

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

Printed 07/09/2024

Page 1 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0000 - INITIAL COMMENTS

Title INITIAL COMMENTS

Type Memo Tag

Regulation Definition

Interpretive Guideline

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

ST - M0001 - Definitions

Title Definitions

Type Memo Tag

395.0197(5-7)(10)(b); 395.002(3)(4)(20)

Regulation Definition

Interpretive Guideline

395.0197(5) & (10)(b)

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

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

Printed 07/09/2024

Page 2 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

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.

(10)(b) Any witness who witnessed or who possesses actual knowledge of the act that is the basis of an allegation of sexual abuse shall:

Notify the hospital risk manager and the administrator.

For purposes of this subsection, "sexual abuse" means acts of a sexual nature committed for the sexual gratification of anyone upon, or in the presence of, a vulnerable adult, without the vulnerable adult's informed consent, or a minor. "Sexual abuse" includes, but is not limited to, the acts defined in s. 794.011(1)(h), fondling, exposure of a vulnerable adult's or minor's sexual organs, or the use of the vulnerable adult or minor to solicit for or engage in prostitution or sexual performance. "Sexual abuse" does not include any act intended for a valid medical purpose or any act which may reasonably be construed to be a normal caregiving action.

395.002(3)(4)(20)

"Ambulatory surgical center" means a facility the primary purpose of which is to provide elective surgical care, in which

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

Printed 07/09/2024

Page 3 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

the patient is admitted to and discharged from such facility within 24 hours, and which is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy, an office maintained by a physician 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 a Medicare ambulatory surgical center shall be licensed as an ambulatory surgical center pursuant to s. 395.003.

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

"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

In addition to definitions contained in Chapters 395, Part I and 408, Part II, F.S. the following definitions shall apply specifically to ambulatory surgical centers.

(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 Chapters 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 Chapters 458 or 459, F.S. as an anesthesiologist assistant.

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

(6) "Certified Registered Nurse Anesthetists" means a person

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

Printed 07/09/2024

Page 4 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

currently licensed and certified pursuant to Chapter 464, F.S., and certified by the Council on Certification of Nurse Anesthetists.

(7) "Dentist" means a person currently licensed to practice dentistry pursuant to Chapter 466, F.S.

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

(9) "Governing board" means an individual owner, partnership, corporation or other legally established authority in whom the ultimate authority and responsibility for management of the ambulatory surgical center is vested.

(10) "Licensed Practical Nurse" means a person currently licensed as defined in Section 464.003(16), F.S.

(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 Chapters 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.

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

Printed 07/09/2024

Page 5 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

(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

As used in this rule chapter:

(1) "Accident prevention" means those risk management techniques that seek to reduce the frequency and/or severity of incidents.

(2) "Accredited institution of higher learning" means universities, colleges, community colleges and junior colleges which are accredited by an accrediting agency.

(3) "Accrediting agency" means those accrediting agencies belonging to the Council on Higher Education Accreditation.

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

(5) "Ambulatory surgical center" means an ambulatory surgical center licensed under Chapters 395 and 408, F.S., and Rule Chapters 59A-5 and 35, F.A.C.

(6) "Basic risk manager" means a person who has a degree, awarded by an accredited institution of higher learning, in risk management or insurance.

(7) "Community interrelationships" means community networks, liaisons and associations that are necessary to promote continuity of care or enhance the delivery of patient care and aid in the prevention and control of health care risks.

(8) "Departmental organization and management" means the organizational structure, goals, objectives, philosophy, policies, procedures, and job descriptions which govern organizational operations of the health care risk management program as it functions within the licensed health care facility.

(9) "General risk management administration" means the establishment, direction and evaluation of procedures, programs and other methods to reduce or minimize personal

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

Printed 07/09/2024

Page 6 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

injury and financial losses. The term includes management of an incident reporting system and reporting of appropriate statistics for hospital and state maintenance.

(10) "Health care administrator" means a person who has a masters degree, awarded by an accredited institution of higher learning, in health or healthcare administration, healthcare management, or other such education which included successful completion of graduate level courses in the management and administration of various healthcare organizations, health care finance, legal and ethical issues related to healthcare, risk management, and health information management.

(11) "Health care facility" or "facility" means an ambulatory surgical center or hospital, as defined in subsections (5) and (13).

(12) "Health care professional" means a physician licensed pursuant to Chapter 458, F.S., an osteopath licensed pursuant to Chapter 459, F.S., a chiropractor licensed pursuant to Chapter 460, F.S., a podiatrist licensed pursuant to Chapter 461, F.S., a pharmacist licensed pursuant to Chapter 465, F.S., a nurse licensed pursuant to Chapter 464, F.S., a radiologic technologist certified pursuant to Chapter 468, F.S., a respiratory therapist licensed pursuant to Chapter 468, F.S., a physical therapist licensed pursuant to Chapter 486, F.S., an occupational therapist licensed pursuant to Chapter 468, F.S., and an emergency medical technician or paramedic certified pursuant to Chapter 401, F.S.

(13) "Hospital" means a hospital licensed under Chapters 395 and 408, F.S., and Rule Chapters 59A-3 and 35, F.A.C.

(14) ICD-10-CM means the International Classification of Diseases, 10th Edition, Clinical Modification and shall be abbreviated as ICD-10-CM in these rules.

(15) "Incident report" means a factual written statement about a particular incident detailing particulars as to time, location, all persons directly involved including functional titles, and

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

Printed 07/09/2024

Page 7 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

the nature of event including description of injuries. The report shall contain a listing of witnesses to the event.

(16) "Incident reporting system" means a series of systematized procedures for detecting, reporting, collating, analyzing, and summarizing incidents.

(17) "Internal risk management program" means the policies and procedures of a health care facility which constitute the internal risk management program as defined in Section 395.0197 or 641.55, F.S.

(18) "Investigation" or "investigate" means the identification, analysis and evaluation of an incident by a risk manager or his designee or by a representative of the Agency.

(19) "Licensed health care risk manager" means an individual licensed under Section 395.10974, F.S.

(20) "Medical care" means that care and treatment rendered by or under the direction of licensed health care professionals.

(21) "Medical intervention" means actions of any health care facility or personnel of the facility, in the provision of health care.

(22) "Medical terminology" means terms and abbreviations most commonly found in medical usage as well as prefixes and suffixes which are employed as elements of medical words.

(23) "Patient care" means those services provided or rendered to meet the patient's physical, emotional and spiritual needs.

(24) "Patient grievance" means any complaint by a patient relating to patient care or the quality of medical services, except for those matters pertaining to the cost of care.

(25) "Personal and social care" means those human resources and services which are available to meet the individual psychosocial needs of patients to promote well-being and continuity of care.

(26) "Personnel" for purposes of this rule means any employee or independent contractor of a facility or member of a facility's medical staff.

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

Printed 07/09/2024

Page 8 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

(27) "Personnel directly involved" for the purposes of reporting to the Agency means personnel as described in subsection (26) who could exercise control over the event which is reportable as an adverse or untoward incident.

(28) "Risk management" means the identification, investigation, analysis, and evaluation of risks and the selection of the most advantageous method of correcting, reducing or eliminating identifiable risks.

(29) "Risk Manager designee" means any person appointed by the facility to work with the licensed health care risk manager or to act as his representative in carrying out risk management activities. This appointment must be in writing.

ST - M0002 - Licensure Requirements - Accreditation

Title Licensure Requirements - Accreditation

Type Rule

59A-5.004(3)

Regulation Definition

(3) Accredited ambulatory surgical centers. The Agency shall accept the report of an accrediting organization in lieu of a 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 subparagraphs (c)1. and 2.

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.

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

Printed 07/09/2024

Page 9 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0003 - GOVERNING BODY

Title GOVERNING BODY

Type Rule

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

Regulation Definition

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

(a) State the qualifications for governing board membership, and the method of selecting members as well as the terms of appointment or election of members, officers and chairmen of committees. Where legally permissible, physicians who are members of the medical staff shall be eligible for, and should be included in, full membership of the centers' governing board and its action committees in the same manner as are other knowledgeable and effective individuals. Also, any other member of the medical staff shall be considered eligible for membership of the governing board.

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

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

(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 be recorded and made available to all members of the governing board.

Interpretive Guideline

When the physician-owner-operator is the governing body, refer to tag 0004 for information.

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.

Review written transfer agreements with one or more local hospitals.

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

Printed 07/09/2024

Page 10 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

- (e) Establish the position of administrator, the incumbent of which shall be responsible for operation and maintenance of the center as a functioning institution, and define the methods established by the governing board for holding such designated person responsible.
- (f) Provide for the appointment, reappointment, or dismissal of members of the medical staff through a credentialing 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 credentialing committee for their recommendation, provided that the governing board may suspend an medical staff member pending final determination of any reappointment or dismissal. The governing board shall only appoint members of the medical staff as recommended by the credentialing committee.
- (g) Provide for the approval of the bylaws, rules and regulations of the medical staff.
- (h) Require that every patient shall be admitted by and remain under the care of a member of the medical staff.
- (i) Require that all medications, treatments and procedures shall be administered upon specific orders of a member of the medical staff.
- (j) Require that all attending medical staff members who do not have admitting privileges at an acute care general hospital document a written agreement with 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 center 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 board, and the administrator to provide a channel for administrative advice.
- (m) Specify the classification of services to be provided in the center and list authorized surgical procedures.

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.

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

Printed 07/09/2024

Page 11 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0004 - GOVERNING BODY

Title GOVERNING BODY

Type Rule

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

Regulation Definition

(2) Where a physician serves as the licensee and governing board, the articles of incorporation or other written organizational plan shall describe the manner in which the licensee executes the governing board responsibility.

Interpretive Guideline

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

ST - M0005 - PATIENT RIGHTS

Title PATIENT RIGHTS

Type Rule

59A-5.0065, F.A.C.

Regulation Definition

Each center shall develop and adopt policies and procedures to ensure the protection of patient rights; which 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.

ST - M0006 - ORGANIZED MEDICAL STAFF

Title ORGANIZED MEDICAL STAFF

Type Rule

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

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

Printed 07/09/2024

Page 12 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

Regulation Definition

(1) Each center shall have an organized medical staff organized under written bylaws approved by the governing board and responsible to the governing board of the 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 quality practices and how they are reported to the governing body.

ST - M0007 - ORGANIZED MEDICAL STAFF

Title ORGANIZED MEDICAL STAFF

Type Rule

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

Regulation Definition

(2) 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 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

Interpretive Guideline

Interview administrator about committee structure.

Review committee organization.

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

Review P&P for approvals and dates

Review P&P for interim functions and disposition

Review medical staff appointments and renewals according to Sections 395.0191 and 395.0193, F.S.

Review for appropriate

- Medical records maintenance/ transfer documentation

-Review infection occurrences records and interview IC designee/appointed staff for surveillance practices

-Review Pharmacy P&P, Pharmacist records, for appropriate standards of practice including disposal, outdated and controlled drug management and counts.

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

Printed 07/09/2024

Page 13 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

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 center admissions with respect to need for admission, discharge practices and evaluation of the services ordered and provided.

(h) Surveillance of the 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, and standards of practice are maintained, including review of at least monthly on-site consultant pharmacist visits, and proper disposal of outdated prescription and controlled drugs in accordance with Rules 64B16-28.702, 64B16-28.110, 64B16-28.303, F.A.C. and Chapters 465 and 893, F.S.

ST - M0009 - SURGICAL SERVICES

Title SURGICAL SERVICES

Type Rule

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

Regulation Definition

(1) 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.

Tour all operative rooms.

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

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

Printed 07/09/2024

Page 14 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0010 - SURGICAL SERVICES

Title SURGICAL SERVICES

Type Rule

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

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.

Review Governing Body position appointment and qualifications

ST - M0011 - SURGICAL SERVICES

Title SURGICAL SERVICES

Type Rule

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

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.

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

Printed 07/09/2024

Page 15 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0012 - SURGICAL SERVICES

Title SURGICAL SERVICES

Type Rule

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

Regulation Definition

(c) Each center shall ensure, prior to any surgery being performed, that the 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.

(d) All infections of surgical cases shall be recorded and reported to the governing board or its designee and a procedure shall exist for the investigation of such cases.

Interpretive Guideline

Review patient medical records for informed consents, verification of and identity of patients, operative sites, and operative procedures to be performed.

Interview IC Designee for surgical acquired infections, investigation, and documentation of these cases- review GB reports.

ST - M0014 - SURGICAL SERVICES

Title SURGICAL SERVICES

Type Rule

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

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.

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

Printed 07/09/2024

Page 16 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0015 - SURGICAL SERVICES

Title SURGICAL SERVICES

Type Rule

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

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

Type Rule

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

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.

Review Safety controls in the surgical suite for non-compliance

Note: If you have questions, contact Life Safety Surveyor

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

Printed 07/09/2024

Page 17 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0018 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

Type Rule

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

Regulation Definition

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

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 to be in the room during the administration of anesthesia.

ST - M0019 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

Type Rule

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

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.

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

Printed 07/09/2024

Page 18 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0020 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

Type Rule

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

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.

Observe for compliance

ST - M0021 - ANESTHESIA SERVICES

Title ANESTHESIA SERVICES

Type Rule

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

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

Type Rule

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

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

Printed 07/09/2024

Page 19 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

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

Type Rule

59A-5.0085(2)(f)(1-6)(a-e), F.A.C.

Regulation Definition

Anesthetic safety regulations shall be developed, posted and enforced. Such regulations shall include 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

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.

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

Printed 07/09/2024

Page 20 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

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.

ST - M0024 - NURSING SERVICE

Title NURSING SERVICE

Type Rule

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

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

Type Rule

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

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.

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

Printed 07/09/2024

Page 21 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0026 - NURSING SERVICE

Title NURSING SERVICE

Type Rule

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

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 center.

Interpretive Guideline

Review facility staffing policy and schedule.

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

ST - M0027 - NURSING SERVICE

Title NURSING SERVICE

Type Rule

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

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

Type Rule

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

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

Printed 07/09/2024

Page 22 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

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.

Observe for compliance

ST - M0029 - NURSING SERVICE

Title NURSING SERVICE

Type Rule

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

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

Type Rule

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

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)

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

Printed 07/09/2024

Page 23 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0031 - NURSING SERVICE

Title NURSING SERVICE

Type Rule

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

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;
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.

Interpretive Guideline

Review policies and procedures.

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

Printed 07/09/2024

Page 24 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0032 - LABORATORIES

Title LABORATORIES

Type Rule

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

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

Type Rule

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

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

Type Rule

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

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

Printed 07/09/2024

Page 25 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

Regulation Definition

If radiological services are provided by center 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

Type Rule

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

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.

ST - M0037 - RADIOLOGICAL SERVICES

Title RADIOLOGICAL SERVICES

Type Rule

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

Regulation Definition

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.

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

Printed 07/09/2024

Page 26 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

Review P&P and/or Written agreement

ST - M0038 - RADIOLOGICAL SERVICES

Title RADIOLOGICAL SERVICES

Type Rule

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

Regulation Definition

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.

ST - M0039 - RADIOLOGICAL SERVICES

Title RADIOLOGICAL SERVICES

Type Rule

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

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.

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

Printed 07/09/2024

Page 27 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0040 - HOUSEKEEPING SERVICE

Title HOUSEKEEPING SERVICE

Type Rule

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

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

Type Rule

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

Regulation Definition

Each 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.

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

Printed 07/09/2024

Page 28 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0042 - SURVEIL, PREVENT & CONTROL OF INFECTION

Title SURVEIL, PREVENT & CONTROL OF INFECTION

Type Rule

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

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

Type Rule

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

Regulation Definition

The policies and procedures devised by the infection control program shall be approved by the governing board, 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. and, OSHA 29 CFR Part 1910.1030, Bloodborne Pathogens.
- (d) Specific policies related to the selection, storage, handling, use and disposition of disposable items.

Interpretive Guideline

Review policies and procedures to ensure compliance.

Observe listed items are properly maintained.

Interview Infection Control person for clarification.

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

Printed 07/09/2024

Page 29 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

- (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-3, F.A.C., be promptly and properly reported in accordance with the provisions of that rule;

ST - M0044 - SURVEIL, PREVENT & CONTROL OF INFECTION

Title SURVEIL, PREVENT & CONTROL OF INFECTION

Type Rule

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

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 board.

Interpretive Guideline

Request and review agendas, minutes and reports.

ST - M0045 - SURVEIL, PREVENT & CONTROL OF INFECTION

Title SURVEIL, PREVENT & CONTROL OF INFECTION

Type Rule

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

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

Printed 07/09/2024

Page 30 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

Regulation Definition

Each 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

Type Rule

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

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.

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

Printed 07/09/2024

Page 31 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0047 - MEDICAL RECORDS

Title MEDICAL RECORDS

Type Rule

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

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

Type Rule

59A-5.012(3-4) F.A.C.

Regulation Definition

(3) 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 board.

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

Interpretive Guideline

Request verification that qualified person has been appointed in writing.

Review job description and the qualifications from the governing board.

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

Printed 07/09/2024

Page 32 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0050 - Medical Records

Title Medical Records

Type Rule

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

Regulation Definition

The medical records service shall:

- (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;
 - 12. The appropriate informed consent signed by the patient;
 - 13. Record of medication and dosage administered;
 - 14. Tissue reports;
 - 15. Physician orders;

Interpretive Guideline

Randomly select medical records based on monthly case volume below:

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

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

Printed 07/09/2024

Page 33 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

- 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

Type Rule

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

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.

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

Printed 07/09/2024

Page 34 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0052 - PHYSICAL PLANT MAINTENANCE

Title PHYSICAL PLANT MAINTENANCE

Type Rule

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

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

Type Rule

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

Regulation Definition

Each center 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.(2) The emergency management plan shall be developed in conjunction with other agencies and providers of health care services within the local community pursuant to Section 252.32(2), F.S., and in accordance with the "Emergency Management Planning Criteria for Ambulatory Surgical Centers", AHCA FORM 3130-2003 July 94, which is incorporated by reference. The form is available at:
<http://www.flrules.org/Gateway/reference.asp?No=Ref-04454> and available from the Agency for Health Care Administration

Interpretive Guideline

Verify the plan has been reviewed on an annual basis.

Also see Z830

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

Printed 07/09/2024

Page 35 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

at:

http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/forms/ASC_CEMP_Reconstructed_122104.pdf

The plan shall include:

- (a) Provisions for internal and external disasters, and emergencies;
- (b) A description of the center's role in a community wide comprehensive emergency management plan;
- (c) Information about how the center plans to implement specific procedures outlined in its comprehensive emergency management plan;
- (d) Precautionary measures, including voluntary cessation of center operations, to be taken by the center in preparation and response to warnings of inclement weather, including hurricanes and tornadoes, or other potential emergency conditions.
- (e) Provisions for the management of patients, including the discharge or transfer of patients and staff to a hospital or subacute care facility, at the direction of the center's administrator, in the event of an evacuation order, or when a determination is made by the Agency that the condition of the center is sufficient to render it a hazard to the health and safety of patients and staff, pursuant to Chapter 59A-5, F.A.C. Such provisions shall address the role and responsibility of the physician in the decision to move or relocate patients;
- (f) Provisions for coordinating with hospitals that would receive patients to be transferred;
- (g) Provisions for the management of staff, including the distribution and assignment of responsibilities and functions, and the assignment of staff to accompany patients to a hospital or subacute care facility;
- (h) A provision that a verification check will be made to ensure patients transferred to a hospital arrive at the designated hospital;

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

Printed 07/09/2024

Page 36 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

- (i) A provision that ensures that copies of medical records and orders accompany patients transferred to a hospital;
 - (j) Provisions for the management of patients who may be treated at the center during an internal or external disaster or emergencies, including control of patient information and medical records, individual identification of patients, transfer of patients to hospital(s) and treatment of mass casualties;
 - (k) Provisions for contacting relatives and necessary persons advising them of patient location changes. A procedure must also be established for responding to inquiries from patient families and the press;
 - (l) A provision for educating and training personnel in carrying out their responsibilities in accordance with the adopted plan;
 - (m) Identification of mutual aid agreements or statements of understanding for services; and,
 - (n) Provisions for coordination with designated agencies.
- (3) 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 fee may be charged for the review of the plan as authorized by Sections 252.35(2)(m) and 252.38(1)(e), F.S.
- (a) The county emergency management agency has 60 days 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.

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

Printed 07/09/2024

Page 37 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0057 - COMP EMERGENCY MGMT PLAN

Title COMP EMERGENCY MGMT PLAN

Type Rule

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

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

Type Rule

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

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

Type Rule

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

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

Printed 07/09/2024

Page 38 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

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 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 board, 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.

Interpretive Guideline

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

ST - M0060 - QUALITY ASSESSMENT & IMPROVEMENT

Title QUALITY ASSESSMENT & IMPROVEMENT

Type Rule

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

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

Printed 07/09/2024

Page 39 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

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;
- (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 clinical laboratory services and radiology services;
- (h) Results of autopsies if needed.

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.

ST - M0061 - QUALITY ASSESSMENT & IMPROVEMENT

Title QUALITY ASSESSMENT & IMPROVEMENT

Type Rule

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

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.

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

Printed 07/09/2024

Page 40 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0063 - Initial Licensure

Title Initial Licensure

Type Rule

59A-5.003(5)

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).

ST - M0064 - License Capacity

Title License Capacity

Type Rule

59A-5.003(8-10)

Regulation Definition

- (8) 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

Interpretive Guideline

Review initial license and compare to on-site observation.

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

Printed 07/09/2024

Page 41 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

operating rooms, procedure rooms, and recovery beds in the center.

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

ST - M0065 - Facility Closure

Title Facility Closure

Type Rule

59A-5.003(16)

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.

ST - M0066 - Pediatric Services

Title Pediatric Services

Type Rule

59A-5.0085(7)

Regulation Definition

(7) Pediatric services.

(a) A center providing surgical services to patients under the age of 18 years (pediatric) must include age- and size-appropriate criteria in written policies and procedures regarding admissions, surgical services, anesthesia services, post-operative recovery, and discharge planning. The policies and procedures must be approved by the medical staff and the governing board, and be reviewed annually, dated at the time of each review, revised as necessary, and enforced.

Interpretive Guideline

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

Printed 07/09/2024

Page 42 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

1. All patients shall meet admission and preoperative clearance criteria established by the medical staff and approved by the governing board. However, no patient may be admitted prior to age 30 days.
2. Patients who were born less than 37 completed weeks gestation (premature) must be at least 60 weeks of age post conception, weaned off apnea monitors, and cleared by an anesthesiologist or certified registered nurse anesthetist under the on-site medical direction of a licensed physician.
3. Patients must not be oxygen dependent at baseline.
 - (b) Accommodations must be made for the parent or guardian to remain at the center from admission through discharge.
 - (c) Surgical services may be provided to patients for conditions that are not emergency medical conditions.
 - (d) Each center must include its pediatric cases in the quality assessment and improvement system as described in Rule 59A-5.019, F.A.C. that includes peer review, multidisciplinary review and the monitoring of processes and outcomes.
 - (e) One or more persons currently certified in Pediatric Advanced Life Support (PALS) must be present and available to the pediatric patient who is sedated, anesthetized, recovering from anesthesia, or receiving perioperative opioids.
 - (f) Each center providing surgical services requiring a length of stay past midnight must be staffed with the following professionals with specialized training and expertise in the treatment of pediatric patients:
 1. A surgeon who is board-certified or eligible in a pediatric surgical subspecialty or a board-certified or eligible surgeon with additional training and expertise with pediatric patients acceptable to the governing board.
 2. 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 present in the room with the pediatric patient throughout all general

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

Printed 07/09/2024

Page 43 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

anesthesia, regional anesthesia and monitored anesthesia care.

3. Nursing and other direct care staff must have specialized training and experience with pediatric patients. Nursing personnel must be PALS and/or Advanced Cardiac Life Support certified. There must be at least one registered professional nurse on duty at all times.

(g) Each center providing surgical services requiring a length of stay past midnight must have facilities and equipment available to store ready-to-eat foods and beverages. Equipment must include handwashing facilities and a refrigerator.

(h) Age- and size-appropriate equipment and resources related to the care of pediatric patients must be available on site, including

1. Operating tables;
2. Pre- and post-operative beds;
3. Anesthesia equipment and supplies;
4. Resuscitation devices;
5. Oxygen saturation monitors;
6. Pharmacologic supplies; and
7. Blood pressure cuffs.

ST - M0401 - INTERNAL RISK MANAGEMENT PROGRAM

Title INTERNAL RISK MANAGEMENT PROGRAM

Type Rule

395.0197(1) FS; 59A-5.003(11) FAC

Regulation Definition

395.0197

(1) Every licensed facility shall, as a part of its administrative functions, establish an internal risk management program that includes all of the following components:

59A-5.003(11)

Interpretive Guideline

The surveyor should review:

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

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

Printed 07/09/2024

Page 44 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

(11) Each center licensed under chapter 395, F.S., shall establish an internal risk management program pursuant to chapter 59A-10, F.A.C., as a part of its administrative function.

ST - M0402 - RM Prog - Investigation & Analysis

Title RM Prog - Investigation & Analysis

Type Rule

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

Regulation Definition

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

Type Rule

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

Regulation Definition

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

Interpretive Guideline

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

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

Printed 07/09/2024

Page 45 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

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.

Review Risk Management Plan for the following:

- Review for identified incident trends, risk/process improvement opportunities including the analysis of the incident and trends regarding risk and safety.
- Interview the Risk Manager to determine their role in the development and implementation of risk reduction and risk prevention strategies.

ST - M0404 - Education & Training - Incident Reporting Sys

Title Education & Training - Incident Reporting Sys

Type Rule

395.0197(1)(b)(1);

Regulation Definition

395.0197(1)(b)(1)

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

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

Interpretive Guideline

Review a total of 6 Personnel Records 2 new (over 30 days), 2 existing employees (over 2 years), and 2 contract/agency personnel (over 30 days) for evidence of training at orientation and annual review in the personnel file.

ST - M0405 - Approp Measure - Recovery Room Prohibition

Title Approp Measure - Recovery Room Prohibition

Type Rule

395.0197(1)(b)(2)

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

Printed 07/09/2024

Page 46 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

Regulation Definition

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

Type Rule

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

Regulation Definition

A prohibition against an unlicensed person from assisting or participating in any surgical procedure unless the facility has authorized the person to do so following a competency assessment, and such assistance or participation is done under the direct and immediate supervision of a licensed physician and is not otherwise an activity that may only be performed by a licensed health care practitioner.

Interpretive Guideline

- Interview surgical staff to ascertain if unlicensed staff participate/assisting in surgical procedures - provisions.
- Identify those unlicensed staff participating in surgical procedures.
- Review the unlicensed staff competencies and competency assessments.
- Review surgical schedules and assignments to determine direct and immediate supervision of an unlicensed person.
- Review competencies for Private or Contractual Scrub individuals.

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

Printed 07/09/2024

Page 47 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

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

Title Approp Measure - Ongoing Eval of Proc/Systems

Type Rule

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

Regulation Definition

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?
- Review documentation to determine the facility compliance for development, implementation and ongoing evaluation process to prevent occurrences

ST - M0408 - RM Prog - Pt Grievance Analysis

Title RM Prog - Pt Grievance Analysis

Type Rule

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

Regulation Definition

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

Interpretive Guideline

- Review a sample of grievances relating to patient care and medical services.
- Review grievance analysis report relating to patient care and medical services.
- Review evidence that issues related to quality of care/medical care are analyzed including outcomes. Were corrective measures placed into facility-wide systems?
- Verify a plan to prevent re-occurrences.
- Interview Risk Manager to confirm grievance information.

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

Printed 07/09/2024

Page 48 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

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

Title RM Prog - Pt Notification of Adv Incidents

Type Rule

395.0197(1)(d); 395.1051

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

Type Rule

395.0197(1)(e); 59A-10.0055(2)(a-b)

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

Printed 07/09/2024

Page 49 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

Regulation Definition

395.0197(1)(e)

The development and implementation of an incident reporting system based upon the affirmative duty of all health care providers and all agents and employees of the licensed health care facility to report adverse incidents to the risk manager, or to his or her designee, within 3 business days after their occurrence.

59A-10.0055(2)(a)(b)

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-10-CM

Interpretive Guideline

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

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

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

Interview a sample of staff to determine if:

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

Note: As of October 1, 2015, we have moved to ICD-10-CM

ST - M0412 - Incident Reporting System - Reports

Title Incident Reporting System - Reports

Type Rule

59A-10.0055(2)(c)-(e), FAC

Regulation Definition

- (c) Whether or not a physician was called; and if so, a brief statement of said physician's recommendations as to medical treatment, if any;
- (d) A listing of all persons then known to be involved directly in the incident, including witnesses, along with locating information for each;

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.

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

Printed 07/09/2024

Page 50 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

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

ST - M0413 - Resp of Governing Board and Risk Manager

Title Resp of Governing Board and Risk Manager

Type Rule

395.0197(2)

Regulation Definition

(2) The internal risk management program is the responsibility of the governing board of the health care facility. Each licensed facility shall hire a risk manager who is responsible for implementation and oversight of the facility's internal risk management program and who demonstrates competence, through education or experience, in all of the following areas:

- (a) Applicable standards of health care risk management.
- (b) Applicable federal, state, and local health and safety laws and rules.
- (c) General risk management administration.
- (d) Patient care.
- (e) Medical care.
- (f) Personal and social care.
- (g) Accident prevention.
- (h) Departmental organization and management.
- (i) Community interrelationships.
- (j) Medical terminology.

Interpretive Guideline

Verify there is a 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.

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

Printed 07/09/2024

Page 51 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0414 - RISK MANAGER ACCESS TO RECORDS

Title RISK MANAGER ACCESS TO RECORDS

Type Rule

395.0197(4), F.S.

Regulation Definition

(4) ...Each internal risk management program shall include the use of incident reports to be filed with an individual of responsibility who is competent in risk management techniques in the employ of each licensed facility, such as an insurance coordinator, or who is retained by the licensed facility as a consultant. The individual responsible for the risk management program shall have free access to all medical records of the licensed facility. The incident reports are part of the workpapers of the attorney defending the licensed facility in litigation relating to the licensed facility and are subject to discovery, but are not admissible as evidence in court. A person filing an incident report is not subject to civil suit by virtue of such incident report.

Interpretive Guideline

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

ST - M0415 - DEVELOPEMENT OF CORRECTIVE PROCEDURES

Title DEVELOPEMENT OF CORRECTIVE PROCEDURES

Type Rule

395.0197(4), F.S.

Regulation Definition

(4) ...As a part of each internal risk management program, the incident reports shall be used to develop categories of incidents which identify problem areas. Once identified, procedures shall be adjusted to correct the problem areas.

Interpretive Guideline

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

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

Printed 07/09/2024

Page 52 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

Verify the issues are tracked and trended. Are these specific to facility problems and issues regarding patient, staff and facility safety.

ST - M0416 - 15 Day Reports

Title 15 Day Reports

Type Rule

395.0197(5) & (7), F.S.

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 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;

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.

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

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

Are the interventions in place. Are those interventions enabling the risk/ quality and staff process to mitigate these types of occurrences for patient safety and error reduction?

If interventions are in place-ask to see that safety process, evaluation and findings. Are they successful- if not what steps has the facility taken to rectify?

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

Printed 07/09/2024

Page 53 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

- (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.

(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 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

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

Printed 07/09/2024

Page 54 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

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.

ST - M0417 - Sexual Misconduct - Facility Personnel

Title Sexual Misconduct - Facility Personnel

Type Standard

395.0197(9), F.S.

Regulation Definition

- (9) The internal risk manager of each licensed facility shall:
- (a) Investigate every allegation of sexual misconduct which is made against a member of the facility's personnel who has direct patient contact, when the allegation is that the sexual misconduct occurred at the facility or on the grounds of the facility.
 - (b) Report every allegation of sexual misconduct to the administrator of the licensed facility.
 - (c) Notify the family or guardian of the victim, if a minor, that an allegation of sexual misconduct has been made and that an investigation is being conducted.
 - (d) Report to the Department of Health every allegation of

Interpretive Guideline

Review a list of incidents and chose those relating to allegations of sexual misconduct. This is for allegations against facility's personnel.
Review the facility's Policy and Procedures regarding the investigation of an allegation of sexual misconduct. Was the Policy and Procedures followed?
If the allegation was confirmed, what corrective action was implemented?
Was the family/guardian of victim and the Department of Health notified?
Interview the facility's staff, can they tell you what they would do if someone accused an employee of sexual misconduct? Does it meet the facility's Policy and Procedures?

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

Printed 07/09/2024

Page 55 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

sexual misconduct, as defined in chapter 456 and the respective practice act, by a licensed health care practitioner that involves a patient.

ST - M0418 - Sexual Abuse Reporting

Title Sexual Abuse Reporting

Type Rule

395.0197 (10), F.S.

Regulation Definition

(10) Any witness who witnessed or who possesses actual knowledge of the act that is the basis of an allegation of sexual abuse shall:

(a) Notify the local police; and

(b) Notify the hospital risk manager and the administrator.

For purposes of this subsection, "sexual abuse" means acts of a sexual nature committed for the sexual gratification of anyone upon, or in the presence of, a vulnerable adult, without the vulnerable adult's informed consent, or a minor. "Sexual abuse" includes, but is not limited to, the acts defined in s. 794.011(1)(h), fondling, exposure of a vulnerable adult's or minor's sexual organs, or the use of the vulnerable adult or minor to solicit for or engage in prostitution or sexual performance. "Sexual abuse" does not include any act intended for a valid medical purpose or any act which may reasonably be construed to be a normal caregiving action.

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.
- Evaluate process success to mitigate reoccurrence and patient safety.
- Check the Patient Safety Committee and Governing Body Agendas to insure the facility administration, quality, risk, Patient safety are aware with planned interventions.
- Assess the facility for proactive safety culture and awareness process

ST - M0419 - RISK MANAGER REVIEW OF INCIDENT REPORTS

Title RISK MANAGER REVIEW OF INCIDENT REPORTS

Type Rule

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

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

Printed 07/09/2024

Page 56 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

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

Type Standard

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

Regulation Definition

(a) At least quarterly, or more often as may be required by the governing body, the risk manager shall provide a summary report to the governing body, which includes information about activities of risk management as defined herein.

Interpretive Guideline

- Interview the Risk Manager and staff about who presents the risk management summary report?
- Review the Governing Body agenda/minutes for risk management reporting of summaries of identified events, safety issues and reporting of current status of corrective action plans including Risk for intervention and follow-up process
- How is the risk management summary report being presented to the Governing Body?

ST - M0421 - ANNUAL REPORT OF JUDGMENTS

Title ANNUAL REPORT OF JUDGMENTS

Type Rule

395.0197 (3)

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

Printed 07/09/2024

Page 57 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

Regulation Definition

In addition to the programs mandated by this section, other innovative approaches intended to reduce the frequency and severity of medical malpractice and patient injury claims shall be encouraged and their implementation and operation facilitated. Such additional approaches may include extending internal risk management programs to health care providers' offices and the assuming of provider liability by a licensed health care facility for acts or omissions occurring within the licensed facility. Each licensed facility shall annually report to the agency and the Department of Health the name and judgments entered against each health care practitioner for which it assumes liability.

Interpretive Guideline

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

ST - M0422 - Annual Report Summarizing Incident Reports

Title Annual Report Summarizing Incident Reports

Type Rule

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

Regulation Definition

(6)(a) Each licensed facility subject to this section shall submit an annual report to the agency summarizing the incident reports that have been filed in the facility for that year. The report shall include:

1. The total number of adverse incidents.
2. A listing, by category, of the types of operations, diagnostic or treatment procedures, or other actions causing the injuries, and the number of incidents occurring within each category.
3. A listing, by category, of the types of injuries caused and the number of incidents occurring within each category.

Interpretive Guideline

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

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

Printed 07/09/2024

Page 58 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

4. A code number using the health care professional's licensure number and a separate code number identifying all other individuals directly involved in adverse incidents to patients, the relationship of the individual to the licensed facility, and the number of incidents in which each individual has been directly involved. Each licensed facility shall maintain names of the health care professionals and individuals identified by code numbers for purposes of this section.

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

(c) The report submitted to the agency must also contain the name of the risk manager of the licensed facility, a copy of its policy and procedures which govern the measures taken by the facility and its risk manager to reduce the risk of injuries and adverse incidents, and the results of such measures. The annual report is confidential and is not available to the public pursuant to s. 119.07(1) or any other law providing access to public records. The annual report is not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board. The annual report is not available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency or the appropriate regulatory board shall make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause.

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

Printed 07/09/2024

Page 59 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0423 - Agency Access to Records

Title Agency Access to Records

Type Rule

395.0197(13); 59A-10.0055(3)

Regulation Definition

395.0197(13)

The agency shall have access to all licensed facility records necessary to carry out the provisions of this section. The records obtained by the agency under subsection (6), subsection (7), or subsection (9) are not available to the public under s. 119.07(1), nor shall they be discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board, nor shall records obtained pursuant to s. 456.071 be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency or the appropriate regulatory board shall make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause, except that, with respect to medical review committee records, s. 766.101 controls.

59A-10.0055(3)(b)

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

Interpretive Guideline

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

NOTE:

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

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

Printed 07/09/2024

Page 60 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0424 - UNLAWFUL COERCION OF REPORTING OBLIGATION

Title UNLAWFUL COERCION OF REPORTING OBLIGATION

Type Rule

395.0197(19), F.S.

Regulation Definition

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

Type Rule

395.1012(1), F.S.

Regulation Definition

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.
- Does the facility utilize information gathered to demonstrate compliance with 42 CFR 482.21 (Quality Assurance and Performance Improvement Plan).

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

Printed 07/09/2024

Page 61 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0426 - PATIENT SAFETY OFFICER AND COMMITTEE

Title PATIENT SAFETY OFFICER AND COMMITTEE

Type Rule

395.1012(2), F.S.

Regulation Definition

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

Interpretive Guideline

- Determine if the facility has appointed a Patient Safety Officer and a patient safety committee.
- Interview the Patient Safety Officer regarding roles and responsibilities.
- Review the composition of the Patient Safety Committee.
- Determine the eligibility of the committee member not employed by the facility, not a contracted employee of the facility, nor in practice at the facility.
- Review facility documentation of the Patient Safety Committee activities such as agenda/minutes, reports, QA/PI projects and outcomes, Patient Safety Initiatives, etc.
- Review the process by which the committee reviews and evaluates the quality of patient safety measures implemented by the facility.
- Review the process by which the committee assists in the implementation of the facility's Patient Safety Plan.
- Is the facility documentation presented during the survey sufficient to determine compliance?

NOTE:

- Reviews of the meeting Agenda(s) may provide sufficient information/evidence required to determine Risk Management Program compliance.
- Determine Patient Safety Program for effective processes.

ST - M0504 - PRICE TRANSPARENCY

Title PRICE TRANSPARENCY

Type Rule

395.301(1) FS; 59A-5.032(2) FAC

Regulation Definition

395.301(1), F.S.

Interpretive Guideline

Interview the Risk Manager and review facility website contents. Review 3 discharged patients, for documentation

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

Printed 07/09/2024

Page 62 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

A facility licensed under this chapter shall provide timely and accurate financial information and quality of service measures to patients and prospective patients of the facility, or to patients' survivors or legal guardians, as appropriate. Such information shall be provided in accordance with this section and rules adopted by the agency pursuant to this chapter and s. 408.05. Licensed facilities operating exclusively as state facilities are exempt from this subsection.

(a) Each licensed facility shall make available to the public on its website information on payments made to that facility for defined bundles of services and procedures. The payment data must be presented and searchable in accordance with, and through a hyperlink to, the system established by the agency and its vendor using the descriptive service bundles developed under s. 408.05(3)(c). At a minimum, the facility shall provide the estimated average payment received from all payors, excluding Medicaid and Medicare, for the descriptive service bundles available at that facility and the estimated payment range for such bundles. Using plain language, comprehensible to an ordinary layperson, the facility must disclose that the information on average payments and the payment ranges is an estimate of costs that may be incurred by the patient or prospective patient and that actual costs will be based on the services actually provided to the patient. The facility's website must:

1. Provide information to prospective patients on the facility's financial assistance policy, including the application process, payment plans, and discounts, and the facility's charity care policy and collection procedures.
2. If applicable, notify patients and prospective patients that services may be provided in the health care facility by the facility as well as by other health care providers who may separately bill the patient and that such health care providers may or may not participate with the same health insurers or health maintenance organizations as the facility.

and transparency records to ensure required components are met as outlined in regulation text 395.301(1) FS. Interview the staff responsible for billing on how estimates and itemized bills are provided to patients.

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

Printed 07/09/2024

Page 63 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

3. Inform patients and prospective patients that they may request from the facility and other health care providers a more personalized estimate of charges and other information, and inform patients that they should contact each health care practitioner who will provide services in the hospital to determine the health insurers and health maintenance organizations with which the health care practitioner participates as a network provider or preferred provider.

4. Provide the names, mailing addresses, and telephone numbers of the health care practitioners and medical practice groups with which it contracts to provide services in the facility and instructions on how to contact the practitioners and groups to determine the health insurers and health maintenance organizations with which they participate as network providers or preferred providers.

(b)1. Upon request, and before providing any nonemergency medical services, each licensed facility shall provide in writing or by electronic means a good faith estimate of reasonably anticipated charges by the facility for the treatment of the patient's or prospective patient's specific condition. The facility must provide the estimate to the patient or prospective patient within 7 business days after the receipt of the request and is not required to adjust the estimate for any potential insurance coverage. The estimate may be based on the descriptive service bundles developed by the agency under s. 408.05(3)(c) unless the patient or prospective patient requests a more personalized and specific estimate that accounts for the specific condition and characteristics of the patient or prospective patient. The facility shall inform the patient or prospective patient that he or she may contact his or her health insurer or health maintenance organization for additional information concerning cost-sharing responsibilities.

2. In the estimate, the facility shall provide to the patient or prospective patient information on the facility's financial assistance policy, including the application process, payment

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

Printed 07/09/2024

Page 64 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

plans, and discounts and the facility's charity care policy and collection procedures.

3. The estimate shall clearly identify any facility fees and, if applicable, include a statement notifying the patient or prospective patient that a facility fee is included in the estimate, the purpose of the fee, and that the patient may pay less for the procedure or service at another facility or in another health care setting.

4. Upon request, the facility shall notify the patient or prospective patient of any revision to the estimate.

5. In the estimate, the facility must notify the patient or prospective patient that services may be provided in the health care facility by the facility as well as by other health care providers that may separately bill the patient, if applicable.

6. The facility shall take action to educate the public that such estimates are available upon request.

7. Failure to timely provide the estimate pursuant to this paragraph shall result in a daily fine of \$1,000 until the estimate is provided to the patient or prospective patient. The total fine may not exceed \$10,000.

The provision of an estimate does not preclude the actual charges from exceeding the estimate.

(c) Each facility shall make available on its website a hyperlink to the health-related data, including quality measures and statistics that are disseminated by the agency pursuant to s. 408.05. The facility shall also take action to notify the public that such information is electronically available and provide a hyperlink to the agency's website.

(d)1. Upon request, and after the patient's discharge or release from a facility, the facility must provide to the patient or to the patient's survivor or legal guardian, as appropriate, an itemized statement or a bill detailing in plain language, comprehensible to an ordinary layperson, the specific nature of charges or expenses incurred by the patient. The initial statement or bill shall be provided within 7 days after the

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

Printed 07/09/2024

Page 65 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

patient's discharge or release or after a request for such statement or bill, whichever is later. The initial statement or bill must contain a statement of specific services received and expenses incurred by date and provider for such items of service, enumerating in detail as prescribed by the agency the constituent components of the services received within each department of the licensed facility and including unit price data on rates charged by the licensed facility. The statement or bill must also clearly identify any facility fee and explain the purpose of the fee. The statement or bill must identify each item as paid, pending payment by a third party, or pending payment by the patient, and must include the amount due, if applicable. If an amount is due from the patient, a due date must be included. The initial statement or bill must direct the patient or the patient's survivor or legal guardian, as appropriate, to contact the patient's insurer or health maintenance organization regarding the patient's cost-sharing responsibilities.

2. Any subsequent statement or bill provided to a patient or to the patient's survivor or legal guardian, as appropriate, relating to the episode of care must include all of the information required by subparagraph 1., with any revisions clearly delineated.

3. Each statement or bill provided pursuant to this subsection:

- a. Must include notice of hospital-based physicians and other health care providers who bill separately.
- b. May not include any generalized category of expenses such as "other" or "miscellaneous" or similar categories.
- c. Must list drugs by brand or generic name and not refer to drug code numbers when referring to drugs of any sort.
- d. Must specifically identify physical, occupational, or speech therapy treatment by date, type, and length of treatment when such treatment is a part of the statement or bill.

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

Printed 07/09/2024

Page 66 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

59A-5.032 Price Transparency and Patient Billing.

(2) Estimate. The center shall provide an estimate upon request of the patient, prospective patient, or legal guardian for nonemergency medical services.

(a) An estimate or an update to a previous estimate shall be provided within 7 business days from receipt of the request.

Unless the patient requests a more personalized estimate, the estimate may be based upon the average payment received for the anticipated service bundle. Every estimate shall include:

1. A statement informing the requestor to contact their health insurer or HMO for anticipated cost sharing responsibilities,
2. A statement advising the requestor that the actual cost may exceed the estimate,
3. The web address to financial assistance policies, charity care policy, and collection procedure,
4. A description and purpose of any facility fees, if applicable,
5. A statement that services may be provided by other health care providers who may bill separately,
6. A statement, including a web address if different from above, that contact information for health care practitioners and medical practice groups that are expected to bill separately is available on the center's website; and,
7. A statement advising the requestor that the patient may pay less for the procedure or service at another facility or in another health care setting.

(b) If the center provides a non-personalized estimate, the estimate shall include a statement that a personalized estimate is available upon request.

(c) A personalized estimate must include the charges specific to the patient's anticipated services.

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

Printed 07/09/2024

Page 67 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

ST - M0505 - PRICE TRANSPARENCY

Title PRICE TRANSPARENCY

Type Rule

395.301(2) FS

Regulation Definition

395.301(2), F.S.

Each itemized statement or bill must prominently display the telephone number of the medical facility's patient liaison who is responsible for expediting the resolution of any billing dispute between the patient, or the patient's survivor or legal guardian, and the billing department.

Interpretive Guideline

Review itemized statement or bills to determine compliance with required information including the telephone number of the patient liaison responsible for billing disputes.

ST - M0507 - PRICE TRANSPARENCY

Title PRICE TRANSPARENCY

Type Rule

395.301(4) FS

Regulation Definition

A licensed facility shall make available to a patient all records necessary for verification of the accuracy of the patient's statement or bill within 10 business days after the request for such records. The records must be made available in the facility's offices and through electronic means that comply with the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. s. 1320d, as amended. Such records must be available to the patient before and after payment of the statement or bill. The facility may not charge the patient for making such verification records available; however, the facility may charge its usual fee for providing copies of

Interpretive Guideline

Review the Policy and procedure for the request and release of patient records needed to verify patient billing statement.

Interview billing staff; ask if any patients requested records in order to verify the accuracy of their billing statement. Inquire about how they ensure this information is available to the patient, legal guardian or patient survivor before or after bill payment. Verify with billing staff how the facility charges for copies of the record. Is it per the policy and procedure?

If any patients requested records in order to verify the accuracy of their billing statements, review one of those patient records to ensure compliance within the 10-business day rule.

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

Printed 07/09/2024

Page 68 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

records as specified in s. 395.3025.

Determine how the facility is offering electronic record review and does this offer the information needed for accuracy review of billed items.

ST - M0508 - PRICE TRANSPARENCY

Title PRICE TRANSPARENCY

Type Rule

395.301(6-7) FS; 59A-5.032(3) FAC

Regulation Definition

(6) Each facility shall establish an internal process for reviewing and responding to grievances from patients. Such process must allow a patient to dispute charges that appear on the patient's itemized statement or bill. The facility shall prominently post on its website and indicate in bold print on each itemized statement or bill the instructions for initiating a grievance and the direct contact information required to initiate the grievance process. The facility must provide an initial response to a patient grievance within 7 business days after the patient formally files a grievance disputing all or a portion of an itemized statement or bill.

(7) Each licensed facility shall disclose to a patient, a prospective patient, or a patient's legal guardian whether a cost-sharing obligation for a particular covered health care service or item exceeds the charge that applies to an individual who pays cash or the cash equivalent for the same health care service or item in the absence of health insurance coverage. Failure to provide a disclosure in compliance with this subsection may result in a fine not to exceed \$500 per incident.

59A-5.032(3) Itemized statement or bill. The center shall provide an itemized statement or bill upon request of the patient or the patient's survivor or legal guardian. The itemized statement or bill shall be provided within 7 business

Interpretive Guideline

Review the Policy and Procedure for addressing patient questions regarding the itemized statement or bill.

Interview the billing staff to determine if the 7-business day response occurs after the question is received.

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

Printed 07/09/2024

Page 69 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

days after the patient's discharge or release, or 7 business days after the request, whichever is later. The itemized statement or bill must include:

- (a) A description of the individual charges from each department or service area by date, as prescribed in paragraph 395.301(1)(d), F.S.;
- (b) Contact information for health care practitioners or medical practice groups that are expected to bill separately based on services provided; and,
- (c) The center's contact information for billing questions and disputes.

ST - M0509 - Price Transparency - Website Posting

Title Price Transparency - Website Posting

Type Rule

59A-5.032(1), FAC

Regulation Definition

59A-5.032 Price Transparency and Patient Billing.

- (1) Website. Each center shall make available to patients and prospective patients price transparency and patient billing information on its website regarding the availability of estimates of costs that may be incurred by the patient, financial assistance, billing practices, and a hyperlink to the Agency's service bundle pricing website. The content on the center's website shall be reviewed at least every 90 days and updated as needed to maintain timely and accurate information. For the purpose of this rule, service bundles means the reasonably expected center services and care provided to a patient for a specific treatment, procedure, or diagnosis as posted on the Agency's website. In accordance with section 395.301, F.S., the center's website must include:
- (a) A hyperlink to the Agency's pricing website upon implementation of the same that provides information on

Interpretive Guideline

Interview the staff responsible for billing to verify information is posted on the Center's website.

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

Printed 07/09/2024

Page 70 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

payments made to the facilities for defined service bundles and procedures. The Agency's pricing website is located at: <http://pricing.floridahealthfinder.gov>;

(b) A statement informing patients and prospective patients that the service bundle information is a non-personalized estimate of costs that may be incurred by the patient for anticipated services and that actual costs will be based on services actually provided to the patient;

(c) A statement informing patients and prospective patients of their right to request a personalized estimate from the center;

(d) A statement informing patients of the center's financial assistance policy, charity care policy, and collection procedure;

(e) A list of names and contact information of health care practitioners and medical practice groups contracted to provide services within the center, grouped by specialty or service; and,

(f) A statement informing patients to contact the health care practitioners anticipated to provide services to the patient while in the center regarding a personalized estimate, billing practices and participation with the patient's insurance provider or health maintenance organization (HMO) as the practitioners may not participate with the same health insurers or HMO as the center.

ST - M0541 - Billing Activities

Title Billing Activities

Type Rule

395.3011

Regulation Definition

395.3011 Billing and collection activities.-

(1) As used in this section, the term "extraordinary collection action" means any of the following actions taken by a licensed

Interpretive Guideline

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

Printed 07/09/2024

Page 71 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

facility against an individual in relation to obtaining payment of a bill for care covered under the facility's financial assistance policy:

- (a) Selling the individual's debt to another party.
- (b) Reporting adverse information about the individual to consumer credit reporting agencies or credit bureaus.
- (c) Deferring, denying, or requiring a payment before providing medically necessary care because of the individual's nonpayment of one or more bills for previously provided care covered under the facility's financial assistance policy.
- (d) Actions that require a legal or judicial process, including, but not limited to:
 - 1. Placing a lien on the individual's property;
 - 2. Foreclosing on the individual's real property;
 - 3. Attaching or seizing the individual's bank account or any other personal property;
 - 4. Commencing a civil action against the individual;
 - 5. Causing the individual's arrest; or
 - 6. Garnishing the individual's wages.
- (2) A facility may not engage in an extraordinary collection action against an individual to obtain payment for services:
 - (a) Before the facility has made reasonable efforts to determine whether the individual is eligible for assistance under its financial assistance policy for the care provided and, if eligible, before a decision is made by the facility on the patient's application for such financial assistance.
 - (b) Before the facility has provided the individual with an itemized statement or bill.
 - (c) During an ongoing grievance process as described in s. 395.301(6) or an ongoing appeal of a claim adjudication.
 - (d) Before billing any applicable insurer and allowing the insurer to adjudicate a claim.
 - (e) For 30 days after notifying the patient in writing, by certified mail, or by other traceable delivery method, that a collection action will commence absent additional action by

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

Printed 07/09/2024

Page 72 of 72

Aspen State Regulation Set: M 3.07 Ambulatory Surgical Center

the patient.

(f) While the individual:

1. Negotiates in good faith the final amount of a bill for services rendered; or
2. Complies with all terms of a payment plan with the facility.