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ASPEN: Regulation Set (RS)**

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Aspen State Regulation Set: M 2.00 AMBULATORY SURGICAL CENTER

ST - M0000 - INITIAL COMMENTS

Title INITIAL COMMENTS

Statute or Rule

Type Memo Tag

Regulation Definition

Interpretive Guideline

ST - M0002 - LICENSURE REQUIREMENTS

Title LICENSURE REQUIREMENTS

Statute or Rule 59A-5.003(14), F.A.C.

Type Rule

Regulation Definition

The agency shall issue a single license which identifies the ambulatory surgical center and the name and location of the ambulatory surgical center. Each license shall specifically state the number of operating rooms and recovery beds in the premise. This license must be displayed in a conspicuous place.

59A-5.003(14), F.A.C.

Interpretive Guideline

"Ambulatory Surgical Center" means a facility which primary purpose is to provide elective surgical care, in which the patient is admitted to and discharged from within the same working day and is not permitted to stay overnight, and which is not part of a hospital. An office maintained by a physician for the practice of medicine, or an office maintained for the practice of dentistry shall not be construed to be an ASC, provided that any facility or office which is certified or seeks certification as a Medicare ambulatory surgical center shall be licensed as an ASC pursuant to s. 395.003, F.S.

"Recovery bed" means an accommodation with support services used for post-operative recovery in an ASC.

"Owner" means the licensee of an ASC.

"Center" means an ambulatory surgical center.

"Regular license" means an unrestricted licensed issued to an ASC in recognition of substantial compliance with rules and standards of Chapter 59A-5, F.A.C., as authorized under Chapter 395, F.S.

"F.A.C." means Florida Administrative Code.

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Verify by direct observation that the current license contains the correct information and is posted in a conspicuous place, visible to the public.

Compare the actual number of operating rooms and recovery beds to determine any discrepancy with the facility's license.

ST - M0003 - GOVERNING BODY

Title GOVERNING BODY

Statute or Rule 59A-5.005(1), F.A.C.

Type Rule

Regulation Definition

GOVERNING BODY. The ambulatory surgical center has a governing body that assumes full responsibility for the legal and ethical conduct of the organization. The governing body is organized under approved written bylaws, rules and regulations. Refer to s. 395.0191, F.S.

(a) State the qualifications for governing body membership, and the method of selecting members as well as the terms of appointment or election of members, officers and chairmen of committees. Where legally permissible, physicians who are members of the organized medical staff shall be eligible for, and should be included in, full membership of ambulatory surgical centers' governing bodies and their action committees in the same manner as are other

Interpretive Guideline

"Governing Body" means an individual owner, partnership, corporation or other legally established authority in whom the ultimate authority and responsibility for management of the center is vested.

"Physician" means a person currently licensed to practice medicine or osteopathy pursuant to Chapter 458 or 459, F.S. "O.R. Technician" means a person with specialized training in operating room techniques and considered by the governing body qualified to serve as a part of the operating room staff.

"Administrator" means a person who is delegated the responsibility of carrying out the policies and programs established by the governing body.

"Continuing care" means care beyond the ASC's scope of practice.

Review policies and procedures for documentation that the ASC has a governing body and qualifications for membership, method of selecting members, terms of appointments or election of members, officers and chairmen of committees.

Verify that the organized medical staff operates under current bylaws, rules and regulations that have been approved by the governing body.

Verify that the governing body retains ultimate responsibility for the operation of the ASC.

Review governing body meeting minutes. Verify that meetings are held at specified frequency and intervals, pursuant

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knowledgeable and effective individuals. Also, any other member of the organized medical staff shall be considered eligible for membership of the governing body.

(b) Provide for the designation of officers, their duties, and for the organization of the governing body into essential committees with the number and type consistent with the size and scope of the ambulatory surgical center's activities.

(c) Coordinate through an executive committee or the governing body as a whole, the policies and activities of the ambulatory surgical centers and special committees established by the governing body.

(d) Specify the frequency of meetings, at regular stated intervals, with a majority of the members constituting a quorum and with the requirement that minutes recorded and made available to all members of the governing body.

(e) Establish a position, the incumbent of which shall be responsible for operation and maintenance of the ambulatory surgical center as a functioning institution, and define the methods established by

to bylaws. Verify that quorums, as specified in the bylaws, are present.

Ensure that minutes are recorded and made available to all members of the governing body.

Verify that the governing body retains ultimate responsibility for the operation of the ASC.

Ensure that appointments, reappointments or dismissal of members of the organized medical staff have been referred to the medical credentialing committee for their recommendation prior to any action being taken.

Verify that any practitioner providing patient care services has been approved by and is accountable to the governing body for the quality of care provided to patients.

Review a random sample of at least ten patient clinical records for verification that all medical care was ordered and rendered only by a member of the organized medical staff.

Review the ASC's policy on physician orders to determine that standing orders procedures are in accordance with the existing rule for all orders.

Verify that podiatrists and dentists who do not have admitting privileges at an acute care general hospital, have a written agreement with a physician who has staff privileges at an acute care general hospital, to accept any patient who requires continuing care.

Review policies and procedures for the transfer of patients requiring emergency care.

Ensure that there a written transfer agreement exists with one or more local hospitals.

Interview appropriate personnel to determine if they are aware of transfer procedures.

Interview members of the staff to determine compliance.

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the governing body for holding such designated person responsible.

(f) Provide for the appointment, reappointment, or dismissal of members of the organized medical staff through a credential committee or its equivalent and a procedure for hearing and appeal. No action on appointment, reappointment or dismissal shall be taken without prior referral to the medical credential committee for their recommendation, provided that the governing body may suspend a organized medical staff member pending final determination of any reappointment or dismissal. The governing body shall only appoint members of the organized medical staff as recommended by the credentials medical committee.

(g) Provide for the approval of the bylaws, rules and regulations of the organized medical staff.

(h) Require that every patient shall be admitted by and remain under the care of a member of the organized medical staff.

(i) Require that all medications, treatments and procedures shall be administered upon specific orders of a member of the organized medical staff.

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(j) Require that all attending organized medical staff members, podiatrists and dentists who do not have admitting privileges at an acute care general hospital, shall have a written agreement from a physician who has staff privileges with one or more acute care general hospitals licensed by the state to accept any patient who requires continuing care; or

(k) Ensure that there is a written facility agreement, with one or more acute care general hospitals licensed by the state, which will admit any patient referred who requires continuing care.

(l) Provide for a formal and official means of liaison among the medical staff, the governing body, and the chief administrative officer to provide a channel for administrative advice.

(m) Specify the classification of services to be provided in the facility and list authorized surgical procedures.

59A-5.005(1), F.A.C.

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ST - M0004 - GOVERNING BODY

Title GOVERNING BODY

Statute or Rule 59A-5.005(2), F.A.C.

Type Rule

Regulation Definition

Where the physician-owner-operator serves as the governing body, the articles of incorporation or other written organizational plan shall describe the manner in which the owner-operator executes the governing body responsibility.

59A-5.005(2), F.A.C.

Interpretive Guideline

An individual may act as the governing body in the case of sole-owner.

Refer to s 395.1055, F.S.

ST - M0005 - PATIENT RIGHTS

Title PATIENT RIGHTS

Statute or Rule 59A-5.0065, F.A.C.

Type Rule

Regulation Definition

PATIENT RIGHTS Ensure that the ASC has developed and adopted policies and procedures for the protection of patient rights which at a minimum includes those specified in ss. 381.026, 395.301, and 395.3025, F.S.
Policies include:

Interpretive Guideline

Review policies and procedures which address patient rights issues.

Verify that Florida Patient's Bill of Rights and Responsibilities is posted in full view.

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- (a) 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;
- (b) The right to participate in the consideration of ethical issues that arise in the care of the patient;
- (c) The right to personal privacy and confidentiality of information including access to information contained in the patient's medical record as specified in s. 395.3025, F.S.;
- (d) The right to a prompt and reasonable response to questions and requests;
- (e) The right to an itemized patient bill upon request as specified under section 395.301, F.S.

59A-5.0065, F.A.C.

ST - M0006 - ORGANIZED MEDICAL STAFF

Title ORGANIZED MEDICAL STAFF

Statute or Rule 59A-5.007(1), F.A.C.

Type Rule

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Regulation Definition

ORGANIZED MEDICAL STAFF. Each ambulatory surgical center shall have an organized medical staff organized under written by-laws approved by the governing body and responsible to the governing body of the ambulatory surgical center for the quality of all medical care provided to patients in the center and for the ethical and professional practices of its members.

59A-5.007(1), F.A.C.

Interpretive Guideline

Verify that the organized medical staff is organized under written by-laws approved by the governing body.

ST - M0007 - ORGANIZED MEDICAL STAFF

Title ORGANIZED MEDICAL STAFF

Statute or Rule 59A-5.007(2), F.A.C.

Type Rule

Regulation Definition

Committees -- The structure of committee organization shall be determined by the organized medical staff provided the following required committee functions are carried out with sufficient periodicity to assure that objectives are achieved by separate committee, combined committees, or committee of the whole:

(a) Approval of the policies, procedures, and the activities of all departments and services.

Interpretive Guideline

Verify that the governing body appoints members to the organized medical staff

Verify that the governing body is periodically appraised concerning organized medical staff evaluation of the quality of all patient services provided.

Review medical staff qualifications, privileges granted and policies and procedures.

Review roster of surgical privileges and compare with surgical procedures performed.

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(b) Interim decision making for the organized medical staff between staff meetings, under such limitations as shall be set by the medical staff.

(c) Follow-up and appropriate disposition of all reports dealing with the various staff functions.

(d) Review of all applications for appointment and biennially review reappointment of all categories of medical staff pursuant to ss. 395.0191 and ss. 395.0193, F.S.

(e) Medical records currently maintained describing the condition, treatment, and progress of patient in sufficient completeness to assure comprehension of transfer of patient information 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 ambulatory surgical center admissions with respect to need for admission, discharge practices and evaluation of the services ordered and provided.

(h) Surveillance of ambulatory

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surgical center's infection potentials and cases and the promotion of a preventive and corrective program, designed to minimize these hazards.

(i) Surveillance of pharmacy policies and procedures, including review of at least monthly on-site consultant pharmacist visit shall insure standards of practice are maintained, including proper disposal of outdated prescription and controlled drugs in accordance with [64B16-28.702, F.A.C.], Chapter 465, F.S., and Chapter 893, F.S.

59A-5.007(2), F.A.C.

ST - M0009 - SURGICAL SERVICES

Title SURGICAL SERVICES

Statute or Rule 59A-5.0085(1) F.A.C.

Type Rule

Regulation Definition

The Surgical Services shall be organized under written policies and procedures relating to surgical staff privileges, anesthesia, functioning standards, staffing patterns and quality maintenance of the surgical suite.

59A-5.0085(1), F.A.C.

Interpretive Guideline

Tour all operative rooms.

Request the use of proper attire for inspection and observation of surgery.

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ST - M0010 - SURGICAL SERVICES

Title SURGICAL SERVICES

Statute or Rule 59A-5.0085(1) F.A.C.

Type Rule

Regulation Definition

A qualified person designated by the administrator shall be responsible for the daily functioning and maintenance of the surgical suite.

59A-5.0085(1)(a), F.A.C.

Interpretive Guideline

"A Qualified Person" means a person who by virtue of education and experience and is determined to be qualified by the governing body.

ST - M0011 - SURGICAL SERVICES

Title SURGICAL SERVICES

Statute or Rule 59A-5.0085(1) F.A.C.

Type Rule

Regulation Definition

A surgery record shall be maintained on a current basis that contains at least the following information:

Patient's name and facility patient number,
pre-operative diagnosis,
post-operative diagnosis, surgical procedure, surgeon, first assistant, anesthesiologist, nurse anesthetist, anesthetic, circulating nurse, O. R. technician, and complications, if any.

Interpretive Guideline

Review the surgery record to ensure compliance.

Review physicians credentials, non-physicians personnel qualifications to ensure that all patient care providers are functioning within their scope of practice as approved by the governing body.

Request documentation ensuring compliance.

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59A-5.0085(1)(b), F.A.C.

ST - M0012 - SURGICAL SERVICES

Title SURGICAL SERVICES

Statute or Rule 59A-5.0085(1) F.A.C.

Type Rule

Regulation Definition

Each facility shall ensure, prior to any surgery being performed, that the original signed informed consent for the procedure, verification of the identity of patient, operative site, and operative procedure to be performed are in the patient's medical record.

59A.5.0085(1)(c), F.A.C.

Interpretive Guideline

Verify the informed consent process.

Verify that the center has a written policy for consent of possible use of blood or blood components and for the refusal of blood or blood components.

ST - M0013 - SURGICAL SERVICES

Title SURGICAL SERVICES

Statute or Rule 59A-5.0085(1) F.A.C.

Type Rule

Regulation Definition

A registered nurse shall serve as O.R. Circulating Nurse.

59A-5.0085(1)(d),F.A.C.

Interpretive Guideline

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ST - M0014 - SURGICAL SERVICES

Title SURGICAL SERVICES

Statute or Rule 59A-5.0085(1) F.A.C.

Type Rule

Regulation Definition

Emergency equipment shall be provided as needed commensurate with the services of the facility, maintained in functional condition, and capable of providing at least the following services:

- (a) Inhalation and therapy;
- (b) Defibrillation;
- (c) Cardiac monitoring;
- (d) Suctioning;
- (e) Maintenance of patient airway.

59A-5.0085(1)(f), F.A.C.

Interpretive Guideline

Request verification that all equipment required is available and functioning.

Verify that policies and procedures are in place that address these concerns.

ST - M0015 - SURGICAL SERVICES

Title SURGICAL SERVICES

Statute or Rule 59A-5.0085(1) F.A.C.

Type Rule

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Regulation Definition

Written procedures in implementation of policies shall relate specifically to the functional activities of the surgical suite and include but not be limited to the following:

- (a) Surgical asepsis: preparation, handling, and maintenance of sterile equipment and supplies.
- (b) Medical asepsis: patients, staff, equipment, traffic, and equipment flow patterns.
- (c) Sterilization and disinfection standards and controls; equipment and supplies.
- (d) Housekeeping.

59A-5.0085(1)(g),F.A.C

Interpretive Guideline

Verify documentation to ensure that policies and procedures address these items.

ST - M0016 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

Statute or Rule 59A-5.0085(2) F.A.C.

Type Rule

Regulation Definition

The Anesthesia Services shall be organized under written policies and procedures relating to anesthesia staff privileges, the administration

Interpretive Guideline

Verify that policies and procedures are in place that address these concerns.

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of anesthesia, and the maintenance of strict safety controls.

59A-5.0085(2),F.A.C.

ST - M0017 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

Statute or Rule 59A-5.0085(2) F.A.C.

Type Rule

Regulation Definition

A qualified anesthesiologist, or certified registered nurse anesthetist, certified pursuant to s. 464.012, F.S., shall be responsible for coordinating the functions, equipment and supplies of the service.

59A-5.0085(2)(a), F.A.C.

Interpretive Guideline

"Anesthesiologist" means a person currently licensed to practice medicine or osteopathy pursuant to Chapters 458 and 459, F.S., and who has completed an approved residency in the field of anesthesiology.

"Certified Registered Nurse Anesthetist" means a person currently licensed and certified pursuant to Chapter 464, F.S., and certified by the Council on Certification of Nurse Anesthetists.

A licensed physician must have documentation of knowledge of the principles of general anesthesia.

It is within the scope of practice for all licensed M.D. and O.D. to administer local anesthesia.

Request documentation verifying that a qualified person has been appointed.

ST - M0018 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

Statute or Rule 59A-5.0085(2) F.A.C.

Type Rule

Regulation Definition

All anesthesia shall be administered by an anesthesiologist or by a certified registered nurse

Interpretive Guideline

Review surgery record to determine compliance.

Review physician credentials to ensure compliance.

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anesthetist, under the on-site medical direction of a licensed physician, except for local anesthesia administered by a podiatrist, and except for local anesthesia administered by a dentist, and such other anesthesia administered by a dentist in accordance with s. 466.017, F.S., and chapter 59Q-14, F.A.C.

59A-5.0085(2)(b), F.A.C.

ST - M0019 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

Statute or Rule 59A-5.0085(2) F.A.C.

Type Rule

Regulation Definition

An anesthesiologist or other physician or a certified registered nurse anesthetist under the on-site medical direction of a licensed physician, shall be in the ambulatory surgical center during the anesthesia and post-anesthesia recovery period until all patients are alert or discharged.

59A-5.0085(2)(c), F.A.C.

Interpretive Guideline

This means either an anesthesiologist, or a certified registered nurse anesthetist under the on-site direction of a licensed physician must be present during this time.

Review surgery record to determine compliance.

Review physician and nurse credentials to ensure compliance.

Determine compliance of patient discharge meeting center's criteria.

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ST - M0020 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

Statute or Rule 59A-5.0085(2) F.A.C.

Type Rule

Regulation Definition

At least one registered professional nurse shall be in the recovery area during the patient's recovery period.

59A-5.0085(2)(d), F.A.C.

Interpretive Guideline

"Registered Professional Nurse (R.N.)" means a person currently licensed as a R.N. pursuant to Chapter 464, F.S.

Review policies and procedures to ensure compliance.

Review staff files to determine licensure of all nurses on staff.

ST - M0021 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

Statute or Rule 59A-5.0085(2) F.A.C.

Type Rule

Regulation Definition

Prior to the administration of anesthesia, patients shall have a history and physical examination including laboratory analysis when indicated.

59A-5.0085(2)(e), F.A.C.

Interpretive Guideline

Review patient's medical record to determine compliance

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ST - M0022 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

Statute or Rule 59A-5.0085(2) F.A.C.

Type Rule

Regulation Definition

Written policies and procedures relative to the administration of anesthesia shall be developed by the anesthesia service, approved by the medical staff and the governing body, and be reviewed annually, dated at time of each review, revised as necessary, and enforced.

59A-5.0085(2)(f), F.A.C.

Interpretive Guideline

Review policies and procedures to ensure compliance.

ST - M0023 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

Statute or Rule 59A-5.0085(2) F.A.C.

Type Rule

Regulation Definition

Anesthetic safety regulations shall be developed, posted and enforced. Such regulations shall include at least the following requirements:

1. All operating room electrical and anesthesia equipment shall be inspected on no less than a

Interpretive Guideline

Review documentation of biomedical and electrical inspections and corrective actions taken.

Review safety regulations to ensure compliance.

Review standard operating procedures to ensure compliance.

Review policies and procedures to ensure compliance.

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semi-annual basis, and a written record of the results and corrective actions be maintained;

2. Flammable anesthetic agents shall not be employed in ambulatory surgical centers;

3. Electrical equipment in anesthetizing areas shall be on an audiovisual line isolation monitor, with the exception of radiologic equipment and fixed lighting more than 5 feet above the floor;

4. Each anesthetic gas machine shall have pin-index system or equivalent safety system and a minimum oxygen flow safety device;

5. All reusable anesthesia equipment in direct contact with the patient shall be cleaned or sterilized as appropriate after each use;

6. At a minimum the following monitors shall be applied to all patients receiving conduction or general anesthesia:

a. Blood pressure cuff;

b. A continuous temperature device, readily available to measure the patient's temperature;

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- c. Pulse Oximeter; and
- d. Electrocardiogram.
- e. An Inspired Oxygen Concentration Monitor and a Capnograph shall be applied to all patients receiving general anesthesia.

59A-5.0085(2)(g), F.A.C.

ST - M0024 - NURSING SERVICE

Title NURSING SERVICE

Statute or Rule 59A-5.0085(3) F.A.C.

Type Rule

Regulation Definition

The Nursing Service shall be organized under written policies and procedures relating to patient care, establishment of standards for nursing care and mechanisms for evaluating such care, and nursing services.

59A-5.0085(3), F.A.C.

Interpretive Guideline

"Qualified Professional Nurse" means an individual qualified by virtue of education, experience and competence.

"Advanced Registered Nurse Practitioner (ARNP)" means a person currently licensed and certified pursuant to Chapter 464, FS.

ST - M0025 - NURSING SERVICE

Title NURSING SERVICE

Statute or Rule 59A-5.0085(3) F.A.C.

Type Rule

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Regulation Definition

A qualified registered professional nurse designated by the administrator shall be responsible for coordinating and supervising all nursing services.

59A-5.0085(3)(a), F.A.C.

Interpretive Guideline

ST - M0026 - NURSING SERVICE

Title NURSING SERVICE

Statute or Rule 59A-5.0085(3) F.A.C.

Type Rule

Regulation Definition

There shall be a sufficient staffing pattern of registered professional nurses to provide quality nursing care to each surgical patient from admission through discharge. Such additional trained nursing service personnel shall be on duty as may be needed commensurate with the service of the facility.

59A-5.0085(3)(b), F.A.C.

Interpretive Guideline

Verify the facility staffing policy addresses this issue..

Request documentation that includes Job descriptions, delineating of duties and responsibilities for each nursing service position.

ST - M0027 - NURSING SERVICE

Title NURSING SERVICE

Statute or Rule 59A-5.0085(3) F.A.C.

Type Rule

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Regulation Definition

A registered professional nurse shall be the operating room circulating nurse.

59A-5.0085(3)(c), F. A.C.

Interpretive Guideline

"Registered Professional Nurse (R.N.)" means a person currently licensed as an R.N. pursuant to Chapter 464, F.S.

Verify compliance by interview of O.R. circulating or recovery room nurse.

ST - M0028 - NURSING SERVICE

Title NURSING SERVICE

Statute or Rule 59A-5.0085(3) F.A.C.

Type Rule

Regulation Definition

A registered professional nurse shall be present in the recovery area at all times when a patient is present.

59A-5.0085(3)(d), F.A.C.

Interpretive Guideline

Review policies and procedures, and observation to ensure compliance.

ST - M0029 - NURSING SERVICE

Title NURSING SERVICE

Statute or Rule 59A-5.0085(3) F.A.C.

Type Rule

Regulation Definition

A record shall be currently maintained of all nursing personnel and include regular and relief as well as full-time and part-time staff. The record shall include the current license number of each licensed

Interpretive Guideline

Verify staff personnel records to ensure compliance.

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person.

59A-5.0085(3)(e), F.A.C.

ST - M0030 - NURSING SERVICE

Title NURSING SERVICE

Statute or Rule 59A-5.0085(3) F.A.C.

Type Rule

Regulation Definition

A current job description delineating duties and responsibilities shall be maintained for each nursing service position.

59A-5.0085(3)(f), F.A.C.

Interpretive Guideline

Review and sample of nursing personnel records.

ST - M0031 - NURSING SERVICE

Title NURSING SERVICE

Statute or Rule 59A-5.0085(3) F.A.C.

Type Rule

Regulation Definition

Written procedures in implementation of policies and to assure quality nursing care shall relate specifically to the functional activities of nursing service and include but not be limited to the following:

- (1) Patient admission;
- (2) Pre- and Post-Operative Care;

Interpretive Guideline

Review policies and procedures to ensure compliance.

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- (3) Physician's and Medical Orders;
- (4) Standing Orders with required signatures;
- (5) Medications; storage and administration;
- (6) Treatments;
- (7) Surgical Asepsis;
- (8) Medical Asepsis;
- (9) Sterilization and Disinfection;
- (10) Documentation: Medical Records and Facility Records;
- (11) Patient Discharge;
- (12) Patient Transfer;
- (13) Emergency Measures;
- (14) Isolation Measures;
- (15) Incident Reports;
- (16) Personnel Orientation;
- (17) Inservice Education Record;
- (18) Equipment and Supplies: availability and maintenance;
- (19) Visitors.

59A-5.0085(3)(g), F.A.C.

ST - M0032 - LABORATORIES

Title LABORATORIES

Statute or Rule 59A-5.0085(4) F.A.C.

Type Rule

Regulation Definition

Clinical Laboratory -- The ambulatory surgical center shall provide on the premises or by written agreement with a laboratory licensed under Chapter 483, F.S., and Chapter 59A-7, F.A.C.,

Interpretive Guideline

Verify that the services are provided in-house or by written agreement.

Verify that there is a written agreement to provide laboratory services from an outside source.

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a clinical laboratory to provide those services commensurate with the ambulatory surgical center's needs and which conform to the provisions of Chapter 483, F.S., and Chapter 59A-7, F.A.C.

59A-5.0085(4), F.A.C.

ST - M0033 - RADIOLOGICAL SERVICES

Title RADIOLOGICAL SERVICES

Statute or Rule 59A-5.0085(5) F.A.C.

Type Rule

Regulation Definition

The ambulatory surgical center shall provide within the institution, or through arrangement, diagnostic radiological services commensurate with the needs of the ambulatory surgical center.

59A-5.0085(5), F.A.C.

Interpretive Guideline

Verify that the services are provided in-house or by written agreement.

Verify that there is a written agreement to provide radiological services from an outside source.

ST - M0034 - RADIOLOGICAL SERVICES

Title RADIOLOGICAL SERVICES

Statute or Rule 59A-5.0085(5) F.A.C.

Type Rule

Regulation Definition

If radiological services are provided by facility staff, the service shall

Interpretive Guideline

Verify that the ASC has adopted policies and procedures to provide safety to patients and staff personnel.

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be maintained free of hazards for patients and personnel.

59A-5.0085(5)(a), F.A.C.

ST - M0035 - RADIOLOGICAL SERVICES

Title RADIOLOGICAL SERVICES

Statute or Rule 59A-5.0085(5) F.A.C.

Type Rule

Regulation Definition

Personnel -The ambulatory surgical center shall have a radiologist either full-time or part-time on a consulting basis, both to supervise the service and to discharge professional radiological services.

59A-5.0085(5)(c)1., F.A.C.

Interpretive Guideline

ST - M0037 - RADIOLOGICAL SERVICES

Title RADIOLOGICAL SERVICES

Statute or Rule 59A-5.0085(5) F.A.C.

Type Rule

Regulation Definition

A technologist shall be on duty or on call at all times when there are patients within the facility.

59A-5.0085(5)(c)2., F.A.C.

Interpretive Guideline

Review staff personnel files to ensure compliance.

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ST - M0038 - RADIOLOGICAL SERVICES

Title RADIOLOGICAL SERVICES

Statute or Rule 59A-5.0085(5) F.A.C.

Type Rule

Regulation Definition

The use of all radiological apparatus shall be limited to personnel designated as qualified by the radiologist; and use of fluoroscopes shall be limited to physicians.

59A-5.0085(5)(c)3., F.A.C.

Interpretive Guideline

Review job descriptions and staff personnel files for compliance

ST - M0039 - RADIOLOGICAL SERVICES

Title RADIOLOGICAL SERVICES

Statute or Rule 59A-5.0085(5) F.A.C.

Type Rule

Regulation Definition

If provided under arrangement with an outside provider, the radiological services must be directed by a qualified radiologist and meet the standards as specified in [Chapter 64E-5, F.A.C.]

59A-5.0085(5)(d), F.A.C.

Interpretive Guideline

59A-5.59A-5.0085(5)(d), F.A.C.

If provided under arrangement with an outside provider, the radiological services must be directed by a qualified radiologist and meet the standards as specified in [Chapter 64E-5, F.A.C.]

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ST - M0040 - HOUSEKEEPING SERVICE

Title HOUSEKEEPING SERVICE

Statute or Rule 59A-5.0085(6) F.A.C.

Type Rule

Regulation Definition

The Housekeeping Service shall be organized under effective written policies and procedures relating to personnel, equipment, materials, maintenance, and cleaning of all areas of the ambulatory surgical center. A qualified person designated by the administrator shall be responsible for all procedures. Policies and procedures shall include but not be limited to the following areas:

- (a) Operating room suite;
- (b) Recovery and pre-operative;
- (c) Clean and soiled utilities;
- (d) Operating room clean-up;
- (e) Operating room materials preparation;
- (f) Storage and dispensing;
- (g) Laboratory, X-ray and Physical examination;
- (h) Isolation units, linen and equipment;
- (i) Staff lounges;
- (j) Admitting and Business areas;
- (k) Separation, handling, and storage of clean and soiled linen.
- (l) Identification, separation,

Interpretive Guideline

Verify that a qualified person has been appointed.

Review policies and procedures to ensure that these items are addressed.

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handling, and storage of biomedical waste.

59A-5.0085(6)(d), F.A.C.

ST - M0041 - SURVEIL, PREVENT & CONTROL OF INFECTION

Title SURVEIL, PREVENT & CONTROL OF INFECTION
Statute or Rule 59A-5.011(1) F.A.C.

Type Rule

Regulation Definition

Each ambulatory surgical center shall establish an Infection Control Program involving members of the medical staff, nursing staff, other professional and administrative staff as appropriate. The program shall provide for:

- (a) The surveillance, prevention, and control of infection among patients and personnel;
- (b) The establishment of a system for identification, reporting, evaluating and maintaining records of infections;
- (c) Ongoing review and evaluation of aseptic, isolation and sanitation techniques employed by the center; and
- (d) Development and coordination of training programs in infection control for all center personnel.

Interpretive Guideline

Verify that review is being accomplished.

Request and review the reports.

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59A-5.011(1), F.A.C.

ST - M0042 - SURVEIL, PREVENT & CONTROL OF INFECTION

Title SURVEIL, PREVENT & CONTROL OF
INFECTION
Statute or Rule 59A-5.011(2) F.A.C.

Type Rule

Regulation Definition

Each center 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 reviewed at least every two years by the infection control program members, dated at the time of each review, revised as necessary, and enforced.

59A-5.011(2), F.A.C.

Interpretive Guideline

Verify that review is being accomplished.

Request minutes of meetings held.

ST - M0043 - SURVEIL, PREVENT & CONTROL OF INFECTION

Title SURVEIL, PREVENT & CONTROL OF
INFECTION
Statute or Rule 59A-5.011(3) F.A.C.

Type Rule

Regulation Definition

The policies and procedures devised by the infection control program shall be approved by the governing body, and shall contain at least the following:

Interpretive Guideline

Review policies and procedures to ensure compliance.

Verify that sterile items are being properly maintained.

Review log to ensure compliance

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- (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 related to the handling and disposal of biomedical waste in accordance with [Chapter 64E-16, F.A.C., and OSHA 29 CFR Part 1910.1030, Bloodborne Pathogens].

- (d) Specific policies related to the selection, storage, handling, use and disposition of disposable items.

- (e) Specific policies related to decontamination and sterilization activities performed at the center, including but not limited to a requirement that steam, gas (ETO) and hot air sterilizers be tested with live bacterial spores at least weekly.

- (f) Specific policies regarding the indications for universal precautions, body substance isolation, CDC isolation guidelines, or equivalent and the types of isolation to be used for the prevention of the transmission of infectious diseases.

- (g) A requirement that soiled linen be collected in such a manner as to

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minimize microbial dissemination into the environment.

(h) A requirement that all cases of communicable diseases as set forth in [Chapter 64D, F.A.C.], be promptly and properly reported in accordance with the provisions of that rule;

59A-5.011(3), F.A.C.

ST - M0044 - SURVEIL, PREVENT & CONTROL OF INFECTION

Title SURVEIL, PREVENT & CONTROL OF INFECTION
Statute or Rule 59A-5.011(4) F.A.C.

Type Rule

Regulation Definition

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 quality assurance committee and the governing body.

59A-5.011(4), F.A.C.

Interpretive Guideline

Request minutes of meetings held.

Request and review reports.

ST - M0045 - SURVEIL, PREVENT & CONTROL OF INFECTION

Title SURVEIL, PREVENT & CONTROL OF INFECTION
Statute or Rule 59A-5.011(5) F.A.C.

Type Rule

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Regulation Definition

Each ambulatory surgical center shall establish an employee health policy to minimize the likelihood of transmission of communicable disease by both employees and patients. Such policies shall include, but not be limited to, 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.

59A-5.011(5), F.A.C.

Interpretive Guideline

Verify that a policy has been established and that it is understood by all employees.

ST - M0046 - MEDICAL RECORDS

Title MEDICAL RECORDS

Statute or Rule 59A-5.012(1) F.A.C.

Type Rule

Regulation Definition

MEDICAL RECORDS. Each ambulatory surgical center shall establish processes to obtain, manage, and utilize information to enhance and improve individual and organizational performance in patient care, management, and support processes. Such processes shall:

(a) Be planned and designed to meet the center's internal and external

Interpretive Guideline

Determine to what extent the facility educates its staff regarding these support processes.

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information needs;

(b) Provide for confidentiality, integrity and security;

(c) Provide education and training in information management principles to decision-makers and other center personnel who generate, collect, and analyze information; and

(d) Provide for information in a timely and accurate manner.

59A-5.012(1) F.A.C.

ST - M0047 - MEDICAL RECORDS

Title MEDICAL RECORDS

Statute or Rule 59A-5.012(2) F.A.C.

Type Rule

Regulation Definition

Each center shall have a medical records service, patient information system or similarly titled unit with administrative responsibility for medical records.

59A-5.012(2), F.A.C.

Interpretive Guideline

Self explanatory.

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ST - M0048 - MEDICAL RECORDS

Title MEDICAL RECORDS

Statute or Rule 59A-5.012(3) F.A.C.

Type Rule

Regulation Definition

The administrator shall appoint in writing a qualified person responsible for the Medical Records Service. This person shall meet the qualifications established for this position, in writing, by the governing body.

59A-5.012(3), F.A.C.

Interpretive Guideline

"Qualified person" means a person who meets the qualifications deemed necessary by the governing body.

Request verification that qualified person has been appointed.

ST - M0049 - MEDICAL RECORDS

Title MEDICAL RECORDS

Statute or Rule 59A-5.012(4) F.A.C.

Type Rule

Regulation Definition

A current job description delineating duties and responsibilities shall be maintained for each medical records service position.

59A-5.012(4), F.A.C.

Interpretive Guideline

Review documentation to ensure compliance.

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ST - M0050 - MEDICAL RECORDS

Title MEDICAL RECORDS

Statute or Rule 59A-5.012(5) F.A.C.

Type Rule

Regulation Definition

Interpretive Guideline

The medical records service shall:

Randomly select at least five medical records to ensure compliance.

(a) Maintain a system of identification and filing to ensure the prompt location of a patient's medical record. Patient records may be stored on electronic medium such as computer, microfilm or optical imaging;

(b) Maintain a current and complete medical record for every patient admitted to the ambulatory surgical center.

(c) All clinical information pertaining to the patient's medical treatment shall be centralized in the patient's medical record.

(d) Ensure that each medical record shall contain the original of the following as appropriate to the service provided:

1. Identification data:

2. Chief complaint;

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3. Present illness;
4. Past personal history;
5. Family medical history;
6. Physical examination report;
7. Provisional and pre-operative diagnosis;
8. Clinical laboratory reports;
9. Radiology, diagnostic imaging, and ancillary testing reports;
10. Consultation reports;
11. Medical and surgical treatment notes and reports;
12. The appropriate informed consent signed by the patient;
13. Record of medication and dosage administered;
14. Tissue reports;
15. Physician orders;
16. Physician and nurse progress notes;

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17. Final diagnosis;

18. Discharge summary; and

19. Autopsy report, if appropriate.

(e) Ensure that:

1. Operative reports signed by the surgeon shall 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

2. Postoperative information shall include vital signs, level of consciousness, medications, blood or blood components, complications and management of those events, identification of direct providers of care, discharge information from post-anesthesia care area.

(f) Index, and maintain on a current basis, all medical records according to surgical procedure and physician.

59A-5.012(5), F.A.C.

ST - M0051 - PHYSICAL PLANT MAINTENANCE

Title PHYSICAL PLANT MAINTENANCE

Statute or Rule 59A-5.016(1) F.A.C.

Type Rule

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Regulation Definition

Each ambulatory surgical center shall establish written policies and procedures designed to maintain the physical plant and overall ambulatory surgical center environment in such a manner that the safety and well-being of patients is assured. The building and mechanical maintenance program shall be under the supervision of a qualified person.

59A-5.016(1), F.A.C.

Interpretive Guideline

Verify that a qualified person has been appointed.

Review the policies and procedures to ensure that there is a schedule for routine maintenance.

ST - M0052 - PHYSICAL PLANT MAINTENANCE

Title PHYSICAL PLANT MAINTENANCE

Statute or Rule 59A-5.016(2) F.A.C.

Type Rule

Regulation Definition

All mechanical and electrical equipment shall be maintained in working order, and shall be accessible for cleaning and inspection.

59A-5.016(2), F.A.C.

Interpretive Guideline

Review policies and procedures covering the repair and maintenance of both the physical plant and equipment.

Verify that all mechanical and electrical equipment is being maintained in working order, and that repairs are made in a timely manner.

ST - M0053 - FIRE CONTROL

Title FIRE CONTROL

Statute or Rule 59A-5.017(1) F.A.C.

Type Rule

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Regulation Definition

FIRE CONTROL. Each ambulatory surgical center shall provide fire protection through the elimination of fire hazards; the installation of necessary safeguards such as extinguishers, sprinkling devices, and fire and smoke barriers as described in 59A-5.020, F.A.C., to insure rapid and effective fire control; and the adoption of written fire control plans rehearsed four (4) times a year by all personnel. To safeguard patients, the ambulatory surgical center shall have:

- (a) Written evidence of regular inspection by local fire control agencies.
- (b) Stairwells kept closed by fire doors equipped with self-closing devices.
- (c) Annual check of fire extinguishers for type, replacement, and renewal dates.
- (d) "No Smoking" signs prominently displayed in those areas where smoking is not permitted.
- (e) Fire regulations and evacuation route prominently posted for each floor and department.

Interpretive Guideline

Review policies and procedures to determine compliance.

Verify that the adopted written fire control plan is being rehearsed four (4) times a year by all personnel.

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59A-5.017(1), F.A.C.

ST - M0054 - FIRE CONTROL

Title FIRE CONTROL

Statute or Rule 59A-5.017(2) F.A.C.

Type Rule

Regulation Definition

Written fire control plan approved by the appropriate local fire authority shall contain provisions for prompt reporting of all fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

59A-5.017(2), F.A.C.

Interpretive Guideline

Request documentation to ensure compliance.

ST - M0055 - FIRE CONTROL

Title FIRE CONTROL

Statute or Rule 59A-5.017(3) F.A.C.

Type Rule

Regulation Definition

There shall be rigidly enforced written rules and regulations governing proper routine methods of handling and storing oxidizing, combustible, and flammable explosive agents.

Interpretive Guideline

Request documentation verifying regulations are enforced.

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59A-5.017(3), F.A.C.

ST - M0056 - COMP EMERGENCY MGMT PLAN

Title COMP EMERGENCY MGMT PLAN

Statute or Rule 59A-5.018(1) F.A.C.

Type Rule

Regulation Definition

The ASC has a written comprehensive emergency management plan for emergency care during an internal or external disaster, or emergencies which is reviewed and updated annually and approved by the county emergency management agency.

59A-5.018(1), F.A.C.

Interpretive Guideline

Verify that the plan has been reviewed and approved by the county emergency management agency on an annual basis.

ST - M0057 - COMP EMERGENCY MGMT PLAN

Title COMP EMERGENCY MGMT PLAN

Statute or Rule 59A-5.018(4) F.A.C.

Type Rule

Regulation Definition

The ambulatory surgical center shall test the implementation of the emergency management plan semiannually, either in response to an emergency or in a planned drill, and shall evaluate and document the facility's performance. This documentation must be on file at the

Interpretive Guideline

Verify that the plan is tested semiannually, either in response to an emergency or in a planned drill.

Ensure that there is documentation that the plan has been tested and an evaluation of facility's performance has been done.

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center and available for inspection by the county emergency management agency and the Agency for Health Care Administration.

59A-5.018(4), F.A.C.

ST - M0058 - COMP EMERGENCY MGMT PLAN

Title COMP EMERGENCY MGMT PLAN

Statute or Rule 59A-5.018(5) F.A.C.

Type Rule

Regulation Definition

The emergency management plan shall be available for immediate access by the staff.

59A-5.018(5), F.A.C.

Interpretive Guideline

Verify that plan is located for immediate access by the staff.

ST - M0059 - QUALITY ASSESSMENT & IMPROVEMENT

Title QUALITY ASSESSMENT & IMPROVEMENT

Statute or Rule 59A-5.019(1) F.A.C.

Type Rule

Regulation Definition

Each ambulatory surgical center shall have an ongoing quality assessment and improvement system designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, and opportunities to improve its

Interpretive Guideline

Review the facility's QA plan to ensure that the program contains monitoring and evaluation of the quality and appropriateness of care, efforts to improve patient care and the identification and resolution of problems impacting on the care of patients.

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performance to enhance and improve the quality of 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 assessment and improvement, which shall include utilization review, must be defined in writing, approved by the governing body, and enforced, and shall include:

1. A written delineation of responsibilities for key staff;
2. A policy for all members of the organized medical staff, whereby staff members do not initially review their own cases for quality assessment and improvement program purposes;
3. A confidentiality policy;
4. Written, measurable criteria and norms;
5. A description of the methods used for identifying problems;

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6. A description of the methods used for assessing problems, determining priorities for investigation, and resolving problems;

7. A description of the methods for monitoring activities to assure that the desired results are achieved and sustained; and

8. Documentation of the activities and results of the program.

59A-5.019(1), F.A.C.

ST - M0060 - QUALITY ASSESSMENT & IMPROVEMENT

Title QUALITY ASSESSMENT & IMPROVEMENT

Statute or Rule 59A-5.019(2) F.A.C.

Type Rule

Regulation Definition

Each center shall have in place a systematic process to collect data on process outcomes, priority issues chosen for improvement, and the satisfaction of the patient.

Processes measured shall include:

- (a) Appropriate surgical procedures;
- (b) Preparation of patient for the procedure;

Interpretive Guideline

Determine that the scope of the QA program includes an evaluation of all services provided directly or under agreement.

Verify that the infection control committee makes a report at least annually to the quality assurance committee and the governing body.

Determine that the ASC has taken appropriate action to correct problems identified by the QA program.

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- (c) Performance of the procedure and monitoring of the patient;
- (d) Provision of post-operative care;
- (e) Use of medications including administration and monitoring of effects;
- (f) Risk management activities;
- (g) Quality assessment and improvement activities including at least clinical laboratory services and radiology services;
- (h) Results of autopsies if needed.

59A-5.019(2), F.A.C.

ST - M0061 - QUALITY ASSESSMENT & IMPROVEMENT

Title QUALITY ASSESSMENT & IMPROVEMENT

Statute or Rule 59A-5.019(3) F.A.C.

Type Rule

Regulation Definition

Each center 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

Determine that the ASC has taken appropriate action to correct problems identified by the QA program.

Examine reports, minutes of meetings, to determine that the ASC has documented the remedial action and its outcome.

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59A-5.019(3), F.A.C.

ST - M0401 - INTERNAL RISK MANAGEMENT PROGRAM

Title INTERNAL RISK MANAGEMENT PROGRAM

Statute or Rule 395.0197(1), F.S.

Type Rule

Regulation Definition

Every licensed facility shall, as a part of its administrative functions, establish an internal risk management program. Such program shall include:

S. 395.0197 (1), F.S.

R.59A-10.002 (15), F.A.C.

R.59A-10.002 (2), F.A.C.

R.59A-10.002 (3), F.A.C.

R.59A-10.002 (14), F.A.C.

Interpretive Guideline

Licensed Hospital and Ambulatory Surgical Centers are required to have an Internal Risk Management Program.

PROBE

The surveyor should review:

- The Risk Management Program/Plan
- Interview the Licensed Health Care Risk Manager responsible for the program
- Review personnel file of the Risk Manager for appropriate licensure
- Review a minimum sample of Incident Reports (review period since the last risk manager survey)
 - o Ambulatory Surgical Centers - 20

ST - M0402 - PROGRAM REQUIREMENTS

Title PROGRAM REQUIREMENTS

Statute or Rule 395.0197(1)(a), F.S.

Type Rule

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Regulation Definition

The internal risk management program shall include:

(a) The investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents to patients.

S. 395.0197(1)(a), F.S.

S. 395.0197(5), F.S.

Interpretive Guideline

The Risk Management Program must establish the general categories and specific types of incidents. Further, the program must contain the investigative process and analysis of the incidents.

PROBES

- Does the plan establish the incident categories?

-Are the incidents specific to this facility?

-Review 5 monthly Logs and 4 Quarterly Summary Reports

ST - M0403 - PROGRAM REQUIREMENTS

Title PROGRAM REQUIREMENTS

Statute or Rule 395.0197(1)(b), F.S.

Type Rule

Regulation Definition

The internal risk management program shall include:

(b) The development of appropriate measures to minimize the risk of adverse incident to patients.

S. 395.0197(1)(b), F.S.

S. 395.0197(5), F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS

1. Review the Risk Manger's role in the development and implementation of risk reduction and risk prevention strategies.

2. Consider evidence that patient and non-patient department staff have involved in the process.

3. Review previous incidents identified as risk/process improvement opportunities including the analysis of the incident and trends.

PROBES

- Review identified incident trends

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- Review measures put in place to correct
- Verify correction measures are systematic and facility-wide
- Has the facility minimized the risk to other patients?
- Validate implementation of measures in departments or units of facility

ST - M0404 - APPROPRIATE MEASURE

Title APPROPRIATE MEASURE

Statute or Rule 395.0197(1)(b)1, F.S.

Type Rule

Regulation Definition

The development of appropriate measures shall include:

1. Risk management and risk prevention education and training of all non-physician personnel as follows:

a. Such education and training of all non-physician 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

GUIDANCE TO SURVEYORS

Review orientation program(s) for documentation that the incident reporting system and adverse incident reporting (Code 15 and Annual Incident Reporting) is included.

Select a sample of new employees, 5 new and 5 existing employees, and agency (contract) personnel for evidence of training at orientation and annual review.

Interview 5 employees in regard to their education and training. (Example: RN's, CNA's, PT's, RT's, etc.)

PROBES

-Review 5 new and 5 existing clinical staff for education and training as required

- Interview 5 clinical staff to ascertain the knowledge of how to report and incident
How do you report an incident?

Are all incidents reported the same way (fall, elopement, allegation of abuse, rape)?

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S. 395.0197(1)(b)1, F.S.

ST - M0405 - APPROPRIATE MEASURE

Title APPROPRIATE MEASURE

Statute or Rule 395.0197(1)(b)2, F.S.

Type Rule

Regulation Definition

The development of appropriate measures shall include:

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 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.

s. 395.0197(1)(b)2, F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review facility Policy and Procedures for prohibitions against staff members attending patients in the recovery room alone.

Review the facility policy, i.e. either each authorized staff person in the recovery room is accompanied by at least one other person or the recovery room has live visual observation; or electronic observation; or any other reasonable measure taken to ensure patient protection and privacy.

PROBES

1. Request the schedule of recovery room personnel for all shifts.
2. Review the Policy and Procedures regarding the two-person requirement.
3. Tour the recovery room, preferably in the afternoon.
4. Interview staff regarding recovery room procedures and staffing patterns.
5. How does the facility handle live visual observation, electronic observation, or any other reasonable measure to ensure patient protection and privacy?
6. What type of electronic observation is used?
7. Who monitors the camera when patients are present in the recovery room?

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8. What type of documentation is maintained by the facility?

ST - M0406 - APPROPRIATE MEASURE

Title APPROPRIATE MEASURE

Statute or Rule 395.0197(1)(b)3, F.S.

Type Rule

Regulation Definition

The development of appropriate measures shall include:

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.

S. 395.0197(1)(b)3, F.S.

Interpretive Guideline

PROBES

Does the facility prohibit unlicensed person from assisting or participating in a surgical procedure, unless complete and direct physician supervision.

Interview surgical staff to ascertain if unlicensed staff participate/assisting in surgical procedures - provisions.

Review surgical schedule or records utilized to record other unlicensed staff surgical participation.

Review competencies for Private or Contractual Scrub individuals.

ST - M0407 - APPROPRIATE MEASURE

Title APPROPRIATE MEASURE

Statute or Rule 395.0197(1)(b)4, F.S.

Type Rule

Regulation Definition

The development of appropriate measures shall include:

4. Development, implementation, and ongoing evaluation of procedures, protocols, and systems to accurately identify patients, planned procedures, and the correct site of the planned procedure so as to minimize the performance of a

Interpretive Guideline

GUIDANCE TO SURVEYORS

Does the facility have an established procedure/protocol to prevent wrong site, wrong procedure, wrong patient surgery?

How does the facility identify the correct patient and the correct site for procedures?

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surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition.

S. 395.0197(1)(b)4, F.S.

How is the surgical site identified?

How does the facility identify and confirm the correct procedure(s)?

Does the facility involve the patient and his/her family members in identifying the patient, correct site, and correct procedure? If so, what systems does the facility have in place for appropriate communication techniques for any identified language or communication barriers?

Does facility staff have a method to verify that the identification process contains correct information?

Are protocols and procedures to prevent wrong site, wrong procedure, wrong patient incidents used facility-wide?

How is education and training of staff (including physicians) regarding the facility's procedures and protocols accomplished? Review documentation.

How does the facility monitor compliance with the protocols for quality control purposes?

Probes

- Review systems which prevent or minimize wrong patient, wrong surgical procedure, wrong site, or a surgical procedure unrelated.

- If an incident, breaches protocols - how is it reviewed to minimize risk to other patients?

ST - M0408 - PROGRAM REQUIREMENT

Title PROGRAM REQUIREMENT

Statute or Rule 395.0197(1)(c), F.S.

Type Rule

Regulation Definition

The internal risk management program shall include:

(c) The analysis of patient grievances that relate to patient care and the quality of medical services.

Interpretive Guideline

GUIDANCE TO SURVEYORS

1. Determine if the facility has a patient satisfaction patient grievance and a system to analyze the quality of medical services.

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S. 395.0197(1)(c), F.S.

Review form(s):

R 59A-10.002(10), F.A.C.

2. Select a sample of patient grievances/patient satisfaction responses related to patient care and the quality of medical services. Trace the process.
3. Review Policy and Procedures establishing the process that refers issues related to quality of care to the Risk Manager, Quality Assurance/Performance Improvement and the facility representative.
4. Review evidence that issues related to quality of care/medical care are analyzed including outcomes.

PROBES

- Is the Risk Manager involved in the analysis of grievances and quality of medical services improvement?
- Is there evidence of grievance analysis in the samples grievances.
- Were corrective measures placed into facility-wide systems?

ST - M0409 - PROGRAM REQUIREMENT

Title PROGRAM REQUIREMENT

Statute or Rule 395.0197 (1)(d), F.S.

Type Rule

Regulation Definition

The internal risk management program shall include:

(d) A system for informing a patient or an individual identified pursuant to Section 765.401(1), F.S., that the patient was the subject of an adverse incident. Such notice shall be given by an appropriately trained person designated by the licensed facility as soon as practicable to allow the patient an opportunity to minimize damage or injury.

S. 395.0197(1)(d), F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review the Policy and Procedures developed to enable patient notification (or the patient's healthcare surrogate) of all adverse incidents.

Refer to definition of adverse incident, s. 395.0197(5), F.S.

Review all Code 15's and Annual Report incidents to determine whether the patient and/or healthcare surrogate was informed of the incident.

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S. 765.401(1), F.S.

Verify documentation that the patient was notified following the adverse incident.

S. 395.0197(5), F.S.

Interview patient(s) involved in adverse incident if the patient is accessible.

PROBES

Did facility develop and implement a system for patient notification?

Does facility staff evaluate the system for informing patients that they have been the subject of an adverse incident?

ST - M0410 - PROGRAM REQUIREMENT

Title PROGRAM REQUIREMENT

Statute or Rule 395.0197(1)(e), F.S.

Type Rule

Regulation Definition

The internal risk management program shall include:

(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.

S. 395.0197 (1)(e), F.S.

R. 59A-10.002(8), F.A.C.

R. 59A-10.002(9), F.A.C.

S. 395.0197(5), F.S.

R. 59A-10.002(21), F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review the Policy and Procedures for incident reporting.

Interview a sample of staff to determine their awareness of the responsibilities, requirements, and method of incident reporting.

Review a sample of personnel files for education and training in incident reporting.

Review a sample of Incident/Occurrence Reports for determining that incidents are reported within three (3) business days to the Risk Manager or to the Risk Manager Designee.

Interview a sample of staff to determine the facility's method for reporting within 3 business days.

If there is a Risk Manager Designee, verify evidence of appointment.

PROBES

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What are the guidelines for reporting incidents?

Does staff understand who reports, what is reported, when and where to report, how to report, and why to report?

Can facility staff provide and account for dissemination of information on the incident reporting system to all health care providers, agents and employees?

Did all new non-physician personnel receive, within 30 days of employment, instruction about the operation of and the responsibilities of the incident reporting system?

ST - M0411 - INCIDENT REPORTING SYSTEM

Title INCIDENT REPORTING SYSTEM

Statute or Rule 59A-10.0055(2), F.A.C.

Type Rule

Regulation Definition

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 incident reporting system and responsibilities of it. At least annually, all non-physician 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.

59A-10.0055(2), F.A.C.

R. 59A-10.002(8), F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS:

Interview the Risk Manager and determine what the facility considers annual? Is it calendar year or date of hire year?

Request a list of non-physician personnel with their hire dates. Include private/contract surgical scrub personnel.

Interview a sample of newly hires and experienced staff to determine their awareness of the responsibilities, requirements, and method for incident reporting.

Review a sample of personnel, both newly hired and personnel who have been employed over 2 years, files for education and training on incident reporting.

PROBES:

What are the guidelines for reporting incidents?

Ask staff which incidents are reportable, who is suppose to report the incidents, how is it done, when does it need to be done by, and where does the report go once they have completed it?

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Did all non-physician personnel receive, within 30 days of employment, instruction about the operation of and the responsibilities of the incident reporting system?

When was the last annual, 1 hour Risk Management and Risk Prevention training conducted?

ST - M0412 - INCIDENT REPORTING SYSTEM

Title INCIDENT REPORTING SYSTEM

Statute or Rule 59A-10.0055(2), F.A.C.

Type Rule

Regulation Definition

Incident 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 time, date, exact location; and elements as needed for the annual report based on ICD-9-CM;
- (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.

R. 59A-10.0055(2), F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review a sample of incident/occurrence reports filed since the date of the previous survey.

Select a sample of incident/occurrence reports to determine compliance with the incident form requirements.

The sample size is based on the issues identified.

PROBES

What are the types of incident reports used in the facility?

Does the incident/occurrence report form contain the required information?

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R. 59A-10.002(18), F.A.C.

R. 59A-10.002(19), F.A.C.

R. 59A-10.002(20), F.A.C.

ST - M0413 - RESP OF GOVERNING BOARD AND RISK MANAGER

Title RESP OF GOVERNING BOARD AND RISK
MANAGER
Statute or Rule 395.0197(2), F.S.

Type Rule

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, licensed under Section 395.10974, F.S., who is responsible for implementation and oversight of such facility's internal risk management program as required by this section. A risk manager must not be made responsible for more than four internal risk management programs in separate licensed facilities, unless the facilities are under one corporate ownership or the risk management programs are in rural hospitals.

S. 395.0197(2), F.S.

S. 395.10974, F.S.

R. 59A-10.002(12)

R. 59A-10.002(15), F.A.C.

R. 59A-10.002(2), F.A.C.

R. 59A-10.002(3), F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS:

Review the facility's organization chart to see who the Risk Manger reports to.

When was the Risk Manager appointed? When was the Risk Manager approved by the Board/Governing Body?

Review reporting lines of authority.

Verify that the Risk Manager is currently licensed.

Interview the licensed Risk Manager and verify the number of current facilities for which the Risk Manager currently has responsibility.

Review the Risk Manger's job description for his/her responsibilities.

PROBES:

Inquire with the Risk Manager and the Hospital Administrator about the amount of time that the Risk Manager spends on-site at each facility for which the Risk Manager is responsible.

What is considered enough time in the facility? Does the Risk Manager only come to the facility for administrative and clinical meetings?

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Verify the participation in administrative and clinical meetings, by reviewing meeting minutes.

ST - M0414 - RISK MANAGER ACCESS TO RECORDS

Title RISK MANAGER ACCESS TO RECORDS

Statute or Rule 395.0197(4), F.S.

Type Rule

Regulation Definition

(4) The individual responsible for the risk management program shall have free access to all medical records of the licensed facility.

S. 395.0197(4), F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS:

Verify that the Risk Manager has access to all medical records of the facility by asking the Risk Manager and the Administrator.

Review the Risk Manager's job description to ensure the Risk Manager has access to all of the medical records.

Review the Governing Body Minutes and the facility's Policy and Procedures.

ST - M0415 - DEVELOPEMENT OF CORRECTIVE PROCEDURES

Title DEVELOPEMENT OF CORRECTIVE

PROCEDURES
Statute or Rule 395.0197(4), F.S.

Type Rule

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.

S. 395.0197(4), F.S.

R. 59A-10.002(7), F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS:

Ask the Risk Manager how they have determined what incidents to track and trend? Are the issues being tracked and trended, facility identified concerns?

Review all tracking and trending reports for the period since the previous survey.

How was the root cause of the concern identified? What investigation was done?

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Review all pertinent documentation for the verification that the Risk Manager's recommendations were developed and the corrective actions(s) were implemented.

How was the corrective action(s) implemented? Staff educated on corrective action?

How was the corrective action measured to determine its effectiveness? If it did not reduce the number of occurrences, what new corrective action(s) was implemented? Training?

PROBES:

How is information shared with other departments? How does the Risk Manager know if problems exist in other areas?

Ask floor staff if they have ever submitted an incident report? If yes, did they receive any feedback after the incident report was reviewed? What was the outcome of that incident report?

Question floor staff regarding how they were informed of the corrective actions implemented after an incident.

ST - M0416 - 15 DAY REPORTS

Title 15 DAY REPORTS

Statute or Rule 395.0197(7), F.S.

Type Rule

Regulation Definition

(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 for Health Care Administration 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

Interpretive Guideline

GUIDANCE TO SURVEYORS:

Review the facility's Policy and Procedures regarding reporting death, brain or spinal damage, wrong patient/wrong cite/wrong surgical procedure, unnecessary surgical procedure, surgical repair of damage resulting from surgical procedure, and removal of unplanned foreign body left after a surgical procedure.

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.

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| patient; | Request a list of patients who have expired in the facility in the past year. |
| (d) The performance of a wrong-site surgical procedure; | Review those deaths which resulted in an autopsy being conducted. What was the outcome? |
| (e) The performance of a wrong surgical procedure; | Did the Risk Manager file the Code 15 within 15 calendar days? |
| (f) The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition; | Review the consent form, signed by the patient prior to surgery, was the incident outcome listed as one of the specific risk of the surgical procedure. |
| (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 | PROBES:

Interview the Risk Manager regarding the facility's process for reporting Code 15 events.

Is the Risk Manager following the facility's Policy and Procedures when a Code 15 reportable incident occurs? |
| (h) The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure. The 15-day report shall be made on AHCA Form 3140-5001-August 1993, Code 15 Report, which is incorporated by reference and may be obtained from the Agency for Health Care Administration. The Agency may require an additional final report. Any reportable incidents pursuant to this section that are submitted more than 15 calendar days from occurrence by the facility must be justified in writing by the facility administrator. | If it is determined, through interview that 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.

NOTE: 15-day reports can be submitted online directly to the Agency's Florida Center for Health Information and Policy Analysis. The facility is no longer required to submit a paper copy of AHCA Form 3140-5001. The online submission meets this requirement. |
| S. 395.0197(7), F.S. | |
| R. 59A-10.0065, F.A.C. | |
| S. 395.0197(5), F.S. | |

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ST - M0417 - SEXUAL MISCONDUCT

Title SEXUAL MISCONDUCT

Statute or Rule 395.0197(9), F.S.

Type Rule

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, F.S., and the respective practice act, by a licensed health care practitioner that involves a patient.

S. 395.0197(9), F.S.

R. 59A-10.002(19), F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS:

Review a list of incidents and chose those relating to allegations of sexual misconduct.

Was the victim safe from further sexual misconduct during the investigation? How?

What is 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?

Were the police, DCF/APS, and the Department of Health notified?

Interview floor staff to see if they are aware of the facility's Policy and Procedures for an allegation of sexual misconduct?

Review the accused and other employees' personnel file to determine if the facility conducted a background screening, prior to the employees working in the facility?

What education/training regarding sexual misconduct and reporting an allegation of sexual misconduct have the employees received?

PROBES: 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?

Review the facility's Policy and Procedures regarding background screening.

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ST - M0418 - SEXUAL ABUSE REPORTS

Title SEXUAL ABUSE REPORTS

Statute or Rule 395.0197 (10), F.S.

Type Rule

Regulation Definition

(10) Any witness who witnessed or who possesses actual knowledge of the act that is the basis of an allegation of sexual 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 Section 794.011(1)(h), F.S., 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 care giving action.

S. 395.0197(10), F.S.

S. 794.011(1)(h), F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS:

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.

Was the alleged victim protected from any further abuse during the facility's investigation? How? If the allegation was confirmed, what did the facility do to rectify the situation which resulted in the abuse? What preventive measures have been taken to ensure this situation does not recur?

What in service/training was conducted in order to educate all of the facility's staff on the new prevention method?

Were the police, DCF/APS, Administrator, and/or the Health Department notified?

Review the accused and other facility employee's file to determine if background checks were conducted prior to the employee working in the facility?

What training have the facility's employees received regarding preventing and reporting abuse or neglect?

PROBES:

Interview facility staff (LPN, RN, CNA, Maintenance, Housekeeping) to determine if they know what to do if someone reports sexual abuse to them. Is the information provided by staff in compliance with the facility's abuse Policy and Procedures?

Did the investigation into allegation of sexual abuse comply with the facility's Policy and Procedures?

What was the outcome of the investigation?

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ST - M0419 - RISK MANAGER REVIEW OF INCIDENT REPORTS

Title RISK MANAGER REVIEW OF INCIDENT
REPORTS
Statute or Rule 59A-10.0055(3), F.A.C.

Type Rule

Regulation Definition

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. Upon emergence of any trend or pattern in incident occurrence, the risk manager shall develop recommendations for corrective actions and risk management prevention education and training. Summary data thus accumulated shall be systematically maintained for 3 years.

R. 59A-10.0055(3), F.A.C.

R. 59A-10.002(7), F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS:

Review all tracking and trending reports for the period since the previous survey.

Review results to ascertain that the Risk Manager has trended the information to identify patterns and any problem areas.

Discuss the guidelines used.

Review all pertinent documents for verification that the Risk Manager's recommendations were developed and the corrective action(s) implemented.

Discuss and review documentation as to whether the corrective action(s) was effective and if not was the plan revised.

Verify that action has been taken to reduce and prevent risks to patients.

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.

PROBES

Describe the manner by which the Risk Manager ensures that staff from individual departments/units identify safety hazards and risk exposures in clinical and facility-wide systems.

Does staff receive feedback regarding incident reports that they completed?

Has an incident report that you filed resulted in a change?

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What type of system does the Risk Manager utilize to track and trend incidents?

ST - M0420 - SUMMARY REPORT TO GOVERNING BODY

Title SUMMARY REPORT TO GOVERNING BODY

Statute or Rule 59A-10.055(3)(a), F.A.C

Type Standard

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.

R. 59A-10.0055(3)(a), F.A.C.

R. 59A-10.002(12), F.A.C

R. 59A-10.002(14), F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review the Governing Body minutes for risk management documentation. Interview the Licensed Risk Manager and staff re: methodology.

Who presents the risk management summary report?

PROBES

Does the Governing Body act on the quarterly reports?

ST - M0421 - ANNUAL REPORT OF JUDGMENTS

Title ANNUAL REPORT OF JUDGMENTS

Statute or Rule 395.0197 (3), F.S.

Type Rule

Regulation Definition

(3) Each licensed facility shall annually report to the Agency for Health Care Administration and the Department of Health the name and judgments entered against each health care practitioner for which it assumes liability.

S. 395.0197(3), F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review documentation of reporting.

PROBES

Does the facility have a report that identifies and summarizes judgments, not actions against practitioners?

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S. 456.001(4), F.S.

Have these identified practitioners been reported to the Department of Health and Agency for Healthcare Administration?

ST - M0422 - ANNUAL REPORT SUMMARIZING INCIDENT REPORTS

Title ANNUAL REPORT SUMMARIZING INCIDENT REPORTS
Statute or Rule 395.0197 (6) (a), (c), F.S.

Type Rule

Regulation Definition

(6)(a) Each licensed facility subject to this section shall submit an annual report to the Agency for Health Care Administration 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

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review the Annual Report(s) submitted to AHCA for:

- Timeliness
- Verification the AHCA form is being used.
- Number of incidents reported.
- Types of incidents.
- Number and types of claims.

The Annual Report includes:

- Death;
- Brain or spinal damage;
- Permanent disfigurement;
- Fracture or dislocation of bones or joints;
- A limitation of neurological, physical, or sensory function which continues after discharge from the facility;
- Any condition that required specialized medical attention or surgical intervention resulting from non-emergency medical intervention other than an emergency medical condition, to which the patient has not given his or her informed consent;
- Any condition that requires the transfer of the patient within or outside the facility to a unit providing a more acute care level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;
- Was the performance of a surgical procedure on the wrong patient;
- A wrong surgical procedure;
- A wrong-site surgical procedure;
- A surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;
- Required the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage

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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 annual report submitted to the Agency shall also contain the name and license number 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.

S. 395.0197(6)(a), (c), F.S.

R. 59A-10.002(7), F.A.C.

S. 395.0197(5), F.S.

S. 766.106(1)(a), F.S.

was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process;
or

--Was a procedure to remove unplanned foreign objects remaining from a surgical procedure?

Review a sample of malpractice claims filed since the date of the last survey.

Review a sample of disciplinary actions and outcomes against practitioners and the reporting of all actions to Department of Health/Medical Quality Assurance.

Review the facility's results of outcome measures, QA/PI initiatives; risk prevention and risk reduction strategies for the year. (Reference s. 395.1097(6)(c), F.S.)

PROBES:

Remind the facility the surveyor has access to any facility record necessary to perform the Risk Management Survey.

Is there a process in place for determining reportable incidents? How does it function?

Is there a system developed to report the required adverse events to the Agency?

Determine who has the final authority for determination that an incident meets the definition of an "adverse incident" to be reported to the Agency.

Have any discharged patients required readmission for previous treatment or surgical episodes?

Have any current patients required additional surgery, and/or treatment interventions as a result of an adverse incident?

Any transfers to a higher level of care?

Review the facility's annual reports for compliance of reporting the following:

Total number of pending and closed claims;

Claim number for each claim;

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Nature of incident;

License numbers of persons involved in the claim and

Status or disposition of the claim.

ST - M0423 - AGENCY ACCESS TO RECORD

Title AGENCY ACCESS TO RECORD

Statute or Rule 395.0197(13), F.S.

Type Rule

Regulation Definition

(13) The Agency for Health Care Administration shall have access to all licensed facility records necessary to carry out the provisions of this section. 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.

S. 395.0197(13), F.S.

R. 59A-10.0055(3)(b), F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS

All facility records are to be made available to surveyors upon request.

ST - M0424 - UNLAWFUL COERCION OF REPORTING OBLIGATION

Title UNLAWFUL COERCION OF REPORTING

OBLIGATION
Statute or Rule 395.0197(19), F.S.

Type Rule

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Regulation Definition

(19) It shall be unlawful for any person over whom the facility exercises control 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.

S. 395.0197(19), F.S.

Interpretive Guideline

Ask the Risk Manager if anyone has ever attempted to interfere with his/her reporting obligations.

ST - M0425 - PATIENT SAFETY PLAN

Title PATIENT SAFETY PLAN

Statute or Rule 395.1012(1), F.S.

Type Rule

Regulation Definition

(1) Each licensed facility must adopt a patient safety plan.

S. 395.1012(1), F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review the facility's patient safety plan.

PROBES

Does the facility have a patient safety plan?

How often is the patient safety plan updated/reviewed?

ST - M0426 - PATIENT SAFETY OFFICER AND COMMITTEE

Title PATIENT SAFETY OFFICER AND COMMITTEE

Statute or Rule 395.1012(2), F.S.

Type Rule

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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.

S. 395.1012(2), F.S.

R. 59A-10.002(15), F.A.C.

R. 59A-10.002(2), F.A.C.

R. 59A-10.002(3), F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Determine if facility management has appointed a Patient Safety Officer.

Review position description.

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.

For ASC's: If the ASC is owned by a corporation, a corporate representative who is not employed by or practicing at that particular licensed facility may serve as that person.

Review facility documentation of the Patient Safety Committee activities such as 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.

PROBES

Do the committee members maintain records (surveys, evaluations, monitoring and corrective actions)?

Does the Patient Safety Committee document the proceedings?

Describe the relationship of the Patient Safety Officer to the Patient Safety Plan.

What are the committee's current projects/goals?

How well attended are the committee meetings?

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ST - M9999 - FINAL OBSERVATIONS

Title FINAL OBSERVATIONS

Statute or Rule

Type Memo Tag

Regulation Definition

Interpretive Guideline