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ST - M0000 - INITIAL COMMENTS

Title INITIAL COMMENTS

Statute or Rule

Type Memo Tag

Regulation Definition

Interpretive Guideline

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

ST - M0001 - Definitions

Title Definitions

Statute or Rule 395.0197(5)& (10)(b); 395.002(3&4&20); 5

Type Memo Tag

Regulation Definition

Interpretive Guideline

395.0197 (5) For purposes of reporting to the agency pursuant to this section, the term " adverse incident " means an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred, and which:

(a) Results in one of the following injuries:

1. Death;
2. Brain or spinal damage;
3. Permanent disfigurement;
4. Fracture or dislocation of bones or joints;
5. A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility;
6. Any condition that required specialized medical attention or surgical intervention resulting from nonemergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or

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7. Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;

(b) Was the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;

(c) Required the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or

(d) Was a procedure to remove unplanned foreign objects remaining from a surgical procedure.

(10)(b) ... " Sexual abuse " includes, but is not limited to, the acts defined in s. 1)(h), fondling, exposure of a vulnerable adult's or minor's sexual organs, or the use of the vulnerable adult or minor to solicit for or engage in prostitution or sexual performance. " Sexual abuse " does not include any act intended for a valid medical purpose or any act which may reasonably be construed to be a normal caregiving action.

395.002

(3) " Ambulatory surgical center " or " mobile surgical facility " means a facility the primary purpose of which is to provide elective surgical care, in which the patient is admitted to and discharged from such facility within the same working day and is not permitted to stay overnight, and which is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy, an office maintained by a physician for the practice of medicine, or an office maintained for the practice of dentistry shall not be construed to be an ambulatory surgical center, provided that any facility or office which is certified or seeks certification as

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a Medicare ambulatory surgical center shall be licensed as an ambulatory surgical center pursuant to s. 395.003. Any structure or vehicle in which a physician maintains an office and practices surgery, and which can appear to the public to be a mobile office because the structure or vehicle operates at more than one address, shall be construed to be a mobile surgical facility.

(4) " Biomedical waste " means any solid or liquid waste as defined in s. 381.0098(2)(a).

(20) " Medically necessary transfer " means a transfer made necessary because the patient is in immediate need of treatment for an emergency medical condition for which the facility lacks service capability or is at service capacity.

59A-5.002

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

(2) " Agency " means the Agency for Health Care Administration.

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

(4) " Anesthesiologist Assistant " means a person currently licensed pursuant to Chapter 458 or 459, F.S. as an anesthesiologist assistant.

(5) " Center " means an ambulatory surgical center.

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

(8) " F.A.C. " means the Florida Administrative Code.

(9) " Governing board " means an individual owner, partnership, corporation or other legally established authority

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in whom the ultimate authority and responsibility for management of the ambulatory surgical center is vested.

(11) " Operating room " means a room designated and equipped for performing surgical operations that requires a restricted environment.

(12) " Operating room technician " means a person with specialized training in operation room techniques and considered by the governing board qualified to serve as part of the operating room staff.

(13) " Medical Staff " means a formal organization of physicians, dentists, podiatrists, or other health professionals, who are appointed by the governing board to attend patients within the ambulatory surgical center.

(14) " Patient " means a person admitted to the ambulatory surgical center.

(15) " Pharmacist " means a person currently licensed pursuant to Chapter 465, F.S.

(16) " Physician " means a person currently licensed to practice medicine or osteopathy pursuant to Chapter 458 or 459, F.S.

(17) " Podiatrist " means a person currently licensed to practice podiatric medicine pursuant to Chapter 461, F.S.

(18) " Procedure Room " means a room designated for the performance of special procedures that do not require a restricted environment but may use sterile instruments or equipment.

(19) " Recovery Bed " means an accommodation with support services used for post-operative recovery in an ambulatory surgical center.

(20) " Registered Professional Nurse " means a person currently licensed as defined in Section 464.003(22), F.S.

59A-10.002

(5) " Injury " for the purposes of reporting to the Agency is any of the following outcomes when caused by an adverse

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incident:

- (a) Death; or
- (b) Brain damage; or
- (c) Spinal damage; or
- (d) Permanent disfigurement; or
- (e) Fracture or dislocation of bones or joints; or
- (f) Any condition requiring definitive or specialized medical attention which is not consistent with the routine management of the patient ' s case or patient ' s preexisting physical condition; or
- (g) Any condition requiring surgical intervention to correct or control; or
- (h) Any condition resulting in transfer of the patient, within or outside the facility, to a unit providing a more acute level of care; or
- (i) Any condition that extends the patient ' s length of stay; or
- (j) Any condition that results in a limitation of neurological, physical, or sensory function which continues after discharge from the facility.

ST - M0002 - Licensure Requirements - Accreditation

Title Licensure Requirements - Accreditation

Statute or Rule 59A-5.004(3)

Type Rule

Regulation Definition

ACCREDITED AMBULATORY SURGICAL CENTERS.
The Agency shall accept the report of an accrediting organization in lieu of an annual licensure inspection for accredited centers and for centers seeking accreditation, provided that the standards used by the accrediting organization are determined by the Agency to incorporate comparable state licensure requirements, found in Chapters 395 and 408, F.S. and Chapters 59A-5 and 59A-35, F.A.C., and the center does not meet the criteria specified under

Interpretive Guideline

Ask if the facility is accredited by an accrediting organization?
If facility states they are accredited, ask for documentation and contact Field Office for questions or additional guidelines.

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subparagraphs (c)1. and 2.

ST - M0003 - GOVERNING BODY

Title GOVERNING BODY

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

Type Rule

Regulation Definition

(1) The ambulatory surgical center organization shall have an effective governing authority responsible for the legal and ethical conduct of the ambulatory surgical center. The governing body in fulfilling its responsibility shall be organized under approved written bylaws, rules and regulations which shall:

(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 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

Interpretive Guideline

When the physician-owner-operator is the governing body, refer to tag 0004 for information. This tag would not be cited for not having a multi-member governing body.

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 chairs of committees.

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

Review governing body meeting agenda/minutes and

- Verify meetings are held at specified frequency and intervals, pursuant to bylaws.
- Verify quorums, as specified in the bylaws, are present.
- Verify minutes are recorded and made available to all members of the governing body.

Review credentialing file to verify 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.

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

Review file of podiatrists and dentists who do not have admitting privileges for a written agreement with a physician who has staff privileges to accept patients who require continuing care.

Review policies and procedures for the transfer of patients to an acute care setting.

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quorum and with the requirement that minutes be 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 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 an 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.

(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.

Review written transfer agreements with one or more local hospitals.

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

Ask for the list of services and surgical procedures provide by the center.

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(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.

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.

Interpretive Guideline

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

ST - M0005 - PATIENT RIGHTS

Title PATIENT RIGHTS

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

Type Rule

Regulation Definition

Each ambulatory surgical center shall develop and adopt policies and procedures to ensure the protection of patient rights; which at a minimum shall include those patient rights specified in Sections 381.026, 395.301, and 395.3025, F.S.

Interpretive Guideline

Review policies and procedures, which address patient rights issues.

Verify the Florida Patient's Bill of Rights and Responsibilities is handed out or posted.

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ST - M0006 - ORGANIZED MEDICAL STAFF

Title ORGANIZED MEDICAL STAFF

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

Type Rule

Regulation Definition

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.

Interpretive Guideline

Interview risk management or quality improvement staff for measures relating to professional and ethical practices and how they are reported to 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.
- (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

Interpretive Guideline

Interview administrator about committee structure.

Review committee organization.

Review agendas or other documents to verify committee is achieving a-i.

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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 Sections 395.0191 and 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 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 ensure standards of practice are maintained, including proper disposal of outdated prescription and controlled drugs in accordance with Rule 59X-28.702, F.A.C. and Chapters 465 and 893, F.S.

ST - M0009 - SURGICAL SERVICES

Title SURGICAL SERVICES

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

Type Rule

Regulation Definition

SURGICAL DEPARTMENT. This department 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.

Interpretive Guideline

Interview administrator for details about the organization of the surgical department

Review written policies and procedures.

Review staff schedule for patterns.

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Tour all operative rooms.

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

ST - M0010 - SURGICAL SERVICES

Title SURGICAL SERVICES

Statute or Rule 59A-5.0085(1)(a), 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.

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)(b), F.A.C.

Type Rule

Regulation Definition

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

1. Patient ' s name, patient number, pre-operative diagnosis, post-operative diagnosis, surgical procedure, anesthetic, and complications, if any; and
2. Name of each member of the surgical team, including the surgeon, first assistant, anesthesiologist, nurse anesthetist, anesthesiologist assistant, circulating nurse and operating room technician.

Interpretive Guideline

Review the surgery record to ensure records are complete with required information.

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ST - M0012 - SURGICAL SERVICES

Title SURGICAL SERVICES

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

Type Rule

Regulation Definition

Emergency equipment shall be provided as needed commensurate with the services of the center, maintained in functional condition, and capable of providing and maintaining cardiorespiratory functioning.

Interpretive Guideline

Verify policies and procedures address the emergency equipment is tested/maintained regularly.

Observe the use or test of equipment, if possible.

Interview staff regarding availability and use of emergency equipment.

ST - M0014 - SURGICAL SERVICES

Title SURGICAL SERVICES

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

Type Rule

Regulation Definition

Emergency equipment shall be provided as needed commensurate with the services of the center, maintained in functional condition, and capable of providing and maintaining cardiorespiratory functioning.

Interpretive Guideline

Verify policies and procedures address the emergency equipment is tested/maintained regularly.

Observe the use or test of equipment, if possible.

Interview staff regarding availability and use of emergency equipment.

ST - M0015 - SURGICAL SERVICES

Title SURGICAL SERVICES

Statute or Rule 59A-5.0085(1)(g),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 the following:

1. Surgical asepsis: preparation, handling, and maintenance of sterile equipment and supplies.
2. Medical asepsis: patients, staff, equipment, traffic, and equipment flow patterns.
3. Sterilization and disinfection standards and controls; equipment and supplies.
4. Housekeeping.

Interpretive Guideline

Review policies and procedures and verify they address these items.

ST - M0016 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

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

Type Rule

Regulation Definition

ANESTHESIA SERVICE. This service shall be organized under written policies and procedures relating to anesthesia staff privileges, the administration of anesthesia, and the maintenance of strict safety controls.

Interpretive Guideline

Review policies and procedures and verify they address these items.

ST - M0018 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

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

Type Rule

Regulation Definition

All anesthesia shall be administered by an anesthesiologist, a credentialed and privileged physician, certified registered

Interpretive Guideline

Review surgery record to determine compliance. Review staffing records. Observe, if possible, a physician is in the building during the visit. NOTE: Licensed Physician must be in the building and available if needed but not required

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nurse anesthetist or anesthesiologist assistant, 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 Section 466.017, F.S., and Chapter 64B5-14, F.A.C.

to be in the room during the administration of anesthesia.

ST - M0019 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

Statute or Rule 59A-5.0085(2)(b), 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 or an anesthesiologist assistant under the direct supervision of an anesthesiologist, shall be in the center during the anesthesia and post-anesthesia recovery period until all patients are cleared for discharge.

Interpretive Guideline

Review surgery record to determine compliance.

Verify time of physician availability during recovery.

ST - M0020 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

Statute or Rule 59A-5.0085(2)(c), 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.

Interpretive Guideline

Review policies and procedures.

Review staff schedule.

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ST - M0021 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

Statute or Rule 59A-5.0085(2)(d), 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.

Interpretive Guideline

Review patient's medical record to determine compliance

ST - M0022 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

Statute or Rule 59A-5.0085(2)(e), 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 board, and be reviewed annually, dated at time of each review, revised as necessary, and enforced.

Interpretive Guideline

Review policies and procedures to ensure compliance.

If questionable, review governing body agendas or minutes.

ST - M0023 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

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

Type Rule

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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 semi-annual basis, and a written record of the results and corrective actions be maintained;
2. Flammable anesthetic agents shall not be employed in 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; and
5. All reusable anesthesia equipment in direct contact with the patient shall be cleaned or sterilized as appropriate after each use;
6. 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;
 - c. Pulse Oximeter; and
 - d. Electrocardiogram.
 - e. An Inspired Oxygen Concentration Monitor and a Capnograph shall be applied to all patients receiving general anesthesia.

Interpretive Guideline

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

Review policies and procedures to ensure regulatory compliance.

Note: If you have questions, contact Life Safety Surveyor.

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ST - M0024 - NURSING SERVICE

Title NURSING SERVICE

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

Type Rule

Regulation Definition

NURSING SERVICE. This 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.

Interpretive Guideline

Review policy and procedures relating to nursing services.

ST - M0025 - NURSING SERVICE

Title NURSING SERVICE

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

Type Rule

Regulation Definition

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

Interpretive Guideline

Review personnel file of designated RN.

ST - M0026 - NURSING SERVICE

Title NURSING SERVICE

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

Type Rule

Regulation Definition

There shall be a sufficient staffing pattern of registered

Interpretive Guideline

Review facility staffing policy and schedule.

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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 center.

Request documentation that includes Job descriptions, delineation of duties and responsibilities for each RN position.

ST - M0027 - NURSING SERVICE

Title NURSING SERVICE

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

Type Rule

Regulation Definition

A registered professional nurse shall be assigned as the circulating nurse for one patient at a time for the duration of the surgical procedure for any procedure performed in the center.

Interpretive Guideline

Review personnel records of circulating nurses.

ST - M0028 - NURSING SERVICE

Title NURSING SERVICE

Statute or Rule 59A-5.0085(3)(d), 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.

Interpretive Guideline

Review policies and procedures.

Review staff schedule.

ST - M0029 - NURSING SERVICE

Title NURSING SERVICE

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

Type Rule

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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 person.

Interpretive Guideline

Verify staff personnel records to ensure compliance.

ST - M0030 - NURSING SERVICE

Title NURSING SERVICE

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

Type Rule

Regulation Definition

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

Interpretive Guideline

Review a sample of nursing personnel records. (example: 5 new, 5 existing and consider size of facility)

ST - M0031 - NURSING SERVICE

Title NURSING SERVICE

Statute or Rule 59A-5.0085(3)(g), 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 the following:

1. Patient admission;
2. Pre- and Post-Operative care;
3. Medical orders from physicians and other members of the medical staff;
4. Standing orders with required signatures;
5. Medications; storage and administration;

Interpretive Guideline

Review policies and procedures.

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6. Treatments;
7. Surgical asepsis;
8. Medical asepsis;
9. Sterilization and disinfection;
10. Documentation: medical records and center 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; and
19. Visitors.

ST - M0032 - LABORATORIES

Title LABORATORIES

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

Type Rule

Regulation Definition

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

Interpretive Guideline

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

ST - M0033 - RADIOLOGICAL SERVICES

Title RADIOLOGICAL SERVICES

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

Type Rule

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Regulation Definition

RADIOLOGICAL SERVICES. Each center shall provide within the institution, or through arrangement, radiological services commensurate with the needs of the center.

Interpretive Guideline

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

ST - M0034 - RADIOLOGICAL SERVICES

Title RADIOLOGICAL SERVICES

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

Type Rule

Regulation Definition

If radiological services are provided by facility staff, the service shall be maintained free of hazards for patients and personnel.

Interpretive Guideline

Review policies and procedures for safety.

Observe for safety concerns and use of monitoring badges.

Interview staff for awareness of safety procedures.

ST - M0035 - RADIOLOGICAL SERVICES

Title RADIOLOGICAL SERVICES

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

Type Rule

Regulation Definition

Personnel monitoring shall be maintained for each individual working in the area of radiation. Readings shall be on at least a monthly basis and reports kept on file and available for review.

1. Personnel - The center shall have a licensed practitioner, as defined in Section 468.301(11), F.S., to supervise the service and to discharge professional radiological services.

Interpretive Guideline

Review logs/reports for monthly readings.

Review personnel file for employment status.

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ST - M0037 - RADIOLOGICAL SERVICES

Title RADIOLOGICAL SERVICES

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

Type Rule

Regulation Definition

(c) Personnel monitoring shall be maintained for each individual working in the area of radiation. Readings shall be on at least a monthly basis and reports kept on file and available for review.
2. A technologist shall be on duty or on call at all times when there are patients within the center.

Interpretive Guideline

Review staff personnel files to ensure compliance.
Review staff schedules.

ST - M0038 - RADIOLOGICAL SERVICES

Title RADIOLOGICAL SERVICES

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

Type Rule

Regulation Definition

(c) Personnel monitoring shall be maintained for each individual working in the area of radiation. Readings shall be on at least a monthly basis and reports kept on file and available for review.
3. The use of all radiological apparatus shall be limited to appropriately licensed personnel; and use of fluoroscopes shall be limited to appropriately licensed, credentialed and privileged personnel.

Interpretive Guideline

Review job descriptions and staff personnel files for compliance
Interview to verify duties or for clarification.

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ST - M0039 - RADIOLOGICAL SERVICES

Title RADIOLOGICAL SERVICES

Statute or Rule 59A-5.0085(5)(d), 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 required by Chapter 64E-5, F.A.C.

Interpretive Guideline

Review contract to determine compliance.

ST - M0040 - HOUSEKEEPING SERVICE

Title HOUSEKEEPING SERVICE

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

Type Rule

Regulation Definition

HOUSEKEEPING SERVICE. 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 center.

Interpretive Guideline

Review policies and procedures for these items.

Observe cleaning.

Interview housekeeping staff.

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

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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.
Interview staff about training received.

Observe for breaks in infection control.

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.

Interpretive Guideline

Review policies and procedures for review dates within last two years.

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

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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:

- (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. June 1995, OSHA 29 CFR Part 1910.1030, Occupational Exposure to Blood Borne Pathogens Final Rule, and the Department of Environmental Protection Code Chapter 62-712, F.A.C., on Biomedical Waste, June 1995.
- (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 minimize microbial dissemination into the environment.
- (h) A requirement that all cases of communicable diseases as set forth in Chapter 64D, F.A.C., June 1995, be promptly and properly reported in accordance with the provisions of that rule;

Interpretive Guideline

Review policies and procedures to ensure compliance.

Observe listed items are properly maintained.

Interview Infection Control person for clarification.

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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.

Interpretive Guideline

Request and review agendas, minutes and 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

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.

Interpretive Guideline

Review employee health policy.

Interview staff for work restrictions and prevention of communicable disease.

ST - M0046 - MEDICAL RECORDS

Title MEDICAL RECORDS

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

Type Rule

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Regulation Definition

Each 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 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;

Interpretive Guideline

Review staff training

Interview staff regarding these support processes.

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.

Interpretive Guideline

Interview staff about medical record system

Observe file system. (paper or EHR)

ST - M0049 - MEDICAL RECORDS

Title MEDICAL RECORDS

Statute or Rule 59A-5.012(3-4) F.A.C.

Type Rule

Regulation Definition

(3) The administrator shall appoint in writing a qualified person responsible for the medical records service. This

Interpretive Guideline

Request verification that qualified person has been appointed in writing.

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person shall meet the qualifications established for this position, in writing, by the governing board.

Review job description and the qualifications from the governing board.

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

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 medical records based on monthly case volume below:

- (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 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 following as appropriate to the service provided:
 - 1. Identification data;
 - 2. Chief complaint;
 - 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;

- 20 files for volume over 50 cases a month
- 10 files for volume 49 and below cases a month.

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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;
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 patient ' s 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.

ST - M0051 - PHYSICAL PLANT MAINTENANCE

Title PHYSICAL PLANT MAINTENANCE

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

Type Rule

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.

Interpretive Guideline

Review the policies and procedures for physical plant maintenance.

Review personnel file or contract for supervision.

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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.

Interpretive Guideline

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

Interview staff about the repair and maintenance of equipment.

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

Each shall develop and adopt a written comprehensive emergency management plan for emergency care during an internal or external disaster or emergency which it shall review and update annually.

Interpretive Guideline

Verify the plan has been reviewed on an annual basis.

Also see Z830

ST - M0057 - COMP EMERGENCY MGMT PLAN

Title COMP EMERGENCY MGMT PLAN

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

Type Rule

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Regulation Definition

The 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 center ' s performance. This documentation must be on file at the center and available for inspection by the county emergency management agency and the Agency.

Interpretive Guideline

Ask for proof the plan is tested semiannually.

Also see Z830

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.

Interpretive Guideline

Interview staff about access to the plan.

Also see Z830

ST - M0059 - QUALITY ASSESSMENT & IMPROVEMENT

Title QUALITY ASSESSMENT & IMPROVEMENT

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

Type Rule

Regulation Definition

General Provisions. 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 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

Interpretive Guideline

Review the QA plan to ensure that the program contains items listed in tag text.

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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;
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.

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;
- (c) Performance of the procedure and monitoring of the patient;

Interpretive Guideline

Interview the QA/PI committee and/or Risk Manager about the QA program process.

Interview the QA/PI committee and/or Risk Manager about appropriate action taken to correct problems identified by the QA program.

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- (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.

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

Interview the QA/PI committee and/or Risk Manager about data collection and process documentation.

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

ST - M0062 - Emergency Management Planning Criteria

Title Emergency Management Planning Criteria

Statute or Rule 59A-5.018(3)

Type Rule

Regulation Definition

The plan, including appendices, as required by the " Emergency Management Planning Criteria for Ambulatory Surgical Centers " , shall be submitted annually to the county emergency management agency for review and approval. ...

- (a) The county emergency management agency has 60 days

Interpretive Guideline

- Are they in compliance with their local emergency management agency?
- Look for the return receipt of the documentation from the county emergency management agency.

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upon receipt of the plan, in which to review and approve the plan, or advise the center of necessary revisions. If the county emergency management agency advises the center of necessary revisions to the plan, those revisions shall be made as authorized by Section 395.1055(1)(c), F.S., and the plan shall be resubmitted to the county emergency management agency within 30 days of notification by the county emergency management agency.

(b) The county emergency management agency shall be the final administrative authority for emergency management plans developed by centers.

ST - M0063 - Initial Licensure

Title Initial Licensure

Statute or Rule 59A-5.003(5)

Type Rule

Regulation Definition

(5) The following documents shall be available for inspection at the center by the Agency area office at the initial licensure inspection:

- (a) The governing board bylaws, rules and regulations, or other written organizational plan;
- (b) Medical staff bylaws, rules and regulations;
- (c) Roster of medical staff members;
- (d) Nursing procedure manual;
- (e) Roster of registered nurses and licensed practical nurses with current license numbers;
- (f) The center ' s fire plan; and
- (g) The Comprehensive Emergency Management Plan pursuant to Rule 59A-5.018, F.A.C.

Interpretive Guideline

Review documentation for items (a) - (g).

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ST - M0064 - License Capacity

Title License Capacity

Statute or Rule 59A-5.003(8-10)

Type Rule

Regulation Definition

All permanent additions to the constructed center 's operating room capacity occurring after the issuance of the initial license shall require a new application for licensure.

(9) Each license shall specifically state the number of operating rooms, procedure rooms, and recovery beds in the center.

(10) There shall not be multiple ambulatory surgical center licenses for the same premises.

Interpretive Guideline

Review initial license and compare to on-site observation.

ST - M0065 - Facility Closure

Title Facility Closure

Statute or Rule 59A-5.003(16)

Type Rule

Regulation Definition

A licensee shall notify the Agency of impending closure of a center not less than 30 days prior to such closure. The center shall be responsible for advising the Agency as to the disposition of medical records.

Interpretive Guideline

If the facility is closed or impending closure, document the disposition location of medical records.

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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 that includes all of the following components:

Interpretive Guideline

The surveyor should review:

- The Risk Management Program/Plan
- Interview the Licensed Health Care Risk Manager responsible for the program.

ST - M0402 - RM Prog - Investigation & Analysis

Title RM Prog - Investigation & Analysis

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

Type Rule

Regulation Definition

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

Interpretive Guideline

- Does the plan establish the incident categories?
- Are the incidents specific to this facility?
- Review 6 Monthly Logs and 4 Quarterly Summary Reports.

ST - M0403 - RM Prog -Develop of Measures to Minimize Risk

Title RM Prog -Develop of Measures to Minimize Risk

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

Type Rule

Regulation Definition

(b) The development of appropriate measures to minimize the risk of adverse incidents to patients, including, but not limited

Interpretive Guideline

- Review Risk Management Plan for the following:
- identified incident trends.

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to:

- measures put in place to correct.
- Review the past year ' s adverse incidents identified as risk/process improvement opportunities including the analysis of the incident and trends.
- Interview the Risk Manager's for their role in the development and implementation of risk reduction and risk prevention strategies.
- Verify correction measures are systematic and facility-wide. Validate implementation of measures in departments or units of facility.
- Has the facility minimized the risk to other patients?
Sample a minimum of ten adverse incidents within the past 12 months. This is a guide as some centers may not have that many within the year.

ST - M0404 - Education & Training - Incident Reporting Sys

Title Education & Training - Incident Reporting Sys

Statute or Rule 395.0197(1)(b)1, F.S.; 59A-10.0055(1) FA

Type Rule

Regulation Definition

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

1. Risk management and risk prevention education and training of all nonphysician personnel as follows:

- a. Such education and training of all nonphysician personnel as part of their initial orientation; and
- b. At least 1 hour of such education and training annually for all personnel of the licensed facility working in clinical areas and providing patient care, except those persons licensed as health care practitioners who are required to complete continuing education coursework pursuant to chapter 456 or the respective practice act.

59A-10.0055(1) FAC (1) INCIDENT REPORTING. An incident reporting system shall be established for each facility. Procedures shall be detailed in writing and disseminated to all employees of the facility. All new employees, within 30 days of employment, shall be instructed about the operation of the system and responsibilities of it. At least annually all

Interpretive Guideline

- Review facility Policy and Procedures
to ensure the procedures are in writing and contain required information outlined in tag text.
- Verify this information is disseminated through interviews with facility staff and Risk Manager .

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nonphysician personnel of the facility working in clinical areas and providing patient care shall receive 1 hour risk management and risk prevention education and training including the importance of accurate and timely incident reporting.

ST - M0405 - Approp Measure - Recovery Room Prohibition

Title Approp Measure - Recovery Room Prohibition

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

Type Rule

Regulation Definition

2. A prohibition, except when emergency circumstances require otherwise, against a staff member of the licensed facility attending a patient in the recovery room, unless the staff member is authorized to attend the patient in the recovery room and is in the company of at least one other person. However, a licensed facility is exempt from the two-person requirement if it has:

- a. Live visual observation;
- b. Electronic observation; or
- c. Any other reasonable measure taken to ensure patient protection and privacy.

Interpretive Guideline

1. Request at least two weeks to a month of schedules of recovery room personnel for all shifts.
2. Review the Policy and Procedures regarding the two-person requirement.
3. Tour the recovery room.
4. Interview staff regarding recovery room procedures and staffing patterns.
5. How does the facility handle exemptions to ensure patient protection and privacy?
6. Is electronic observation used? If so,
7. Who monitors the camera when patients are present in the recovery room?
8. What type of observation documentation is maintained by the facility?

ST - M0406 - RM Prog - Investigation & Analysis

Title RM Prog - Investigation & Analysis

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

Type Rule

Regulation Definition

3. A prohibition against an unlicensed person from assisting or participating in any surgical procedure unless the facility has

Interpretive Guideline

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

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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.

- Review the unlicensed staff competencies and competency assessments.
- Review schedules and assignments to determine direct and immediate supervision of an unlicensed person.
- Review competencies for Private or Contractual Scrub individuals.

ST - M0407 - Approp Measure - Ongoing Eval of Proc/Systems

Title Approp Measure - Ongoing Eval of Proc/Systems

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

Type Rule

Regulation Definition

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

Interpretive Guideline

- After the review of adverse incidents for the past year, review the plan/policy document to address identity of patient/procedures.
- Verify the system in place to prevent/minimize wrong patient, wrong surgical procedure, wrong site, or a surgical procedure unrelated.
- If an incident breaches protocol, is it reviewed to minimize risk to other patients?
- How does the facility monitor compliance with the protocols for quality program purposes?

ST - M0408 - RM Prog - Pt Grievance Analysis

Title RM Prog - Pt Grievance Analysis

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

Type Rule

Regulation Definition

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

Interpretive Guideline

Review a sample of grievances relating to patient care and medical services.
Review grievance analysis report relating to patient care and medical services.
Review evidence that issues related to quality of care/medical care are analyzed including outcomes. Were corrective measures placed into facility-wide systems?

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ST - M0409 - RM Prog - Pt Notification of Adv Incidents

Title RM Prog - Pt Notification of Adv Incidents

Statute or Rule 395.0197 (1)(d), F.S.; 395.1051F.S.

Type Rule

Regulation Definition

395.0197(1)(d) A system for informing a patient or an individual identified pursuant to s. 765.401(1) that the patient was the subject of an adverse incident, as defined in subsection (5). Such notice shall be given by an appropriately trained person designated by the licensed facility as soon as practicable to allow the patient an opportunity to minimize damage or injury.

395.1051 Duty to notify patients.-An appropriately trained person designated by each licensed facility shall inform each patient, or an individual identified pursuant to s. 765.401(1), in person about adverse incidents that result in serious harm to the patient. Notification of outcomes of care that result in harm to the patient under this section shall not constitute an acknowledgment or admission of liability, nor can it be introduced as evidence.

Interpretive Guideline

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

Interview Risk Manager as needed to clarify compliance.

Review sample of adverse incidents to verify the trained person is the person notifying patients/surrogate of the adverse incident.

ST - M0410 - RM Prog - Incident Reporting System

Title RM Prog - Incident Reporting System

Statute or Rule 395.0197(1)(e), F.S.; 59A-10.0055(2)(a-b)

Type Rule

Regulation Definition

395.0197(1)(e) The development and implementation of an incident reporting system based upon the affirmative duty of

Interpretive Guideline

Review the Policy and Procedures for incident reporting to determine facility time frame (no more than 3 days)

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all health care providers and all agents and employees of the licensed health care facility to report adverse incidents to the risk manager, or to his or her designee, within 3 business days after their occurrence.

59A-10.0055.

(2) INCIDENT REPORTS. The incident reporting system shall include the prompt, within 3 calendar days, reporting of incidents to the risk manager, or his designee. Reports shall be on a form developed by the facility for the purpose and shall contain at least the following information:

(a) The patient ' s name, locating information, admission diagnosis, admission date, age and sex;

(b) A clear and concise description of the incident including time, date, exact location; and elements as needed for the annual report based on ICD-9-CM ;

Review a sample of Incident/Occurrence Reports to determine incidents are reported within three (3) business days to the Risk Manager or to the Risk Manager Designee and form contains all information as required in F.A.C.

If there is a Risk Manager Designee, verify the facility documentation identifying the staff member in the Risk Management Designee position.

Interview a sample of staff to determine if:

- The facility has a developed an incident reporting system
- The facility has a method for reporting incidents within 3 business days of the date of occurrence
- The staff is able to identify the Risk Manager or Risk Manager Designee

ST - M0412 - INCIDENT REPORTING SYSTEM - Reports

Title INCIDENT REPORTING SYSTEM - Reports

Statute or Rule 59A-10.0055(2)(c)-(e), FAC

Type Rule

Regulation Definition

(c) Whether or not a physician was called; and if so, a brief statement of said physician ' s recommendations as to medical treatment, if any;

(d) A listing of all persons then known to be involved directly in the incident, including witnesses, along with locating information for each;

(e) The name, signature and position of the person completing the reports, along with date and time that the report was completed

Interpretive Guideline

Review a sample (minimum of 10) of incident/occurrence reports to verify

- Was the physician is notified? If so, is the documentation included in the form.
- Review the patient(s) medical records to verify record shows the incident.
- Determine compliance with the incident form requirements.
- Witness locating information should be documented on the form.

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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 s. 395.10974, 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.

Interpretive Guideline

Verify there is a licensed Risk Manager.
Review the Risk Manger's job description for his/her responsibilities.
Verify the number of current facilities for which the Risk Manager currently has responsibility .

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. ...

Interpretive Guideline

Interview the Risk Manager and the Administrator.
Review the Risk Manager's job description.
Review the Policy and Procedures to confirm access to medical records is addressed.

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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.

Interpretive Guideline

Ask the Risk Manager how they have determined what incidents to track and trend?
Review tracking and trending reports based on findings and reported concerns.
Review documentation for Policy and Procedure adjustments, category development and facility corrective actions/ interventions of identified problem areas.

ST - M0416 - 15 DAY REPORTS

Title 15 DAY REPORTS

Statute or Rule 395.0197(5) & (7), F.S. 59A-10.0065

Type Rule

Regulation Definition

(5) For purposes of reporting to the agency pursuant to this section, the term " adverse incident " means an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred, and which:

(a) Results in one of the following injuries:

1. Death;
2. Brain or spinal damage;
3. Permanent disfigurement;
4. Fracture or dislocation of bones or joints;
5. A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility;
6. Any condition that required specialized medical attention or

Interpretive Guideline

- Interview the Risk Manager regarding reporting Code 15 events.
- Review the facility's Policy and Procedures regarding reporting an adverse incident. Is the Risk Manager following the facility's Policy and Procedures when a Code 15 reportable incident occurs?
- Request a list of any discharged patient that was re-admitted into the facility within days of being discharge.
- Review a few re-admitted patients' records to determine if any were admitted for the previous treatment or surgical procedure.
- Request a list of patients who have expired in the facility in the past year.
- Review those deaths, which resulted in an autopsy being conducted. What was the outcome?
- Review to determine if anyone was transferred to a higher level of care
- Did the Risk Manager file the Code 15 within 15 calendar days?
- Review the consent form, signed by the patient prior to surgery, was the incident outcome listed as one of the specific risk of the surgical procedure.
- If the Risk Manager was unable to submit an adverse incident within 15 calendar days, did the Risk Manager request an extension from AHCA? Review the extension request.

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surgical intervention resulting from nonemergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or

7. Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;

(b) Was the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;

(c) Required the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or

(d) Was a procedure to remove unplanned foreign objects remaining from a surgical procedure.

How is it determined an incident meets the definition of an "adverse incident" to be reported to the Agency?

(7) Any of the following adverse incidents, whether occurring in the licensed facility or arising from health care prior to admission in the licensed facility, shall be reported by the facility to the agency within 15 calendar days after its occurrence:

- (a) The death of a patient;
- (b) Brain or spinal damage to a patient;
- (c) The performance of a surgical procedure on the wrong patient;
- (d) The performance of a wrong-site surgical procedure;
- (e) The performance of a wrong surgical procedure;
- (f) The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition;
- (g) The surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage is not a recognized specific risk, as disclosed to the patient and

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documented through the informed-consent process; or
(h) The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure.
The agency may grant extensions to this reporting requirement for more than 15 days upon justification submitted in writing by the facility administrator to the agency. The agency may require an additional, final report. These reports shall not be available to the public pursuant to s. 119.07(1) or any other law providing access to public records, nor be discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board, nor shall they be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency or the appropriate regulatory board shall make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause. The agency may investigate, as it deems appropriate, any such incident and prescribe measures that must or may be taken in response to the incident. The agency shall review each incident and determine whether it potentially involved conduct by the health care professional who is subject to disciplinary action, in which case the provisions of s. 456.073 shall apply.

59A-10.0065, F.A.C.

The facility shall report all incidences meeting the criteria specified in Section 395.0197(6), F.S., to the Agency within 15 calendar days of occurrence. The 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

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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.

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(5) " Injury " for the purposes of reporting to the Agency is any of the following outcomes when caused by an adverse incident:

- (a) Death; or
- (b) Brain damage; or
- (c) Spinal damage; or
- (d) Permanent disfigurement; or
- (e) Fracture or dislocation of bones or joints; or
- (f) Any condition requiring definitive or specialized medical attention which is not consistent with the routine management of the patient ' s case or patient ' s preexisting physical condition; or
- (g) Any condition requiring surgical intervention to correct or control; or
- (h) Any condition resulting in transfer of the patient, within or outside the facility, to a unit providing a more acute level of care; or
- (i) Any condition that extends the patient ' s length of stay; or
- (j) Any condition that results in a limitation of neurological, physical, or sensory function which continues after discharge from the facility.

ST - M0417 - SEXUAL MISCONDUCT by facility's personnel

Title SEXUAL MISCONDUCT by facility's personnel

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

Interpretive Guideline

Review a list of incidents and chose those relating to allegations of sexual misconduct. This is for allegations against facility ' s personnel.

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made against a member of the facility ' s personnel who has direct patient contact, when the allegation is that the sexual misconduct occurred at the facility or on the grounds of the facility.

(b) Report every allegation of sexual misconduct to the administrator of the licensed facility.

(c) Notify the family or guardian of the victim, if a minor, that an allegation of sexual misconduct has been made and that an investigation is being conducted.

(d) Report to the Department of Health every allegation of sexual misconduct, as defined in chapter 456 and the respective practice act, by a licensed health care practitioner that involves a patient.

Review the facility's Policy and Procedures regarding the investigation of an allegation of sexual misconduct. Was the Policy and Procedures followed?

If the allegation was confirmed, what corrective action was implemented?

Was the family/guardian of victim and the Department of Health notified?

Interview the facility's staff, can they tell you what they would do if someone accused an employee of sexual misconduct? Does it meet the facility's Policy and Procedures?

ST - M0418 - SEXUAL ABUSE REPORTing

Title SEXUAL ABUSE REPORTing

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 s. 794.011(1)(h), fondling, exposure of a vulnerable adult ' s or minor ' s sexual organs, or the use of the vulnerable adult or minor to solicit for or engage in prostitution or sexual performance. " Sexual abuse " does not include any act intended for a valid medical purpose or any act which may

Interpretive Guideline

- Review a list of incidents and chose some incidents regarding allegations of sexual abuse.
- Review the facility's Policy and Procedures regarding the prevention and investigation of sexual abuse.
- Were the police Risk Manager and Administrator notified?
- Interview facility staff (LPN, RN, CNA, Maintenance, Housekeeping) to determine if they know what to do if someone reports sexual abuse to them.

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reasonably be construed to be a normal caregiving action.

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

(3) INCIDENT REPORT REVIEW AND ANALYSIS. The risk manager shall be responsible for the regular and systematic reviewing of all incident reports including 15-day incident reports for the purpose of identifying trends or patterns as to time, place or persons: and upon emergence of any trend or pattern in incident occurrence shall develop recommendations for corrective actions and risk management prevention education and training. Summary data thus accumulated shall be systematically maintained for 3 years.

Interpretive Guideline

Review incident reports for the year and verify Risk Manager is using them to determine patterns and problem areas. Are the Code 15 reports included in the trending data?
Interview the risk manager regarding the method utilized to identify trends, patterns, analysis, and corrective action. Review all pertinent documents for verification that the Risk Manager's recommendations were developed and the corrective action(s) implemented.
Review in-service education documents for programs pertinent to risk management education and training relating to the corrective action(s).
Verify that the past 3 years of accumulated summary data has been maintained and reviewed.

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.

Interpretive Guideline

Review the Governing Body agenda/minutes for risk management documentation.
Interview the Licensed Risk Manager and staff about who presents the risk management summary report?

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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. S. 456.001(4), F.S.

Interpretive Guideline

- Review annual documentation of reporting which identifies and summarizes judgments, not actions against practitioners?
- Have these identified practitioners been reported to the Department of Health and Agency for Healthcare Administration?

ST - 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,

Interpretive Guideline

Review the Annual Report(s) submitted to AHCA for items 1 through 5.
Review a sample of disciplinary actions and outcomes against practitioners and the reporting of all actions to Department of Health/Medical Quality Assurance.
Is the policy and procedures document included in the annual report?

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the relationship of the individual to the licensed facility, and the number of incidents in which each individual has been directly involved. Each licensed facility shall maintain names of the health care professionals and individuals identified by code numbers for purposes of this section.

5. A description of all malpractice claims filed against the licensed facility, including the total number of pending and closed claims and the nature of the incident which led to, the persons involved in, and the status and disposition of each claim. Each report shall update status and disposition for all prior reports.

(c) The 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.

ST - M0423 - AGENCY ACCESS TO RECORD

Title AGENCY ACCESS TO RECORD

Statute or Rule 395.0197(13), F.S. 59A-10.0055(3)(b)

Type Rule

Regulation Definition

(13) The agency shall have access to all licensed facility records necessary to carry out the provisions of this section. The records obtained by the agency under subsection (6), subsection (7), or subsection (9) are not available to the public under s. 119.07(1), nor shall they be discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board, nor shall records obtained pursuant to s. 456.071 be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate

Interpretive Guideline

- All facility records are to be made available to surveyors upon request.
- Surveyors are to notify their field office managers if a facility refuses access to records.
- The Agency shall have access to all records necessary to carry out the provisions of this section.
- The Agency may request the provider ' s meeting minutes as pursuant to Subsection 395.0197(13).
- These meeting minutes, however, are confidential and exempt from public records disclosure pursuant to Subsection 395.0197(14).
- Surveyors are to notify their field office managers/ supervisors if a facility refuses access to record or if there is a question regarding the need to review meeting minutes to determine compliance
- Document the facility observations, interviews and record review findings on the appropriate survey form.

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regulatory board. However, the agency or the appropriate regulatory board shall make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause, except that, with respect to medical review committee records, s. 766.101 controls.

Reviews of the meeting Agenda(s) may provide sufficient information/evidence required to determine Risk Management Program compliance.

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

(b) Evidence of the incidents reporting and analysis system and copies of summary reports, incident reports filed within the facility, and evidence of recommended and accomplished corrective actions shall be made available for review to any authorized representative of the Agency upon request during normal working hours.

ST - M0424 - UNLAWFUL COERCION OF REPORTING OBLIGATION

Title UNLAWFUL COERCION OF REPORTING OBLIGATION

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

Type Rule

Regulation Definition

(19) It shall be unlawful for any person to coerce, intimidate, or preclude a risk manager from lawfully executing his or her reporting obligations pursuant to this chapter. Such unlawful action shall be subject to civil monetary penalties not to exceed \$10,000 per violation.

Interpretive Guideline

Interview the Risk Manager regarding their ability to report.

ST - M0425 - PATIENT SAFETY PLAN

Title PATIENT SAFETY PLAN

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

Type Rule

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Regulation Definition

(1) Each licensed facility must adopt a patient safety plan. A plan adopted to implement the requirements of 42 C.F.R. part 482.21 shall be deemed to comply with this requirement.

Interpretive Guideline

Review the facility's patient safety plan for compliance with 42 CFR 482.21 (Quality Assurance and Performance Improvement Plan).

Was the plan implemented? If not, contact field office manager/supervisor for further guidance.

As relevant, consider information the facility representatives utilized to demonstrate compliance with 42 CFR 482.21 (Quality Assurance and Performance Improvement Plan)

ST - M0426 - PATIENT SAFETY OFFICER AND COMMITTEE

Title PATIENT SAFETY OFFICER AND COMMITTEE

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

Type Rule

Regulation Definition

(2) Each licensed facility shall appoint a patient safety officer and a patient safety committee, which shall include at least one person who is neither employed by nor practicing in the facility, for the purpose of promoting the health and safety of patients, reviewing and evaluating the quality of patient safety measures used by the facility, and assisting in the implementation of the facility patient safety plan.

Interpretive Guideline

Determine if the facility has appointed a Patient Safety Officer and a patient safety committee.

Interview the Patient Safety Officer regarding roles and responsibilities.

Review the composition of the Patient Safety Committee.

Determine the eligibility of the committee member not employed by the facility, not a contracted employee of the facility, nor in practice at the facility.

Review facility documentation of the Patient Safety Committee activities such as agenda/minutes, reports, QA/PI projects and outcomes, Patient Safety Initiatives, etc.

Review the process by which the committee reviews and evaluates the quality of patient safety measures implemented by the facility.

Review the process by which the committee assists in the implementation of the facility's Patient Safety Plan.

Is the facility documentation presented during the survey sufficient to determine compliance?

NOTE:

Reviews of the meeting Agenda(s) may provide sufficient information/evidence required to determine Risk Management Program compliance.