient or prospective patient that services may be provided in the health care facility by the facility as well as by other health care providers that may separately bill the patient, if applicable.

6. The facility shall take action to educate the public that such estimates are available upon request.

(c) Each facility shall make available on its website a hyperlink to the health-related data, including quality measures and statistics that are disseminated by the agency



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 273 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

pursuant to s. 408.05. The facility shall also take action to notify the public that such information is electronically available and provide a hyperlink to the agency's website.

(d)1. Upon request, and after the patient's discharge or release from a facility, the facility must provide to the patient or to the patient's survivor or legal guardian, as appropriate, an itemized statement or a bill detailing in plain language, comprehensible to an ordinary layperson, the specific nature of charges or expenses incurred by the patient. The initial statement or bill shall be provided within 7 days after the patient's discharge or release or after a request for such statement or bill, whichever is later. The initial statement or bill must contain a statement of specific services received and expenses incurred by date and provider for such items of service, enumerating in detail as prescribed by the agency the constituent components of the services received within each department of the licensed facility and including unit price data on rates charged by the licensed facility. The statement or bill must also clearly identify any facility fee and explain the purpose of the fee. The statement or bill must identify each item as paid, pending payment by a third party, or pending payment by the patient, and must include the amount due, if applicable. If an amount is due from the patient, a due date must be included. The initial statement or bill must direct the patient or the patient's survivor or legal guardian, as appropriate, to contact the patient's insurer or health maintenance organization regarding the patient's cost-sharing responsibilities.

2. Any subsequent statement or bill provided to a patient or to the patient's survivor or legal guardian, as appropriate, relating to the episode of care must include all of the information required by subparagraph 1., with any revisions clearly delineated.

3. Each statement or bill provided pursuant to this subsection:

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 274 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

- a. Must include notice of hospital-based physicians and other health care providers who bill separately.
- b. May not include any generalized category of expenses such as "other" or "miscellaneous" or similar categories.
- c. Must list drugs by brand or generic name and not refer to drug code numbers when referring to drugs of any sort.
- d. Must specifically identify physical, occupational, or speech therapy treatment by date, type, and length of treatment when such treatment is a part of the statement or bill.

59A-3.256 Price Transparency and Patient Billing.

(2) Estimate. The hospital shall provide an estimate upon request of the patient, prospective patient, or legal guardian for nonemergency medical services.

(a) An estimate or an update to a previous estimate shall be provided within 7 business days from receipt of the request. Unless the patient requests a more personalized estimate, the estimate may be based upon the average payment received for the anticipated service bundle. Every estimate shall include:

1. A statement informing the requestor to contact their health insurer or HMO for anticipated cost sharing responsibilities,
2. A statement advising the requestor that the actual cost may exceed the estimate,
3. The web address of the hospital's financial assistance policies, charity care policy, and collection procedures,
4. A description and purpose of any facility fees, if applicable,
5. A statement that services may be provided by other health care providers who may bill separately,
6. A statement, including a web address if different from above, that contact information for health care practitioners and medical practice groups that are expected to bill separately is available on the hospital's website; and,
7. A statement advising the requestor that the patient may pay less for the procedure or service at another facility or in another health care setting.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 275 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(b) If the hospital provides a non-personalized estimate, the estimate shall include a statement that a personalized estimate is available upon request.

(c) A personalized estimate must include the charges specific to the patient's anticipated services.

**ST - H0505 - Price Transparency - Patient Liaison Phone**

**Title** Price Transparency - Patient Liaison Phone

**Type** Rule

395.301(2) FS

**Regulation Definition**

(2) Each itemized statement or bill must prominently display the telephone number of the medical facility's patient liaison who is responsible for expediting the resolution of any billing dispute between the patient, or the patient's survivor or legal guardian, and the billing department.

**Interpretive Guideline**

Review itemized statement or bills to determine compliance with required information including the telephone number of the patient liaison responsible for billing disputes.

**ST - H0506 - Price Transparency - Observation vs IP Status**

**Title** Price Transparency - Observation vs IP Status

**Type** Rule

395.301(3) FS; 59A-3.270(12) FAC

**Regulation Definition**

395.301(3) If a licensed facility places a patient on observation status rather than inpatient status, the licensed facility must immediately notify the patient of such status using the form adopted under 42 C.F.R. s. 489.20 for Medicare patients or a form adopted by agency rule for non-Medicare patients. Such notification must be documented in the patient's medical records and discharge papers. The

**Interpretive Guideline**

Follow survey process outline in the current risk management documents.

- Review 1 record for patient on "observation status" who has been discharged for documentation.
- Review the facility policy and procedure for the notification of observation services/status and determine the method/mode of notification to patient, legal guardian, or patient survivor.
- The methods or mode of communication may include discharge papers, brochures, signage or other communication methods.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 276 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

patient's survivor or legal guardian must be notified of observation services through discharge papers, which may also include brochures, signage, or other forms of communication for this purpose.

59A-3.270(12) Each hospital must immediately notify a non-Medicare patient or the patient's representative when the patient is placed on observation status. Notification must utilize the Hospital Outpatient Observation Notice, AHCA Form 3190-2000, April 2021, incorporated by reference and available at

<https://www.flrules.org/Gateway/reference.asp?No=Ref-13012>

. The form is available online at

<http://www.ahca.myflorida.com/HQAlicensureforms>.

(a) A hospital may provide AHCA Form 3190-2000 in electronic format, including electronic signature, unless the patient requests a paper version.

(b) The signed version must be incorporated into the patient's medical record and provided to the patient, patient's survivor, or legal guardian through discharge papers.

**ST - H0507 - Price Transparency - Records to Verify Accur**

**Title** Price Transparency - Records to Verify Accur

**Type** Rule

395.301(4) FS

**Regulation Definition**

(4) A licensed facility shall make available to a patient all records necessary for verification of the accuracy of the patient's statement or bill within 10 business days after the request for such records. The records must be made available in the facility's offices and through electronic means that comply with the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. s. 1320d, as amended.

**Interpretive Guideline**

- Review the Policy and procedure for the request and release of patient records needed to verify patient billing statement.
- Interview billing staff; ask if any patients requested records in order to verify the accuracy of their billing statement. Inquire about how they ensure this information is available to the patient, legal guardian or patient survivor before or after bill payment. Verify with billing staff how the facility charges for copies of the record. Is it per the policy and procedure?
- If any patients requested records in order to verify the accuracy of their billing statements, review one of those

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 277 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

Such records must be available to the patient before and after payment of the statement or bill. The facility may not charge the patient for making such verification records available; however, the facility may charge its usual fee for providing copies of records as specified in s. 395.3025.

patient records to ensure compliance within the 10-business day rule.

- Determine how the facility is offering electronic record review and does this offer the information needed for accuracy review of billed items.

**ST - H0508 - Price Transparency - Billing Request**

**Title** Price Transparency - Billing Request

**Type** Rule

395.301(5) FS; 59A-3.256(3) FAC

**Regulation Definition**

395.301  
(5) Each facility shall establish a method for reviewing and responding to questions from patients concerning the patient's itemized statement or bill. Such response shall be provided within 7 business days after the date a question is received. If the patient is not satisfied with the response, the facility must provide the patient with the contact information of the agency to which the issue may be sent for review.

59A-3.256

(3) Itemized statement or bill. The hospital shall provide an itemized statement or bill upon request of the patient or the patient's survivor or legal guardian. The itemized statement or bill shall be provided within 7 business days after the patient's discharge or release, or 7 business days after the request, whichever is later. The itemized statement or bill must include:

- (a) A description of the individual charges from each department or service area by date, as prescribed in subsection 395.301(1)(d), F.S.;
- (b) Contact information for health care practitioners or medical practice groups that are expected to bill separately

**Interpretive Guideline**

- Review the Policy and Procedure for addressing patient questions regarding the itemized statement or bill. Does the Policy and Procedure include the within 7 business day response timeframe?
- Review 1 patient's submission of questions (Additional patient submissions may be added to determine compliance status) to determine if facility responded within 7 business days after the question was submitted. If there were any patients not satisfied with the facility's response, review that record to determine if the facility provided the patient with AHCA contact information.
- Interview the billing staff to determine if the 7-business day response occurs after the question is received. How is the billing staff monitoring for compliance within the timeframe once a question is submitted?

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 278 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

based on services provided; and,  
(c) The hospital's contact information for billing questions and disputes.

**ST - H0509 - Price Transparency - Website Posting**

**Title** Price Transparency - Website Posting

**Type** Rule

395.301(6-7);59A-3.256(1) & 59A-3.066(7)

**Regulation Definition**

395.301  
(6) Each facility shall establish an internal process for reviewing and responding to grievances from patients. Such process must allow a patient to dispute charges that appear on the patient's itemized statement or bill. The facility shall prominently post on its website and indicate in bold print on each itemized statement or bill the instructions for initiating a grievance and the direct contact information required to initiate the grievance process. The facility must provide an initial response to a patient grievance within 7 business days after the patient formally files a grievance disputing all or a portion of an itemized statement or bill.  
(7) Each licensed facility shall disclose to a patient, a prospective patient, or a patient's legal guardian whether a cost-sharing obligation for a particular covered health care service or item exceeds the charge that applies to an individual who pays cash or the cash equivalent for the same health care service or item in the absence of health insurance coverage. Failure to provide a disclosure in compliance with this subsection may result in a fine not to exceed \$500 per incident.

59A-3.256 Price Transparency and Patient Billing.

(1) Website. Each hospital shall make available to patients and

**Interpretive Guideline**

Review hospital website during off-site prep.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 279 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

prospective patients price transparency and patient billing information on its website regarding the availability of estimates of costs that may be incurred by the patient, financial assistance, billing practices, and a hyperlink to the Agency's service bundle pricing website. The content on the hospital's website shall be reviewed at least every 90 days and updated as needed to maintain timely and accurate information. For the purpose of this rule, service bundles means the reasonably expected hospital services and care provided to a patient for a specific treatment, procedure, or diagnosis as posted on the Agency's website. In accordance with section 395.301, F.S., the hospital's website must include:

- (a) A hyperlink to the Agency's pricing website upon implementation of the same that provides information on payments made to the facilities for defined service bundles and procedures. The Agency's pricing website is located at: <http://pricing.floridahealthfinder.gov>;
- (b) A statement informing patients and prospective patients that the service bundle information is a non-personalized estimate of costs that may be incurred by the patient for anticipated services and that actual costs will be based on services actually provided to the patient;
- (c) A statement informing patients and prospective patients of their right to request a personalized estimate from the hospital;
- (d) A statement informing patients of the hospital's financial assistance policy, charity care policy, and collection procedure;
- (e) A list of names and web addresses of health insurers and health maintenance organizations (HMO) contracted with the hospital as a network provider or participating provider;
- (f) A list of names and contact information of health care practitioners and medical practice groups contracted to provide services within the hospital, grouped by specialty or service; and,
- (g) A statement informing patients to contact the health care

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 280 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

practitioners anticipated to provide services to the patient while in the hospital regarding a personalized estimate, billing practices, and participation with the patient's insurance provider or HMO as the practitioners may not participate with the same health insurers or HMO as the hospital.

59A-3.066(7) All hospitals must make available on their Internet websites a description of and link to the Agency's webpage which contains the hospital patient charge and performance outcome data that is collected pursuant to Section 408.061(1), F.S. and, if requested, hospitals must provide a hard copy of the description and the link.

**ST - H0510 - EMERGENCY SERVICES; DISCRIMINATION; LIABILITY**

**Title** EMERGENCY SERVICES; DISCRIMINATION; LIABILITY

**Type** Rule

395.1041(3)(i)

**Regulation Definition**

(j) If a hospital subject to the provisions of this chapter does not maintain an emergency department, its employees shall nevertheless exercise reasonable care to determine whether an emergency medical condition exists and shall direct the persons seeking emergency care to a nearby facility which can render the needed services and shall assist the persons seeking emergency care in obtaining the services, including transportation services, in every way reasonable under the circumstances.

**Interpretive Guideline**



**Agency for Health Care Administration  
ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 281 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0511 - Emergency Services - Off Campus ED**

**Title** Emergency Services - Off Campus ED

**Type** Rule

395.1041(3)(m)

**Regulation Definition**

**Interpretive Guideline**

(3) EMERGENCY SERVICES; DISCRIMINATION;  
LIABILITY OF FACILITY OR HEALTH CARE  
PERSONNEL.-

(m)1. A hospital-based off-campus emergency department may not hold itself out to the public as an urgent care center and must clearly identify itself as a hospital emergency department, using, at a minimum, prominent lighted external signage that includes the word "EMERGENCY" or "ER" in conjunction with the name of the hospital. If a hospital-based off-campus emergency department is located on the same premises as an urgent care center, the signage may also identify the urgent care center.

2. A hospital-based off-campus emergency department shall conspicuously post signs at locations that are readily accessible to and visible by patients outside the entrance to the facility and in patient waiting areas which state the following: "THIS IS A HOSPITAL EMERGENCY DEPARTMENT."  
Unless the hospital-based off-campus emergency department shares a premises and a public entrance with an urgent care center, the signs must also state the following: "THIS IS NOT AN URGENT CARE CENTER. HOSPITAL EMERGENCY DEPARTMENT RATES ARE BILLED FOR OUR SERVICES." The signs must also specify the facility's average facility fee, if any, and notify the public that the facility or a physician providing medical care at the facility may be an out-of-network provider. The signs must be at least 2 square feet in size and the text must be in at least 36 point type.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 282 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

3. Except as provided in this subparagraph, any advertisement for a hospital-based off-campus emergency department must include the following statement: "This emergency department is part of (insert hospital name)." Unless the hospital-based off-campus emergency department is located on the same premises as an urgent care center that is advertised in the same advertisement, the advertisement must also include the following statement: "This is not an urgent care center. Its services and care are billed at hospital emergency department rates." Any billboard advertising a hospital-based off-campus emergency department which measures at least 200 square feet must include the following statement in clearly legible contrasting color text at least 15 inches high: "(INSERT NAME OF HOSPITAL) EMERGENCY DEPARTMENT." Unless the hospital-based off-campus emergency department is located on the same premises as an urgent care center that is advertised on the same billboard, such billboard must also include the following statement in clearly legible contrasting color text at least 15 inches high: "THIS IS NOT AN URGENT CARE CENTER."

4. The agency shall post on its website, and annually update, information that describes the differences between a hospital-based off-campus emergency department and an urgent care center. Each hospital shall post a link to such information in a prominent location on its website. Such description must include:

- a. At least two examples illustrating the impact on insured and insurer paid amounts of inappropriate utilization of nonemergent services and care in a hospital emergency department setting compared to utilization of nonemergent services and care in an urgent care center;
- b. An interactive tool to locate local urgent care centers; and
- c. What to do in the event of a true emergency.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 283 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0512 - REPORTING OF CONTROLLED SUBSTANCE OVERDOSES**

**Title** REPORTING OF CONTROLLED SUBSTANCE OVERDOSES

**Type** Rule

395.1041(8) FS

**Regulation Definition**

**Interpretive Guideline**

395.1041 Access to emergency services and care.-  
(8) REPORTING OF CONTROLLED SUBSTANCE OVERDOSES.-A hospital emergency department or an urgent care center that treats and releases a person in response to a suspected or actual overdose of a controlled substance must report such incident to the department if the patient was not transported by a transport service operating pursuant to part III of chapter 401. Such reports must be made using an appropriate method with secure access, including, but not limited to, the Washington/Baltimore High Intensity Drug Trafficking Overdose Detection Mapping Application Program, the Florida Prehospital EMS Tracking and Reporting System (EMSTARS), or another program identified by department rule. If a hospital emergency department or an urgent care center reports such an incident, it must use its best efforts to make the report to the department within 120 hours after becoming aware of the incident.

**ST - H0525 - Hospital Classification**

**Title** Hospital Classification

**Type** Rule

59A-3.252(2-5) FAC

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 284 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

(2) In addition to other requirements specified in these rules, all licensed hospitals shall have at least the following:

- (a) Inpatient beds;
- (b) A governing authority legally responsible for the conduct of the hospital;
- (c) A chief executive officer or other similarly titled official to whom the governing authority delegates the full-time authority for the operation of the hospital in accordance with the established policy of the governing authority;
- (d) An organized medical staff to which the governing authority delegates responsibility for maintaining proper standards for medical and other health care;
- (e) A current and complete medical record for each patient admitted to the hospital;
- (f) A policy requiring that all patients be admitted on the authority of and under the care of a member of the organized medical staff;
- (g) Facilities and professional staff available to provide food to patients to meet their nutritional needs;
- (h) A procedure for providing care in emergency cases;
- (i) A method and policy for infection control; and,
- (j) An on-going organized program to enhance the quality of patient care and review the appropriateness of utilization of services.

(3) In addition to the requirements of subsection (2) and other requirements of these rules, Class I, and Class II hospitals shall have at least the following:

- (a) One licensed registered nurse on duty at all times on each floor or similarly titled part of the hospital for rendering patient care services;
- (b) A pharmacy supervised by a licensed pharmacist either in the facility or by contract sufficient to meet patient needs;
- (c) Diagnostic imaging services either in the facility or by contract sufficient to meet patient needs;

**Interpretive Guideline**

- Refer to 59A-3.252 for classification of hospital.
- Observe for requirements in regulation for the class of the hospital.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 285 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

- (d) Clinical laboratory services either in the facility or by contract sufficient to meet patient needs;
- (e) Operating room services; and,
- (f) Anesthesia service.

(4) In addition to the requirements of subsection (2) and other requirements of these rules, all Class II, Class III and Class IV hospitals shall provide the treatment services, equipment, supplies and staff appropriate to the particular category of patients treated at the facility.

(5) All Class III hospitals, in addition to meeting the requirements of subsection (2) and other requirements of these rules, must provide:

- (a) For at least one qualified staff person at all times on each floor or similarly titled part of the hospital for rendering patient care services;
- (b) A pharmacy supervised by a licensed pharmacist either in the facility or by contract sufficient to meet patient needs;
- (c) Diagnostic imaging services either in the facility or by contract sufficient to meet patient needs;
- (d) Clinical laboratory services, either in the facility or by contract sufficient to meet patient needs; and,
- (e) Any other services, when provided by a Class III or Class IV hospital, shall meet the standards pertinent to that particular service as promulgated in rules 59A-3.065 through 59A-3.303, F.A.C., as applicable.

**ST - H0526 - Patient Rights - Treatment**

**Title** Patient Rights - Treatment

**Type** Rule

395.1041(6)

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 286 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

**(6) RIGHTS OF PERSONS BEING TREATED.-**

- (a) A hospital providing emergency services and care to a person who is being involuntarily examined under the provisions of s. 394.463 shall adhere to the rights of patients specified in part I of chapter 394 and the involuntary examination procedures provided in s. 394.463, regardless of whether the hospital, or any part thereof, is designated as a receiving or treatment facility under part I of chapter 394 and regardless of whether the person is admitted to the hospital.
- (b) Each hospital with an emergency department shall develop a best practices policy to promote the prevention of unintentional drug overdoses. The policy may include, but is not limited to:
1. A process to obtain the patient's consent to notify the patient's next of kin, and each physician or health care practitioner who prescribed a controlled substance to the patient, regarding the patient's overdose, her or his location, and the nature of the substance or controlled substance involved in the overdose.
  2. A process for providing the patient or the patient's next of kin with information about licensed substance abuse treatment services, voluntary admission procedures under part IV of chapter 397, involuntary admission procedures under part V of chapter 397, and involuntary commitment procedures under chapter 394.
  3. Guidelines for emergency department health care practitioners authorized to prescribe controlled substances to reduce the risk of opioid use, misuse, and addiction.
  4. The use of licensed or certified behavioral health professionals or peer specialists in the emergency department to encourage the patient to seek substance abuse treatment.
  5. The use of Screening, Brief Intervention, and Referral to Treatment protocols in the emergency department.
- This paragraph may not be construed as creating a cause of action by any party.

**Interpretive Guideline**

- Review related policies and confirm items a-b1-6.
- Interview staff as it relates to the topics covered in items a-b1-6.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 287 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0527 - Spontaneous Fetal Demise**

**Title** Spontaneous Fetal Demise

**Type** Rule

59A-3.281, FAC

**Regulation Definition**

When a spontaneous fetal demise occurs after a gestation of less than 20 completed weeks, the health care facility identified in section 383.33625(4), F.S., shall follow the provisions of that section and shall provide AHCA Form 3100-0006, January 2005, Notification of Disposition of Fetal Demise, to the mother for her completion. AHCA Form 3100-0006, January 2005 is incorporated in this rule by reference and available at [http://ahca.myflorida.com/MCHQ/Health\\_Facility\\_Regulation/Hospital\\_Outpatient/hospital.shtml](http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/hospital.shtml), or from the Hospital and Outpatient Services Unit at 2727 Mahan Drive, MS #31, Tallahassee, FL 32308. A copy of the signed and completed form shall be retained in the mother's medical record and shall be available for review by the Agency or Department of Health.

**Interpretive Guideline**

- Interview risk management staff for spontaneous fetal demise occurrences
- Review the medical records for the notification of disposition of fetal demise form.

**ST - H0528 - ADULT CARDIO LEVEL I**

**Title** ADULT CARDIO LEVEL I

**Type** Rule

59A-3.246(2)(a)8-(b)

**Regulation Definition**

- (2) Level I Adult Cardiovascular Services.
- (a) Licensure.

**Interpretive Guideline**

Interview the American College of Cardiology-National Cardiovascular Data Registry site manager about reporting to registry

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 288 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

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:

Review current profile with registry

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;



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 289 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

- 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

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

*Printed 08/07/2024*

Page 290 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

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. 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 update the information in two through five above shall cause the license to expire.

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

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

2. At licensure renewal, interventional cardiologists shall perform a minimum of 50 interventional cardiology procedures per year averaged over a 2-year period or be

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

*Printed 08/07/2024*

Page 291 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

confirmed by the review process described in subparagraph 59A-3.246(3)(b)3., F.A.C.

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

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

5. Coronary care unit nursing staff must be trained and experienced with invasive hemodynamic monitoring, operation of temporary pacemaker, management of 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.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 292 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0529 - BURN UNITS**

**Title** BURN UNITS

**Type** Rule

59A-3.246(5)(a) & (d), FAC

**Regulation Definition**

(5) Burn Units.

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

(d) Each provider of burn unit services shall maintain a policy and procedure manual, available for review by the Agency,

**Interpretive Guideline**

Interview medical director about guidelines for operation of a burn center and ask about verification evidence from the American Burn Association.

Review the policy and procedure manual for the required documentation of a plan to provide services to Medicaid and charity care patients.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 293 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

which documents a plan to provide services to Medicaid and charity care patients.

**ST - H0530 - Adult Cardio Lev1- Emerg Svcs/PP Mdc-d-Charity**

**Title** Adult Cardio Lev1- Emerg Svcs/PP Mdc-d-Charity

**Type** Rule

59A-3.246(2)(c)-(d), FAC

**Regulation Definition**

(2) Level I Adult Cardiovascular Services.

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

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

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

**Interpretive Guideline**

- Review protocol for emergency transporting patients to a hospital providing open heart surgery (Level II adult cardiovascular services). Would travel time be sixty minutes or less by emergency vehicle under average travel conditions?

-Review documentation that transfer and transport agreements have been tested and the results indicate a transfer time of no more than 60 minutes from the time the emergency was recognized and the patient arrived at the receiving hospital.

Who does the facility consider at high risk for diagnostic catheterization complications?  
Do they have a policy for referring high risk patients?

-Review the policy and procedure manual to determine if the hospital has a plan for providing adult diagnostic cardiac catheterization program services to Medicaid and charity care patients.

Do the policies and procedures document specific outreach programs directed at Medicaid and charity care patients?

-Interview the cardiac cath director.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 294 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

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

**ST - H0532 - Patient and personnel records; copies; examin**

**Title** Patient and personnel records; copies; examin

**Type** Rule

395.3025(1-3), FS

**Regulation Definition**

(1) Any licensed facility shall, upon written request, and only after discharge of the patient, furnish, in a timely manner, without delays for legal review, to any person admitted therein for care and treatment or treated thereat, or to any such person's guardian, curator, or personal representative, or in the absence of one of those persons, to the next of kin of a decedent or the parent of a minor, or to anyone designated by such person in writing, a true and correct copy of all patient records, including X rays, and insurance information concerning such person, which records are in the possession of the licensed facility, provided the person requesting such records agrees to pay a charge. The exclusive charge for copies of patient records may include sales tax and actual postage, and, except for nonpaper records that are subject to a charge not to exceed \$2, may not exceed \$1 per page. A fee of up to \$1 may be charged for each year of records requested. These charges shall apply to all records furnished, whether directly from the facility or from a copy service providing these services on behalf of the facility. However, a patient whose records are copied or searched for the purpose of continuing to receive medical care is not required to pay a charge for copying or for the search. The licensed facility shall further allow any such person to examine the original records in its possession, or microforms or other suitable

**Interpretive Guideline**

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 295 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

reproductions of the records, upon such reasonable terms as shall be imposed to assure that the records will not be damaged, destroyed, or altered.

(2) This section does not apply to records maintained at any licensed facility the primary function of which is to provide psychiatric care to its patients, or to records of treatment for any mental or emotional condition at any other licensed facility which are governed by the provisions of s. 394.4615.

(3) This section does not apply to records of substance abuse impaired persons, which are governed by s. 397.501.

**ST - H0540 - Birthing Quality Improvement Initiatives**

**Title** Birthing Quality Improvement Initiatives

**Type** Rule

395.1054 FS

**Regulation Definition**

395.1054 Birthing quality improvement initiatives.-A hospital that provides birthing services shall at all times participate in at least two quality improvement initiatives developed in collaboration with the Florida Perinatal Quality Collaborative within the University of South Florida College of Public Health

**Interpretive Guideline**

The Florida Perinatal Quality Collaborative can be accessed at <https://health.usf.edu/publichealth/chiles/fpqc> and participation of a specific hospital can be validated under the QI Initiatives tab by selecting the title of the initiative and scrolling to the "Participating Hospitals"

**ST - H0541 - Billing Activities**

**Title** Billing Activities

**Type** Rule

395.3011

**Regulation Definition**

395.3011 Billing and collection activities.-

**Interpretive Guideline**

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 296 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(1) As used in this section, the term "extraordinary collection action" means any of the following actions taken by a licensed facility against an individual in relation to obtaining payment of a bill for care covered under the facility's financial assistance policy:

- (a) Selling the individual's debt to another party.
- (b) Reporting adverse information about the individual to consumer credit reporting agencies or credit bureaus.
- (c) Deferring, denying, or requiring a payment before providing medically necessary care because of the individual's nonpayment of one or more bills for previously provided care covered under the facility's financial assistance policy.
- (d) Actions that require a legal or judicial process, including, but not limited to:
  - 1. Placing a lien on the individual's property;
  - 2. Foreclosing on the individual's real property;
  - 3. Attaching or seizing the individual's bank account or any other personal property;
  - 4. Commencing a civil action against the individual;
  - 5. Causing the individual's arrest; or
  - 6. Garnishing the individual's wages.

(2) A facility may not engage in an extraordinary collection action against an individual to obtain payment for services:

- (a) Before the facility has made reasonable efforts to determine whether the individual is eligible for assistance under its financial assistance policy for the care provided and, if eligible, before a decision is made by the facility on the patient's application for such financial assistance.
- (b) Before the facility has provided the individual with an itemized statement or bill.
- (c) During an ongoing grievance process as described in s. 395.301(6) or an ongoing appeal of a claim adjudication.
- (d) Before billing any applicable insurer and allowing the insurer to adjudicate a claim.
- (e) For 30 days after notifying the patient in writing, by



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 297 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

certified mail, or by other traceable delivery method, that a collection action will commence absent additional action by the patient.

(f) While the individual:

1. Negotiates in good faith the final amount of a bill for services rendered; or
2. Complies with all terms of a payment plan with the facility.

**ST - H0600 - NICU Level I Neonatal Services**

**Title** NICU Level I Neonatal Services

**Type** Rule

59A-3.249

**Regulation Definition**

59A-3.249

Each hospital with an obstetrical department as described in subsection 59A-3.244(2), F.A.C. must have a neonatal nursery to provide Level I neonatal services. Level I neonatal services means well-baby care services including sub-ventilation care, intravenous feedings, intravenous medications, and gavage to neonates, as needed. Services in a Level I neonatal nursery are restricted to neonates born at 35 weeks gestation or later and who are considered low risk and physiologically stable. Ventilation assistance must not be provided except for resuscitation and stabilization. Upon beginning ventilation, the hospital must implement a patient treatment plan which includes the transfer of the neonate to a hospital providing Level II, III, or IV NICU services at such time that it becomes apparent that ventilation assistance will be required beyond the neonate's resuscitation and stabilization. A hospital only providing Level I neonatal services must establish a triage procedure to assess the need for transfer of obstetrical patients to hospitals providing Level II, III, or IV NICU services prior to their delivery when there is an obstetrical indication that

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 298 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

resuscitation will be required for their neonates.

**ST - H0601 - NICU Licensure**

**Title** NICU Licensure

**Type** Rule

59A-3.249(2)

**Regulation Definition**

59A-3.249(2) Licensure.

- (a) A hospital may not provide neonatal intensive care services prior to obtaining licensure of NICU beds as evidenced by the bed type appearing on the face of the hospital's license. A hospital authorized to provide neonatal intensive care services as of the effective date of this rule shall be licensed to provide the same level of care for neonatal intensive care services and must meet all of the requirements of this rule within one year from the effective date. This does not preclude a hospital from qualifying for a higher level during the transition year.
- (b) A hospital establishing neonatal intensive care services must apply for licensure of Level II, III, or IV NICU services and NICU beds by submitting a hospital licensure application as specified in subsection 59A-3.066(2), F.A.C.
- (c) A hospital may utilize any licensed NICU bed at the level of neonatal intensive care services required to meet the patient's needs if the licensure, staffing, equipment, and supplies requirements established by this rule for the necessary level of service is met.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 299 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0602 - NICU Emergency Transportation**

**Title** NICU Emergency Transportation

**Type** Rule

59A-3.249(3)

**Regulation Definition**

59A-3.249(3) Emergency Transportation. A hospital providing Level II, III, or IV neonatal intensive care services must have, directly or by contract, an emergency 24-hour neonatal transportation system in accordance with Rule 64J-1.006, F.A.C. administered by the Department of Health.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

**ST - H0603 - NICU Level IV Emergency Transportation**

**Title** NICU Level IV Emergency Transportation

**Type** Rule

59A-3.249(7)(l)2

**Regulation Definition**

59A-3.249(7)  
(l) Hospitals providing Level IV NICU services must:  
2. Assure age and size appropriate transport to and from other facilities;

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

**ST - H0604 - NICU Transfer Agreements**

**Title** NICU Transfer Agreements

**Type** Rule

59A-3.249(3-4) & (7)(h & j)

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 300 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

59A-3.249

(3) Hospitals providing Level II neonatal intensive care services must have a written transfer agreement with a hospital providing Level III or Level IV neonatal intensive care services, and hospitals providing Level III neonatal intensive care services must have a written transfer agreement with a hospital providing Level IV neonatal intensive care services. A hospital providing Level IV neonatal intensive care services that does not provide pediatric cardiovascular surgery and pediatric cardiothoracic surgery onsite must have a written transfer agreement with a hospital providing Level IV neonatal intensive care services including onsite pediatric cardiovascular surgery and pediatric cardiothoracic surgery as specified in paragraph (7)(h).

(4) Transfer agreements. A hospital providing Level II, III, or IV neonatal intensive care services must have transfer agreements for all neonatal intensive care services that are not provided by the hospital with another hospital that provides such services. A transfer agreement must specifically address the services included in the transfer agreement. The hospital must maintain a policy requiring that such transfer agreements be made with other hospitals in reasonable geographic proximity, taking into account the services in question, the location of the hospital, and other factors relevant to the care of the patient. Medically necessary transfers shall be made in accordance with section 395.1041(3)(e), F.S.

(7)(h) If a hospital providing Level IV NICU services does not provide pediatric cardiovascular surgery and pediatric cardiothoracic surgery onsite, it must have a transfer agreement for such surgeries.

(7)(j) Other Pediatric Services. A Level IV may provide pediatric dialysis onsite or, if it does not provide pediatric

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 301 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

dialysis onsite, must have a transfer agreement for pediatric dialysis.

**ST - H0606 - NICU Level II Standards**

**Title** NICU Level II Standards

**Type** Rule

59A-3.249(5)(a-d)

**Regulation Definition**

- 59A-3.249(5) Level II Neonatal Intensive Care Services.
- (a) Hospitals that are licensed for Level II NICU services may only provide care for infants at greater than or equal to 30 weeks' gestation and/or have reached a weight of greater than or equal to 1250 grams.
  - (b) Hospitals that are licensed for Level II NICU services, but not Level III or Level IV NICU services, may perform only Level II NICU services.
  - (c) Each Level II NICU must be capable of providing invasive ventilation up to 72 hours, or continuous positive airway pressure as needed.
  - (d) An infant in a Level II NICU must be transferred to a higher level NICU if the infant requires more than 72 hours of invasive ventilation.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

**ST - H0607 - NICU Level III Standards**

**Title** NICU Level III Standards

**Type** Rule

59A-3.249(6)(a)

**Regulation Definition**

59A-3.249 (6) Level III Neonatal Intensive Care Services

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 302 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(a) Hospitals providing Level III NICU services must meet the staffing and personnel, equipment, and service standards required of hospitals providing Level II NICU services, in addition to the standards set forth within this subsection. Hospitals providing Level III NICU services may perform Level II and Level III NICU services.

**ST - H0608 - NICU Level IV Standards**

**Title** NICU Level IV Standards

**Type** Rule

59A-3.249(7)(a-b) & (k) & (l)1, 3-4

**Regulation Definition**

59A-3.249 (7) Level IV Neonatal Intensive Care Services.

(a) Hospitals providing Level IV NICU services must meet the staffing and personnel, equipment, and service standards required of Level III NICUs in addition to the standards set forth within this subsection.

(b) Hospitals providing Level IV NICU services may perform Level II, Level III and Level IV NICU services.

(k) General hospitals providing Level IV NICU services must provide obstetric services for women with high risk pregnancies onsite, on a 24-hour basis. Specialty children's hospitals are excluded from this requirement.

(l) Hospitals providing Level IV NICU services must:

1. Maintain continuous availability of neonatal surgery;
3. Coordinate continuing education programs for staff; and
4. Provide outreach education for other hospitals in their service area.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

**Agency for Health Care Administration  
ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 303 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0610 - NICU Level II Director**

**Title** NICU Level II Director

**Type** Rule

59A-3.249(5)(e)

**Regulation Definition**

59A-3.249(5)(e) Director. Each Level II NICU must be directed by a board certified pediatrician with experience in the care of newborn infants including intubation and invasive ventilation, or a board certified neonatologist.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

**ST - H0611 - NICU Level III & IV Director**

**Title** NICU Level III & IV Director

**Type** Rule

59A-3.249(6)(b) & (7)(c)

**Regulation Definition**

59A-3.249(6)(b) Director. Each Level III NICU must be directed by a full-time, board certified neonatologist.

59A-3.249(7)(c) Director. Each Level IV NICU must be directed by a full-time, board certified neonatologist.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

**ST - H0613 - NICU Level II Personnel**

**Title** NICU Level II Personnel

**Type** Rule

59A-3.249(5)(f)

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 304 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

59A-3.249(5)(f) Personnel. Each Level II NICU must have physically present in the facility at all times, a board certified or board eligible neonatologist or other neonatal provider with demonstrated competence in the management of severely ill infants as evidenced by completion of the Neonatal Resuscitation Program and continuing education requirements specific to the care of infants. Other neonatal providers, for the purposes of this subsection, must be either pediatric hospitalists, neonatal physician assistants, or neonatal advanced practice registered nurses. If the personnel present at the facility at any time pursuant to this paragraph is not a board certified or board eligible neonatologist, at all such times a neonatologist must be available for consultation and must be available to arrive onsite within 30 minutes of an urgent request. If the neonatologist designated to be either at the facility or available for consultation and arrival upon an urgent request is covering more than one facility, the facility must ensure that a back-up neonatologist be available, documented in an on-call schedule and readily available to facility staff, for consultation or to arrive within 30 minutes upon an urgent request.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

**ST - H0614 - NICU Level IV Personnel**

**Title** NICU Level IV Personnel

**Type** Rule

59A-3.249(7)(d)

**Regulation Definition**

59A-3.249(7)(d) Personnel. Each Level IV NICU must have a board certified or board eligible neonatologist available at all times at the facility.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.



**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 305 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0616 - NICU Level II Subspecialties**

**Title** NICU Level II Subspecialties

**Type** Rule

59A-3.249(5)(g)

**Regulation Definition**

59A-3.249(5)(g) Pediatric Medical Subspecialties. Each Level II NICU must have the following pediatric medical subspecialties available onsite or via telemedicine:

1. Cardiology;
2. Maternal-fetal medicine, including a board certified obstetrician who is qualified by training, experience, or special competent certification in maternal-fetal medicine, if the hospital provides delivery services;
3. Neurology; and
4. Ophthalmologist or retinal specialist with expertise in retinopathy of prematurity.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

Review facility records that demonstrate the required subspecialists are available to the facility when needed.

Review the facility's policies, procedures, and bylaws relating to the availability of, and provision of care by subspecialists, including those providing telemedicine.

Review the facility's subspecialist contracts with providers or provider groups, staff rosters, relevant patient records, call records, or other records to demonstrate whether required subspecialists were actually available to provide consultation and/or care to NICU patients in a timely and medically appropriate manner.

**ST - H0617 - NICU Level III Subspecialties**

**Title** NICU Level III Subspecialties

**Type** Rule

59A-3.249(6)(c-e)

**Regulation Definition**

59A-3.249(6)  
(c) Onsite Medical Subspecialties. Each Level III NICU must provide an anesthesiologist onsite with sufficient expertise in pediatric anesthesiology and with the ability to consult with a pediatric anesthesiologist through a prearranged and documented consultative agreement.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

Review facility records that demonstrate the required subspecialists are available to the facility when needed.

Review the facility's policies, procedures, and bylaws relating to the availability of, and provision of care by subspecialists, including those providing telemedicine.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 306 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(d) Other Pediatric Medical Subspecialties. Each Level III NICU must provide the pediatric medical subspecialties required of Level II NICUs. In addition, each Level III NICU must provide the following pediatric medical subspecialties onsite or via telemedicine:

1. Endocrinology;
2. Gastroenterology;
3. Genetics;
4. Hematology-oncology;
5. Infectious disease;
6. Nephrology;
7. Otolaryngology;
8. Pulmonary;
9. Radiology; and
10. Urology.

(e) Onsite Surgical Subspecialties. Each Level III NICU must provide pediatric general surgery onsite or provide onsite a general surgeon with sufficient expertise in pediatric general surgery with the ability to consult with a pediatric general surgeon through a prearranged and documented consultative agreement.

Review the facility's subspecialist contracts with providers or provider groups, staff rosters, relevant patient records, call records, or other records to demonstrate whether required subspecialists were actually available to provide consultation and/or care to NICU patients in a timely and medically appropriate manner.

**ST - H0618 - NICU Level IV Subspecialties**

**Title** NICU Level IV Subspecialties

**Type** Rule

59A-3.249(7)(e-g)

**Regulation Definition**

59A-3.249(7)

(e) Onsite Pediatric Medical Subspecialties. Each Level IV NICU must provide the following pediatric medical subspecialties onsite:

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

Review facility records that demonstrate the required subspecialists are available to the facility when needed.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 307 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

1. Anesthesiology;
2. Cardiology;
3. Endocrinology;
4. Gastroenterology;
5. Hematology-oncology;
6. Infectious Disease;
7. Maternal-fetal medicine, including a board certified obstetrician who is qualified by training, experience, or special competent certification in maternal-fetal medicine, if the hospital provides delivery services;
8. Nephrology;
9. Neurology;
10. Ophthalmologist or retinal specialist with expertise in retinopathy of prematurity;
11. Orthopedics;
12. Otolaryngology;
13. Palliative care;
14. Pulmonology;
15. Radiology; and
16. Urology.

Review the facility's policies, procedures, and bylaws relating to the availability of, and provision of care by subspecialists, including those providing telemedicine.

Review the facility's subspecialist contracts with providers or provider groups, staff rosters, relevant patient records, call records, or other records to demonstrate whether required subspecialists were actually available to provide consultation and/or care to NICU patients in a timely and medically appropriate manner.

(f) Other Pediatric Medical Subspecialties. Each Level IV NICU must provide genetics services onsite or via telemedicine.

(g) Onsite Pediatric Surgical Subspecialties. Each Level IV NICU must provide the following pediatric surgical subspecialties onsite:

1. Craniofacial surgery;
2. General surgery; and
3. Neurosurgery.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 308 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0620 - NICU Level II Pediatric Services**

**Title** NICU Level II Pediatric Services

**Type** Rule

59A-3.249(5)(h)

**Regulation Definition**

59A-3.249(5)(h) Onsite Pediatric Services. Each Level II NICU must have the following pediatric services available onsite:

1. Echocardiogram;
2. Electroencephalogram;
3. Laboratory services;
4. Lactation;
5. Nutrition;
6. Pastoral care;
7. Pharmacy;
8. Physician-led multidisciplinary NICU follow up clinic or affiliation with a clinic and referral system;
9. Radiology, including magnetic resonance imaging, computed tomography, and ultrasound;
10. Rehabilitation therapy;
11. Retinopathy of prematurity screening (screening may be reviewed via telemedicine);
12. Respiratory therapy; and
13. Social work.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

Review facility records that demonstrate the required subspecialists are available to the facility when needed.

Review the facility's policies, procedures, and bylaws relating to the availability of, and provision of care by subspecialists, including those providing telemedicine.

Review the facility's subspecialist contracts with providers or provider groups, staff rosters, relevant patient records, call records, or other records to demonstrate whether required subspecialists were actually available to provide consultation and/or care to NICU patients in a timely and medically appropriate manner.

**ST - H0621 - NICU Level III Pediatric Services**

**Title** NICU Level III Pediatric Services

**Type** Rule

59A-3.249(6)(f)

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 309 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

59A-3.249(6)(f) Pediatric Services. Each Level III NICU must provide the pediatric services required of a Level II NICU. In addition, a Level III NICU must provide therapeutic hypothermia services onsite and may provide inhaled nitric oxide services.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

**ST - H0623 - NICU Level IV Pediatric Services**

**Title** NICU Level IV Pediatric Services

**Type** Rule

59A-3.249(7)(i)

**Regulation Definition**

59A-3.249(7)(i) Onsite Pediatric Services. Each Level IV NICU must provide the following pediatric services onsite:

1. Echocardiogram;
2. Electroencephalogram;
3. Extracorporeal membrane oxygenation;
4. Inhaled nitric oxide;
5. Laboratory services;
6. Lactation;
7. Nutrition;
8. Pastoral care;
9. Pharmacy;
10. Physician-led multidisciplinary NICU follow up clinic
11. Radiology, including magnetic resonance imaging, computed tomography, and ultrasound;
12. Rehabilitation therapy;
13. Respiratory therapy;
14. Retinopathy prematurity screening;
15. Social work; and
16. Therapeutic hypothermia.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 310 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0626 - NICU Level II Neonatal Nursing**

**Title** NICU Level II Neonatal Nursing

**Type** Rule

59A-3.249(5)(i)

**Regulation Definition**

59A-3.249(5)(i) Neonatal Nursing.

1. Supervision. The nursing staff must be under the supervision of a registered professional nurse with experience and training in neonatal intensive care nursing.
2. Training and Qualifications. Nurses must be trained to administer cardio-respiratory monitoring, assist in ventilation, administer intravenous fluids, provide pre-operative and post-operative care of patients requiring surgery, manage patients being transported, and provide emergency treatment of conditions such as apnea, seizures, and respiratory distress. All nurses must maintain current certification in the Neonatal Resuscitation Program.
3. Staffing.
  - a. There must be at least one nurse for every four patients receiving Level II neonatal intensive care services.
  - b. At least one-half of the nursing personnel assigned to each work shift in Level II NICUs must be registered professional nurses.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

**ST - H0627 - NICU Level III Neonatal Nursing**

**Title** NICU Level III Neonatal Nursing

**Type** Rule

59A-3.249(6)(g)

**Agency for Health Care Administration  
ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 311 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

59A-3.249(6)(g) Neonatal Nursing.

1. Each Level III NICU must meet the supervision, training, and qualifications standards for neonatal nurses for Level II NICUs.
2. There must be at least one nurse for every two patients receiving Level III neonatal intensive care services. Patients requiring neonatal surgery or multi-system support must have at least one nurse for every patient during the immediate preoperative, intraoperative, and immediate postoperative periods.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

**ST - H0628 - NICU Level II Respiratory Therapist**

**Title** NICU Level II Respiratory Therapist

**Type** Rule

59A-3.249(5)(i)

**Regulation Definition**

59A-3.249(5)(j) Respiratory Therapist. There must be at least one certified respiratory therapist with current certification in the Neonatal Resuscitation Program and expertise in the care of neonates continuously available in the hospital at all times. There must be at least one respiratory therapy technician for every four patients receiving assisted ventilation.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

**ST - H0630 - NICU Level II Equipment**

**Title** NICU Level II Equipment

**Type** Rule

59A-3.249(5)(k-1)

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 312 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

59A-3.249(5)

(k) Level II NICU Bed Equipment. Each bed must have:

1. One cardiopulmonary monitor and pulse oximeter;
2. At least one resuscitation bag and mask; and
3. At least one infusion pump.

(l) Level II NICU Equipment. Each unit must have available on demand:

1. At least one oxygen analyzer for every three occupied beds;
2. At least one non-invasive blood pressure monitoring device for every three occupied beds;
3. At least one ventilator for every three occupied beds;
4. An EKG machine with printout capability;
5. Continuous blood pressure measurement equipment;
6. A portable digital x-ray capable of directly displaying radiography and digital images in the NICU;
7. An incubator or radiant warmer for each occupied bed;
8. One heated humidifier and humidified oxygen delivery systems for each occupied bed; and
9. At least one neonatal fixed or portable suction device for each occupied bed.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.

**ST - H0631 - NICU Level III Equipment**

**Title** NICU Level III Equipment

**Type** Rule

59A-3.249(6)(h)

**Regulation Definition**

59A-3.249(6)(h) Level III NICU Equipment. A Level III NICU must be capable of life support as needed. Level III NICUs must have the equipment and services required of a Level II NICU.

**Interpretive Guideline**

Rule 59A-3.249 is effective 5/19/2022, but hospitals have a year to comply in accordance with 395.1055(8), F.S.



**Agency for Health Care Administration  
ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 313 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0632 - Newborn, Infant, and Toddler Hearing screen**

**Title** Newborn, Infant, and Toddler Hearing screen

**Type** Rule

383.145 (3)a, c, f-j, and l

**Regulation Definition**

**Interpretive Guideline**

(3) REQUIREMENTS FOR SCREENING OF NEWBORNS, INFANTS, AND TODDLERS; INSURANCE COVERAGE; REFERRAL FOR ONGOING SERVICES.-

(a) 1. Each hospital or other state-licensed birth facility that provides maternity and newborn care services shall ensure that all newborns are, before discharge, screened for the detection of hearing loss to prevent the consequences of unidentified disorders. If a newborn fails the screening for the detection of hearing loss, the hospital or other state-licensed birth facility must administer a test approved by the United States Food and Drug Administration or another diagnostically equivalent test on the newborn to screen for congenital cytomegalovirus before the newborn becomes 21 days of age or before discharge, whichever occurs earlier.

2. Each hospital that provides neonatal intensive care services shall administer a test approved by the United States Food and Drug Administration or another diagnostically equivalent test to screen for congenital cytomegalovirus in each newborn admitted to the hospital as a result of a premature birth occurring before 35 weeks' gestation, for cardiac care, or for medical or surgical treatment requiring an anticipated stay of 3 weeks or longer. Such screening must be initiated before the newborn becomes 21 days of age.

3. If a newborn requires transfer to another hospital for a higher level of care, the receiving hospital must initiate the congenital cytomegalovirus screening if it was not already performed by the transferring hospital or birthing facility. For

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 314 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

newborns transferred or admitted for intensive and prolonged care, the congenital cytomegalovirus screening must be initiated regardless of whether the newborn failed a hearing screening.

(c) If the parent or legal guardian of the newborn objects to the screening, the screening must not be completed. In such case, the physician, midwife, or other person attending the newborn shall maintain a record that the screening has not been performed and attach a written objection that must be signed by the parent or guardian.

(f) All newborn and infant hearing screenings must be conducted by an audiologist, a physician, or an appropriately supervised individual who has completed documented training specifically for newborn hearing screening. Every hospital that provides maternity or newborn care services shall obtain the services of an audiologist, a physician, or another newborn hearing screening provider, through employment or contract or written memorandum of understanding, for the purposes of appropriate staff training, screening program supervision, monitoring the scoring and interpretation of test results, rendering of appropriate recommendations, and coordination of appropriate follow-up services. Appropriate documentation of the screening completion, results, interpretation, and recommendations must be placed in the medical record within 24 hours after completion of the screening procedure.

(g) The screening of a newborn's hearing must be completed before the newborn is discharged from the hospital or licensed birth center. However, if the screening is not completed before discharge due to scheduling or temporary staffing limitations, the screening must be completed within 21 days after the birth. Screenings completed after discharge or performed because of initial screening failure must be completed by an audiologist, a physician, a hospital, or another newborn hearing screening provider.

(h) Each hospital shall formally designate a lead physician

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 315 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

responsible for programmatic oversight for newborn hearing screening. Each birth center shall designate a licensed health care provider to provide such programmatic oversight and to ensure that the appropriate referrals are being completed.

(i) When ordered by the treating physician, screening of a newborn's, infant's, or toddler's hearing must include auditory brainstem responses, or evoked otoacoustic emissions, or appropriate technology as approved by the United States Food and Drug Administration.

(j) The results of any test conducted pursuant to this section, including, but not limited to, newborn hearing loss screening, congenital cytomegalovirus testing, and any related diagnostic testing, must be reported to the department within 7 days after receipt of such results.

(l) A child diagnosed as having permanent hearing loss or a congenital cytomegalovirus infection must be referred to the primary care physician for medical management, treatment, and follow-up services. Furthermore, in accordance with Part C of the Individuals with Disabilities Education Act, Pub. L. No. 108-446, Infants and Toddlers with Disabilities, any child from birth to 36 months of age diagnosed as having hearing loss that requires ongoing special hearing services must be referred to the Children's Medical Services Early Intervention Program serving the geographical area in which the child resides. A child diagnosed with a congenital cytomegalovirus infection without hearing loss must be referred to the Children's Medical Services Early Intervention Program and be deemed eligible for a baseline evaluation and any medically necessary follow-up reevaluations and monitoring.

**ST - H0640 - Treatment Alternatives – COVID 19**

**Title** Treatment Alternatives – COVID 19

**Type** Rule

395.1057

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 316 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**Regulation Definition**

Patients' right to choose COVID-19 treatment alternatives.-A hospital may not interfere with a patient's right to choose COVID-19 treatment alternatives as recommended by a health care practitioner with privileges at the hospital if the health care practitioner has obtained informed consent from the patient in accordance with s. 456.62. Any hospital that violates this section by preventing a health care practitioner from exercising his or her sound judgment is subject to agency disciplinary action under s. 395.1065(2).

**Interpretive Guideline**

**ST - H0650 - Patient immigration status data collection**

**Title** Patient immigration status data collection

**Type** Rule

395.3027

**Regulation Definition**

(1) Each hospital that accepts Medicaid must include a provision on its patient admission or registration forms for the patient or the patient's representative to state or indicate whether the patient is a United States citizen or lawfully present in the United States or is not lawfully present in the United States. The inquiry must be followed by a statement that the response will not affect patient care or result in a report of the patient's immigration status to immigration authorities.

**Interpretive Guideline**

**Agency for Health Care Administration  
ASPEN: Regulation Set (RS)**

Printed 08/07/2024

Page 317 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

**ST - H0651 - Life Threatening Conditions**

**Title** Life Threatening Conditions

**Type** Rule

59AER24-1

**Regulation Definition**

Medical Records Procedures for Treatment of Premature Rupture of Membranes and Other Life Threatening Conditions.

Each hospital shall maintain written policies and procedures governing the maintenance of medical records for the treatment of premature rupture of membranes, ectopic pregnancies, trophoblastic tumors, and other life-threatening conditions. The policies and procedures shall be reviewed at least annually, dated to indicate time of last review, and revised as necessary. At a minimum, the policies and procedures shall address the following:

- (1) When a patient receives a diagnosis of premature rupture of membranes, the patient shall be admitted for observation unless the treating physician determines that another course of action is more medically appropriate under the circumstances to ensure the health of the mother and the unborn baby. When the treating physician determines that another course of action is more medically appropriate, the physician shall document the reasons why the alternate course of action is more appropriate.
- (2) When a physician attempts to induce the live birth of an unborn baby, regardless of gestational age, to treat the premature rupture of membranes, and the unborn baby does not survive, the incident does not constitute an abortion and shall not be reported pursuant to Rule 59A-9.034. The treating physician shall document the treatment in the patient ' s medical record.

**Interpretive Guideline**

**Agency for Health Care Administration**  
**ASPEN: Regulation Set (RS)**

*Printed 08/07/2024*

Page 318 of 318

**Aspen State Regulation Set: H 6.15 HOSPITAL LICENSURE**

(3) The treatment of an ectopic pregnancy is not an abortion and shall not be reported pursuant to Rule 59A-9.034. The treating physician shall document the treatment in the patient's medical record.

(4) The treatment of a trophoblastic tumor is not an abortion and shall not be reported pursuant to Rule 59A-9.034. The treating physician shall document the treatment in the patient's medical record.