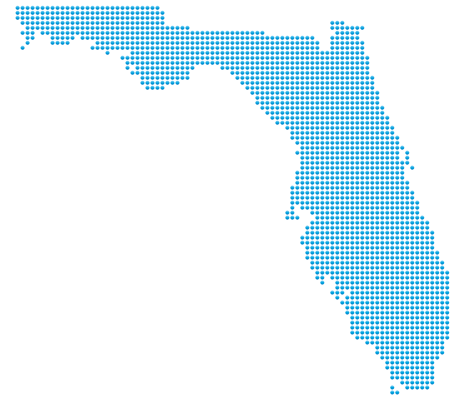


# Florida Risk Management *and Related Regulations*

*Fifth Edition*

*Written by:*

Sandra Jones, CPHRM, CASC, CHCQM, FHFMA  
Donna Slosburg, RN, BSN, CASC



*Prepared for the*

Florida Society of

**FSASC**

Ambulatory Surgical Centers



**-- Disclaimer --**

The Florida Society of Ambulatory Surgical Centers (“FSASC”) has published this document, entitled Florida Risk Management and Related Regulations, Fifth Edition. The information contained and assembled in this document is provided by regulatory and risk management experts as a resource for the benefit of FSASC members. The document provides an overview or quick reference guide to the elements of a successful risk management program and identifies known related statutes and regulations. This document does not supersede any statute or regulation enforced by the state of Florida. It is not intended to provide a complete analysis, legal or otherwise, on how to specifically implement or structure a risk management program for a particular ambulatory surgical center. FSASC and/or Task Force Members cannot be held responsible for the use or implementation of this resource guide. As with any guide or resource, please consult the advice of an attorney and risk management expert before implementing any program.

# Florida Risk Management and Related Regulations

*Fifth Edition*

*Prepared for the*

**Florida Society of Ambulatory Surgical Centers**

Fifth Edition

*Written by:*

Sandra Jones, MBA, MSM, CPHRM, CASC, CHCQM, FHFMA

Donna Slosburg, RN, BSN, CASC

## Table of Contents

Florida Risk Management and Related Regulations.....	3
Requirements .....	3
Risk Management Program Requirements .....	3
Governing Body Responsibility.....	5
Approaches to Reduce Frequency and Severity of Medical Malpractice and Patient Injury Claims .....	5
Florida Statutes Governing the Establishment of Internal Risk Management Program .....	5
Adverse Incident Defined.....	6
State Reporting Requirements.....	6
Sexual Abuse .....	7
Patient Safety Officer and a Patient Safety Committee.....	7
Correct Patient, Correct Procedure, Correct Site Procedures .....	7
Reporting Incidents to the Risk Manager .....	7
Record Retention .....	8
Incident Report Content.....	8
Investigation and Follow Up .....	8
Adverse Incident Reporting Guide .....	9
Recommendations.....	10
Resources for Forms and Regulations .....	11

### Appendices

Appendix A: Abbreviations and References.....	Page 12
Appendix B: Risk Manager and Risk Manager Designee Checklist.....	Page 13
Appendix C: F.S. 395.0197 Internal Risk Management Program.....	Page 14
Appendix D: F.S. 395.1012 Patient Safety.....	Page 19
Appendix E: Chapter 59A-5 Ambulatory Surgical Center Licensure.....	Page 20
Appendix F: Chapter 59A-10 Internal Risk Management Program .....	Page 37
Appendix G: Chapter 64B-8-9.007 Standards of Practice for Medical Doctors.....	Page 40
Appendix H: CFR 416.43 Condition for Coverage: Quality Assessment and Performance Improvement.....	Page 42

© 2019 Florida Society of Ambulatory Surgical Centers

# Task Force Member Biographies

## Fifth Edition

### **Sandra Jones, MBA, MSM, CPHRM, CASC, CHCQM, FHFMA**

Sandra Jones is President of Ambulatory Strategies, providing management, development, regulatory compliance, accreditation preparation, ASC licensing and CMS certification compliance consulting, and risk management services to surgical centers. Sandra is a Certified Professional in Healthcare Risk Management; Certified Administrator Surgery Center; Fellow of the Health Care Financial Management Association; and Certified in Health Care Quality Management. She is a contributor on regulatory compliance and operational issues for several professional publications. Sandra was a hospital president for eight years and a hospital department administrator for several years prior to her development of surgery centers and regional positions with national ASC management companies. She serves on the Standards and Survey Procedures Committee for the AAAHC, an accrediting organization, and is a former board member. For nine years, she served on the board of the ASC Association, the national membership, education and advocacy organization for ambulatory surgery centers where she served on Governance and other Committees. She was the ASC Association committee chair for the HIPAA Task Force and HIPAA guidebooks.

### **Donna Slosburg, RN, BSN, CASC**

Donna Slosburg is Executive Director of the Ambulatory Surgery Center Quality Collaboration. In this role, she oversees and participates in a broad range of quality-related projects on behalf of the ASC industry and speaks across the country regarding ASC quality measurement. In addition to directing internal ASC quality measure development and overseeing the public reporting of ASC quality data, she has also collaborated with many other organizations focused on advancing quality, including recent work with the CDC and AHRQ.

Donna has worked in the healthcare industry for over 30 years and joined the ASC industry in 1987. Her nursing experience has included working in the Intensive Care Unit, Peri-Operative care areas, and nursing education. Her leadership roles include ASC nurse manager, ASC administrator, and overseeing regional operations for an ASC management company. She was a senior vice president of surgery operations and national surgery specialist for HealthSouth, one of the nation's largest healthcare services providers, and received the HealthSouth Special Achievement Award for Clinical Excellence. Donna recently served on the editorial board for the Association of peri-Operative Registered Nurses and has also served on the Board of Directors for the Florida Society of Ambulatory Surgical Centers. Donna is currently a member of several Technical Expert Panels. She is a speaker for the AORN Administrator Skills Course. Donna was one of the first to receive the Certified Administrator Surgery Center industry certification.

# Florida Risk Management And Related Regulations

Ambulatory Surgical Centers licensed in the State of Florida are required to have a risk management program. The following is information about the risk management requirements to provide guidance to the surgical center administrative staff to achieve and maintain compliance.

In 2018, Florida changed its risk management regulations to delete the requirement for licensure of a risk manager. Instead, Florida Statute 395.0197 now reads that the risk manager through education or experience must meet requirements that were once in administrative rule 59A-10.037. See Resources for updated F.S. 395.0197. The address for the location of these guidelines on the Internet is listed under Resources for Forms and Regulations on page 11.

Additionally, the Medicare Conditions for Coverage Interpretive Guidelines, released in 2009 and updated last in April 2015, as of the publication of this white paper, include risk assessment of infection control, time out, prevention of surgical fires and other areas that emphasize the integration with quality improvement as well as governing body oversight. Full discussion of the Medicare Conditions for Coverage Interpretive Guidelines is not included in this publication. For a full text of the guidelines go to FSASC.org for a link to that document.

## Requirements

### RISK MANAGEMENT PROGRAM REQUIREMENTS

The components of the risk management program must include:

#### ***INVESTIGATION AND ANALYSIS***

The program must have a component for the investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents to patients.

#### ***DEVELOPMENT OF APPROPRIATE MEASURES TO REDUCE RISK***

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

**Education and Training:** Within 30 days of hire, risk management and risk prevention education for all non-physician personnel must take place. In addition, there must be one hour minimum of annual education and training of all personnel working in clinical areas and providing patient care. Physicians are excluded from this requirement; allied health professionals are not. Therefore, education and training of CRNAs, PAs, or other allied health professionals who provide patient care in your surgical center must have this initial and annual education. Education must include risk management and risk

prevention, including the importance of accurate and timely incident reporting; the legal obligation of all health care providers and all agents and employees of the facility to report incidents to the risk manager; reporting an adverse incident to the risk manager or risk manager designee within three business days; the statutory definition of an “adverse incident” and the required reporting to AHCA; the location of risk management policies, procedures, and the incident reporting form. A surveyor or inspector may interview staff and ask a staff member to state what training occurred, who is notified when an adverse event occurs, and where the reporting forms are located.

**Staffing in the Recovery Area (PACU):** One staff member and at least one other person shall attend a patient in the recovery room. There shall always be two persons in the recovery area when a patient is recovering from anesthesia and the procedure. One of these persons must be a registered nurse. The second person may be any employee, a physician, or a significant other of the patient. Instead of two people performing live observation in the PACU, the facility can have (1) electronic observation or (2) any other reasonable measure taken to ensure patient protection and privacy. When electronic observation is used, live observation/monitoring of the camera must be occurring. The monitoring does not replace the requirement of one RN in PACU.

**Unlicensed persons assisting or participating in any surgical procedures:** There is a prohibition against an unlicensed person assisting or participating in any surgical procedure unless the facility has authorized the person to do so following a competency assessment of that unlicensed person. The unlicensed person must be under the direct and immediate supervision of a licensed physician. The activity cannot be one that may only be performed by a licensed health care practitioner. One example of a prohibition would be an equipment sales person without clinical skills actively participating in a procedure or other patient care activity.

**Development, implementation, and ongoing evaluation:** The development, implementation, and ongoing evaluation of procedures, protocols, and systems to accurately identify patients, planned procedures, the correct site of the planned procedure, and the availability of correct implant, 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 of medical condition. The surveyors and inspectors may look for policies as well as observe the process of conducting a time out, marking of the site, and involvement of the patient and the physician in this process.

The evaluation of the procedures, protocols and measures to reduce risk is closely tied to risk management integration into the performance improvement program and oversight by the governing body. This Florida requirement is aligned with the Medicare Conditions for Coverage requirement that the governing body has oversight and accountability for the quality assessment and performance improvement program to ensure policies and programs are administered to provide quality healthcare in a safe environment.

## **PATIENT GRIEVANCES**

The analysis of patient grievances that relate to patient care and the quality of medical services is another component of the risk management program requirements.

The Medicare Conditions for Coverage contain significant requirements for a patient grievance program. It requires that the facility develop a time table to address grievances and a communication process. For example, if a patient complains about quality of care and the issue can be

addressed and resolved quickly, it may not be considered a grievance. If the complaint cannot be resolved with a quick or immediate response, the complaint escalates into a grievance that now requires time frames for each step. The first step is clarifying the grievance. Per regulation, the patient cannot be required to put it in writing. If the patient refuses a request to document the grievance, the staff should write the information down and ask the patient to confirm. The second step would be investigating, follow up and setting a deadline, (e.g. 10 days), for an action plan to communicate findings to the patient. Your facility policy may include another round of investigation and communication if the initial findings and action plan are not satisfactory to the patient.

Surgical centers may elect to keep a grievance notebook that contains the grievance policy and related forms, as well as any grievances filed and processed, to show to surveyors and inspectors the system and its implementation.

The state inspectors may also review how patient satisfaction in general is measured, how complaints written on patient satisfaction surveys are investigated and if a corrective action plan is developed and is implemented.

## **INFORMING A PATIENT OF AN ADVERSE INCIDENT**

Another component of a risk management program is a system for informing a patient or an individual pursuant to s. 765.401 (1) Florida Statutes (FS) that the patient was the subject of an adverse incident, as defined in s. 395.0197 (5) FS. This notice shall be given by an appropriately trained person, designated by the facility, as soon as feasible to minimize damage or injury. The organization must designate an appropriately trained person as responsible for coordinating disclosure communication. The patient, parents of a minor and/or significant others or designated healthcare surrogate must be advised if the patient should experience an adverse event that resulted in serious harm to the patient. The patient or other designee shall receive information as soon as possible in order that he or she may understand what is happening in his or her treatment, why any changes have taken place in that plan, what to be aware of in the form of reactions or consequences, and what actions the patient can consider in order to minimize the injury. Note: There is also a requirement under s. 456.0575 FS for all licensed health care practitioners to notify patients about adverse incidents that result in serious harm to the patient.

There should be documentation that the patient was informed of the incident. Regulation does not require that

this documentation occur in the medical record. It can be recorded on the incident investigation form or another document that has restricted access.

### **INCIDENT REPORTING SYSTEM**

The development and implementation of an incident reporting system must be in place and include procedures detailed in writing and disseminated to all employees. It is the affirmative duty of all health care providers and all agents and employees of the licensed ASC to report adverse incidents to the risk manager, or to his or her designee, within three business days after their occurrence.

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.

This is another example of how risk management activities become part of the quality improvement activities. An inspector or surveyor may ask to see how trends or frequency of events have resulted in actions such as education of staff, clarification or addition of policies, monitoring changes in process to see if the planned corrective action worked, and additional actions taken to monitor and change protocols and practices.

### **GOVERNING BODY RESPONSIBILITY**

The governing body is responsible for the internal risk management program.

A Florida licensed ambulatory surgical center must have a health care risk manager to provide oversight and implementation of the internal risk management program. The health care risk manager must have documented education or experience as specified in F.S. 395.0197.

The health care risk manager can be an employee or can be a consultant retained by the ambulatory surgical center. The ambulatory surgical center will also have a risk manager designee to act in the absence of the health care risk manager. Whether the health care risk manager is an employee or contracted, the health care risk manager should work with the Center's administration to determine which duties may be assigned to the risk manager designee. In order for the designee to review incident reports, he/she must be determined to be competent in risk management techniques. A risk manager designee competency check list sample is located in the Appendices. The duties assigned to the risk manager designee are performed under the supervision of the health care risk manager. All risk

management duties and functions remain the responsibility of the health care risk manager and the health care risk manager shall maintain responsibility for the oversight and implementation of the internal risk management program.

The ambulatory surgical center's governing body must appoint the health care risk manager and the risk manager designee. This appointment must be documented in writing. Surveyors and inspectors will want to see documentation of these appointments. Documentation should occur in governing body minutes and a job descriptions signed and dated by the health care risk manager and the risk manager designee.

The governing body is to receive a quarterly report on the facility's risk management activities from the health care risk manager. This report should be included or attached to governing body minutes. Include discussion of any action taken by the governing body on the quarterly reports. For surgical centers that have a governing body meeting less than once a quarter, document the review of the risk management report by the governing body by having the chair initial and date the report.

### **APPROACHES TO REDUCE FREQUENCY AND SEVERITY OF MEDICAL MALPRACTICE AND PATIENT INJURY CLAIMS**

Each licensed facility shall annually report to the Agency for Health Care Administration and the Department of Health the name and judgments entered against each health care practitioner for which it assumes liability. The risk management activities may include extending internal risk management programs to providers' offices.

### **FLORIDA STATUTES GOVERNING THE ESTABLISHMENT OF INTERNAL RISK MANAGEMENT PROGRAM**

The program must use an incident report. 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. Incident reports must be filed with the individual of responsibility who is employed or retained and competent in risk management techniques.

The facility may have an incident report that is separate from the investigation, findings, action plan, and outcome of the incident.

## ADVERSE INCIDENT DEFINED

An 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 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. 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. the need to perform 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. a procedure performed to remove unplanned foreign objects remaining from a surgical procedure.

The ambulatory surgical center may include other items for their internal reporting program. Near misses, staff noted opportunities for improvement, system problems that could negatively impact patient care, audits of compliance to nationally recognized standards and other events may be part of the risk management program and/or part of the quality assurance and performance improvement program. The surgical center may elect to have the same or different reporting systems that bring attention to the potential for adverse outcomes or events. Only those adverse events

that must be reported to the state would be reported, but other events or indicators may be reported internally to provide options for quality improvement activities and risk reduction.

## STATE REPORTING REQUIREMENTS

### ANNUAL REPORTS

Incidents, as previously defined, that have been filed in the facility between January 1 and December 31 must be summarized and submitted to the Agency for Health Care Administration by April 1 of the following year.

### "CODE 15" REPORTS

A "Code 15" Report must be filed with the agency within 15 calendar days of the occurrence of any of the following adverse incidents: (a) Death; (b) Brain or spinal damage; (c) the performance of a surgical procedure on the wrong patient; (d) a wrong-site surgical procedure; (e) a wrong surgical procedure; (f) 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 was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or (h) the procedure to remove unplanned foreign objects remaining from a surgical procedure.

The reporting mechanism and instructions for completion are available on the AHCA at <http://ahca.myflorida.com/SCHS/RiskMgtPubSafety/RiskManagement.shtml>.

### OTHER REPORTING

Each licensed facility shall annually report to the Agency for Health Care Administration and the Department of Health the name and judgments entered against each health care practitioner for which it assumes liability. Per ss 458.337 FS and 459.016 FS, any disciplinary action taken shall be reported to the Department of Health within 30 working days after its initial occurrence, regardless of whether the physician is appealing the disciplinary action or not. The notification shall identify the disciplined physician, the action taken, and the reason for such action.

Florida Statute 395.0191, which addresses medical staff appointments and privileging, also requires in s. 395.0191 (6) FS that the denial of staff membership or clinical privileges to any applicant be reported in writing to the applicant's respective licensing board.



## SEXUAL ABUSE

The internal risk manager must investigate an 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 to a patient at the facility or on the grounds of the facility. Any person who witnessed or who possesses actual knowledge of the act that is the basis of an allegation of sexual abuse shall notify the local police, the risk manager, and the administrator.

The internal risk manager must report every allegation of sexual misconduct to the administrator; if the victim is a minor, notify the family or guardian that an allegation of sexual misconduct has been made, and that an investigation is being conducted. Sexual misconduct is defined in F.S. 456.063 and respective practice acts. The allegation of sexual misconduct by a licensed health care professional that involves a patient must be reported to the Department of Health.

“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) FS, fondling, exposure of a vulnerable adult's or minor's sexual organs, or the use of the vulnerable adult or minor to solicit or engage in prostitution or sexual performance. “Sexual abuse” does not include any act intended for a valid medical purpose or any act which may reasonably be construed to be a normal care-giving action.

**Other forms of abuse:** Health care professionals or personnel who know or have a reasonable cause to suspect that an aged person, disabled adult, or child is an abused, neglected, or exploited person shall immediately report such knowledge or suspicion to the central abuse registry and tracking system on the single statewide toll-free telephone number of 1-800-962-2873. A follow-up written report confirming the initial report must be submitted within 48 hours to the local State office. Regulations about reporting and about an online reporting system can be located at <http://www.dcf.state.fl.us/service-programs/abuse-hotline/report-online.shtml>.

## PATIENT SAFETY OFFICER AND A PATIENT SAFETY COMMITTEE

Each facility must have a patient safety officer and a patient safety committee. At least one member of the committee must be a person who is neither employed by nor practicing

in the facility. There must be a patient safety plan, similar to what Medicare requires in 42 CFR 416.43. See the appendices for s 395.1012 FS.

The plan of Quality Assurance and Performance Improvement as outlined in the 42 CFR 416.43, which is part of the Medicare Conditions for Coverage for ambulatory surgical centers, requires in part that the ASC conduct an ongoing, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of care.

The purpose of the patient safety committee is to: (1) promote the health and safety of patients; (2) review and evaluate the quality of patient safety measures used by the facility; and (3) to assist in the implementation of the facility safety plan.

While the state requires a patient safety officer and committee, Medicare does not. However, the goal of integrating patient safety, risk management, infection control, quality assurance, and performance improvement are discussed in the state and Medicare surgical center regulations.

## CORRECT PATIENT, CORRECT PROCEDURE, CORRECT SITE PROCEDURES

The organization must develop, implement and have an ongoing evaluation of the procedures, protocols, and systems to accurately identify patients, planned procedures, and the correct site of the planned procedure, availability of correct implant in order to minimize the risk of wrong site/wrong implant/wrong procedures.

See the appendices to review Chapter 64B -8-9.007 FAC, Standards of Practice for Medical Doctors, regarding the physician's responsibility.

## REPORTING INCIDENTS TO THE RISK MANAGER

The State requires that an incident be reported to the healthcare risk manager or the risk manager designee within three business days after the occurrence.

## RECORD RETENTION

Risk management accumulated data summary reports must be retained for three years. Summary reports are often, but not always, the governing body reports. There are no requirements for the retention of other risk management records, but patient medical records must be retained for seven years. Therefore, retaining incident reports and the related investigation of the incidents for at least seven years should be considered.

## INCIDENT REPORT CONTENT

Per 59A-10.0055(2), the following items, at a minimum, must be on the incident report form:

Patient's name, locating information, admission diagnosis, admission date, age and sex;

A clear and concise description of the incident including time, date, exact location, and exact elements as needed for the annual report based on ICD-10-CM;

Whether or not a physician was called; and, if so, a brief statement of said physician's recommendations for medical treatments, if any;

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

The name, signature, and position of the person completing the reports and the time and date the report was completed.

## INVESTIGATION AND FOLLOW UP

The state requirement for the incident report content focuses on information about the incident. The incident report content requirement does not include investigation and action. Therefore, the facility can elect to have a separate form to record the investigation, findings, and action plan, if any.

For adverse events and near miss events (events might have resulted in injury, illness, or damage but did not because of intervention or luck), the organization may organize its investigation into a Root Cause Analysis (RCA). The RCA is a series of why questions that attempt to reveal gaps in processes, protocols and systems that led to the adverse event or the near miss.

The RCA may reveal many gaps, not just the one that led directly to an adverse event or near miss. Action should be taken to address the findings to improve steps, policies, education and training, checklists, and other tools that can reduce the risk of adverse events. There is presently no requirement that the surgery center submit its RCA to the Agency for Health Care Administration even if AHCA asks to receive it if a Code 15 has been filed.

Several resources to guide a Root Cause Analysis are available on the internet including:  
Agency for Healthcare Research and Quality, Patient Safety Network - <https://psnet.ahrq.gov/primers/primer/10/Root-Cause-Analysis>.

U.S. Department of Veterans Affairs, VA National Center for Patient Safety - <https://www.patientsafety.va.gov/professionals/onthejob/rca.asp>.

Institute for Healthcare Improvement, Resources, Tools (Note: registration for access is required, but there is no fee.) - <http://www.ihl.org/resources/Pages/Tools/RCA2-Improving-Root-Cause-Analysis-and-Actions-to-Prevent-Harm.aspx>.

*The first paragraph of the following guide, first published by AHCA, is critical to the decision of whether an incident meets or does not meet the definition of adverse. Was the incident something over which health care personnel could exercise control? Gathering of information, in some cases including peer review, will be necessary to make that determination. Note that there is not a time limit from the date of service to the patient to the date of an adverse incident. For example, a patient could die or be admitted for additional surgery weeks after an infection caused by improper sterilization of instruments or a retained foreign object. The health care personnel would have had control over instrument sterilization and over a process to assure a foreign object was not retained. It is important to note that if an adverse incident occurred prior to admission, the facility providing patient care due to the adverse incident is required to report the adverse incident. An example would be a hospital reporting a patient admitted from a surgery center due to brain or spinal damage.*

---

## Adverse Incident Reporting Guide

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 results in one of the following injuries:

### ANNUAL REPORT

- Death
- Brain or spinal damage
- Permanent disfigurement
- Fracture or dislocation of bones or joints
- A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility
- Any condition that required specialized medical attention or surgical intervention resulting from non-emergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent
- Any condition that 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
- The performance of a surgical procedure on the wrong patient
- The performance of a wrong surgical procedure
- The performance of a wrong-site surgical procedure
- The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient’s diagnosis or medical condition
- 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
- The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure

### CODE 15 REPORT

- Death
- Brain or spinal damage
- The performance of a surgical procedure on the wrong patient
- The performance of a wrong-site surgical procedure
- The performance of a wrong surgical procedure
- The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient’s diagnosis or medical condition
- 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
- The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure

Any of the above incidents, whether occurring in the licensed facility or arising from health care prior to admission in the licensed facility shall be reported to AHCA.

# Recommendations

If the risk manager is an employee, place the risk manager's job descriptions in the individual's employee file along with documentation of his/her qualifications by experience or education. If the risk manager is contracted, place the copy of the agreement for services in his/her file and obtain information about certification (CPHRM), education, or experience.

See Appendix C for FS 395.0197(2) for expected competence, through education or experience.

A risk manager designee may be appointed to assist the risk manager and/or to act in the absence of the risk manager. A job description for the risk manager designee and information on education, experience, or training should be placed in the designee's file.

Document appointment of risk manager and any risk manager designee in board minutes. Consider re-appointment annually which will make the board action easier to locate when there is a survey. A note in the file of the risk manager and any designee about the date of appointment by the governing body is also a method to document board appointment.

Review incident/occurrence report forms to ensure that all data fields required by the state are included on the form and are completed. Check that the risk manager or risk manager designee has received the incident/occurrence reports within three business days of the incident. If this is not occurring, review reasons and implement changes. This shall be documented by the risk manager or risk manager designee signing and dating the receipt of the report.

Document attendance of employees, including full-time, part-time, PRN staff, and allied health professionals at risk management education and training and keep in a file or notebook for review during an inspection. All employees including full-time, part-time, PRN, contract agency staff, and allied health professionals are to have risk management education and training. The facility should maintain a copy of the education and training program that is presented to staff to fulfill the regulatory requirements. Education and training should include at least (1) the operation and responsibilities of the incident reporting system; (2) timely and accurate reporting of incidents (HOW, WHAT, WHEN, WHY, WHERE); (3) the state definition of an adverse incident and reporting requirements; (4) staff duty

to report allegations of patient sexual misconduct/abuse; (5) two-person requirement in recovery room; (6) duty to notify patients of an adverse incident; (7) risk management and risk prevention education; (8) purpose and function of risk management and patient safety programs.

Track and trend all incident reports. Develop categories to identify problem areas. Tracking and trending can assist in highlighting frequency and severity of incidents. It can help call attention to opportunities to improve processes and reduce the chance of problems and injuries. Develop categories to identify problem areas. Track and trend all patient grievances and complaints. Perform an analysis of all patient complaints that relate to patient care and medical services.

Establish steps and time tables to investigate grievances, communicate findings to patients and staff, develop action plans, and evaluate effectiveness of changes in processes or systems.

To compare select performance measures, you may locate information on how others are performing on key performance measures through specialty groups, ASC groups, and national studies. Your Ambulatory Surgical Center Quality Reporting (ASCQR) report from the Quality Net website ([www.qualitynet.org](http://www.qualitynet.org)), which shows your performance compared to others, may pinpoint areas where your surgery center's performance could improve.

Risk management processes to reduce risk are similar to quality improvement processes to identify the problem, review alternatives or ways to overcome the problem, implement an action plan, and review to determine if the action plan worked. Risk management should be integrated into quality improvement activities. If there are any trends or patterns in categories of incidents or if an adverse event occurs, processes and procedures shall be adjusted to correct the problem areas. Once actions have occurred, monitor to determine if the desired result was achieved. This step integrates the risk management program with the quality assessment/performance improvement program. Recommendations and actions taken to correct problem areas should be communicated to the board and feedback from the board should be communicated to the risk manager.

- Risk management processes include:
- » Identify and analyze loss exposures.
  - » Consider alternative risk management techniques.
  - » Select the best risk management technique or combination of techniques.
  - » Implement the selected technique(s).
  - » Monitor and improve the risk management program.

At least quarterly, the risk manager shall provide a summary report to the center’s governing body which includes information about the activities of risk management.

Incident reports are discoverable. However, your investigation and analysis, when part of your quality improvement and peer review process, is protected. Consider how you record your investigation and analysis

and separate the investigation and analysis from the incident report which contains only the brief facts of what occurred.

Have the governing body chair initial and date the review of the risk management quarterly report. Or, if the governing body meets each quarter, note the review of the report in the governing body minutes and attach the report to governing body minutes.

Periodically audit performance.

Maintain a copy of current state and federal regulations and periodically review them and check for statutory and rule changes.

## Resources for Forms and Regulations

The Agency for Health Care Administration’s risk management regulations and forms can be found at <http://ahca.myflorida.com/SCHS>. Click on Risk Management and Patient Safety section to locate reporting mechanisms and instructions.

Statutes and rules related to risk management can be located at <http://ahca.myflorida.com/SCHS/RiskMgtPubSafety/RiskManagement.shtml>.

The Medicare Conditions for Coverage of ambulatory surgical centers is available through a link at the Florida Society of Ambulatory Surgical Centers at [www.fsasc.org](http://www.fsasc.org) or the Ambulatory Surgery Center Association at [www.ascassociation.org](http://www.ascassociation.org). Direct access to the Center for Medicare and Medicaid publication is located at [www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_1\\_ambulatory.pdf](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_1_ambulatory.pdf). The Medicare regulations are known as Appendix L.

## Appendices

<b>Appendix A:</b> Abbreviations and References.....	Page 12
<b>Appendix B:</b> Risk Manager and Risk Manager Designee Checklist.....	Page 13
<b>Appendix C:</b> F.S. 395.0197 Internal Risk Management Program.....	Page 14
<b>Appendix D:</b> F.S. 395.1012 Patient Safety.....	Page 19
<b>Appendix E:</b> Chapter 59A-5 Ambulatory Surgical Center Licensure.....	Page 20
<b>Appendix F:</b> Chapter 59A-10 Internal Risk Management Program.....	Page 37
<b>Appendix G:</b> Chapter 64B-8-9.007 Standards of Practice for Medical Doctors.....	Page 40
<b>Appendix H:</b> CFR 416.43 Condition for Coverage: Quality Assessment and Performance Improvement.....	Page 42

# Appendix A: Abbreviations and References

AHCA	Agency for Health Care Administration
AHRQ	Agency for Healthcare Research and Quality
ASHRAE	American Society of Heating, Refrigerating and Air-Conditioning Engineers
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CHAPTER	Refers to a chapter in the Florida Administrative Code. These are the regulations adopted by each agency of the state.
CMS	Centers for Medicare and Medicaid Services
CRNA	Certified Registered Nurse Anesthetist
FAC	The Florida Administrative Code contains all rules adopted by each agency of the state.
FS	Florida Statutes – “ a permanent collection of state laws organized by subject areas into a code made up of titles, chapters, parts, and sections. The Florida Statutes are updated annually by laws that create, amend, transfer or repeal statutory material.” Title XXIX, Public Health, contains Chapter 395, which contains the Hospital Licensing and Regulations. Part 1 is Hospitals and Other Licensed Facilities.
PA	Physician Assistant
QAPI	Quality Assessment Performance Improvement

# Appendix B: Risk Manager and Risk Manager Designee Checklist

Facility Name: \_\_\_\_\_

Name of Risk Manager or Risk Manager Designee: \_\_\_\_\_

Item	Risk Manager's Initials & Date	Risk Manager Designee's Initials & Date	Comments
Has a thorough understanding of Florida Statutes Chapter 395.0197 Internal Risk Management program.			
Is able to review incident reports and determine if event meets criteria for a Code 15 reporting.			
Able to gather information for Code 15 reports.			
Able to complete a Code 15 report as required by AHCA.			
Understands the facility's internal chain of command to receive incident reports, follow-up investigations and reporting to appropriate departments, committees and legal (if applicable).			
Can effectively communicate with patients and their representatives, facility staff, management, and medical staff relating to quality of care complaints and incident/claims investigation of the incident.			
Demonstrates ability to do a clinical review of a medical chart related to an incident and summarize findings needed to proceed with investigation of the incident.			
Can effectively present educational information with relation to risk management and incident reporting.			
Demonstrates ability to analyze risk management trending data and make recommendations for improvement in identified areas. Understands coordination with quality improvement activities.			
Demonstrates ability to facilitate an analysis related to adverse events.			
Preserves confidentiality of all information related to incidents, complaints, claims investigation, and other risk management responsibilities.			
Demonstrates ability to notify a patient or an individual identified that the patient was the subject of a serious adverse incident.			
Audits for compliance to Risk Management regulations.			
Provides organization with documentation of risk management certification or specialized education through attendance at risk management seminars, webinars, and meetings.			
Receives from Risk Manager education on state regulations, guidelines and other materials to improve understanding of risk manager designee's duties and responsibilities.			

# Appendix C: F.S. 395.0197 Internal Risk Management Program

## **395.0197 Internal risk management program.**

(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:

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

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

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

a. Such education and training of all nonphysician personnel as part of their initial orientation; and

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

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

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

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

4. Development, implementation, and ongoing evaluation of procedures, protocols, and systems to

accurately identify patients, planned procedures, and the correct site of the planned procedure so as to minimize the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition.

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

(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.

(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.

(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.

(3) 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. The agency and Department of Health, in their respective annual reports, shall include statistics that report the number of licensed facilities that assume such liability and the number of health care practitioners, by profession, for whom they assume liability.

(4) The agency shall adopt rules governing the establishment of internal risk management programs to meet the needs of individual licensed facilities. 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. 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.

(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;

(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.

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

1. The total number of adverse incidents.
2. A listing, by category, of the types of operations, diagnostic or treatment procedures, or other actions causing the injuries, and the number of incidents occurring within each category.
3. A listing, by category, of the types of injuries caused and the number of incidents occurring within each category.
4. A code number using the health care professional's licensure number and a separate code number identifying all other individuals directly involved in adverse incidents to patients, the relationship of the individual to the licensed facility, and the number of incidents in which each individual has been directly involved. Each licensed facility shall maintain names of the health care professionals and individuals identified by code numbers for purposes of this section.
5. A description of all malpractice claims filed against the licensed facility, including the total number of pending and closed claims and the nature of the incident which led to, the persons involved in, and the status and disposition of each claim. Each report shall update status and disposition for all prior reports.

(b) The information reported to the agency pursuant to paragraph (a) which relates to persons licensed under chapter 458, chapter 459, chapter 461, or chapter 466 shall be reviewed by the agency. The agency shall determine whether any of the incidents potentially involved conduct by a health care professional who is subject to disciplinary action, in which case the provisions of s. 456.073 shall apply.

(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.

(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 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.

(8) The agency shall publish on the agency's website, no less than quarterly, a summary and trend analysis of adverse incident reports received pursuant to this section, which shall not include information that would identify the patient, the reporting facility, or the health care practitioners involved. The agency shall publish on the agency's website an annual summary and trend analysis of all adverse incident reports and malpractice claims information provided by facilities in their annual reports, which shall not include information that would identify the patient, the reporting facility, or the practitioners involved. The purpose of the publication of the summary and trend analysis is to promote the rapid dissemination of information relating to adverse incidents and malpractice claims to assist in avoidance of similar incidents and reduce morbidity and mortality.

(9) The internal risk manager of each licensed facility shall:

- (a) Investigate every allegation of sexual misconduct which is made against a member of the facility's personnel who has direct patient contact, when the allegation is that the sexual misconduct occurred at the facility or on the grounds of the facility.
- (b) Report every allegation of sexual misconduct to the administrator of the licensed facility.

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

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

(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.

(11) A person who, with malice or with intent to discredit or harm a licensed facility or any person, makes a false allegation of sexual misconduct against a member of a licensed facility’s personnel is guilty of a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

(12) In addition to any penalty imposed pursuant to this section or part II of chapter 408, the agency shall require a written plan of correction from the facility. For a single incident or series of isolated incidents that are nonwillful violations of the reporting requirements of this section or part II of chapter 408, the agency shall first seek to obtain corrective action by the facility. If the correction is not demonstrated within the timeframe established by the agency or if there is a pattern of nonwillful violations of this section or part II of chapter 408, the agency may impose an administrative fine, not to exceed \$5,000 for any violation of the reporting requirements of this section or part II of chapter 408. The administrative fine for repeated nonwillful violations may not exceed \$10,000 for any violation. The administrative fine for each intentional and willful violation may not exceed \$25,000 per violation, per day. The fine for an intentional and willful violation of this section or part II of chapter 408 may not exceed \$250,000. In determining

the amount of fine to be levied, the agency shall be guided by s. 395.1065(2)(b).

(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.

(14) The meetings of the committees and governing board of a licensed facility held solely for the purpose of achieving the objectives of risk management as provided by this section shall not be open to the public under the provisions of chapter 286. The records of such meetings are confidential and exempt from s. 119.07(1), except as provided in subsection (13).

(15) The agency shall review, as part of its licensure inspection process, the internal risk management program at each licensed facility regulated by this section to determine whether the program meets standards established in statutes and rules, whether the program is being conducted in a manner designed to reduce adverse incidents, and whether the program is appropriately reporting incidents under this section.

(16) There shall be no monetary liability on the part of, and no cause of action for damages shall arise against, any risk manager, for the implementation and oversight of the internal risk management program in a facility licensed under this chapter or chapter 390 as required by this section, for any act or proceeding undertaken or performed within the scope of the functions of such internal risk management program if the risk manager acts without intentional fraud.

(17) A privilege against civil liability is hereby granted to any risk manager or licensed facility with regard to information furnished pursuant to this chapter, unless the risk manager or facility acted in bad faith or with malice in providing such information.

(18) If the agency, through its receipt of any reports required under this section or through any investigation, has a reasonable belief that conduct by a staff member or employee of a licensed facility is grounds for disciplinary action by the appropriate regulatory board, the agency shall report this fact to such regulatory board.

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

*History.—s. 3, ch. 75-9; s. 3, ch. 76-168; s. 2, ch. 76-260; s. 1, ch. 77-64; s. 1, ch. 77-457; s. 286, ch. 79-400; s. 3, ch. 81-318; ss. 9, 52, ch. 85-175; s. 2, ch. 86-287; s. 6, ch. 88-1; s. 3, ch. 88-97; s. 3, ch. 88-277; s. 14, ch. 89-527; s. 16, ch. 90-344; s. 23, ch. 92-33; ss. 15, 16, 98, ch. 92-289; s. 1, ch. 95-319; s. 214, ch. 96-406; s. 25, ch. 98-89; s. 22, ch. 98-166; s. 14, ch. 2000-160; s. 63, ch. 2001-277; s. 4, ch. 2003-416; s. 44, ch. 2007-230; s. 30, ch. 2018-24.*

*Note.—Former ss. 395.18, 768.41; s. 395.041.*

# Appendix D: F.S. 395.1012 Patient Safety

## **395.1012 Patient safety.**

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

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

*History.—s. 6, ch. 2003-416; s.43, ch.2016-10.*

**Note: 42 C.F.R. part 482.21 is for hospitals. The 42 C.F.R. part 416.43 for surgery centers is equivalent.**

**See Appendix H for 42 C.F.R. 416.43 section on Quality Assessment Performance Improvement, which includes integration of risk management and adverse events.**

# Appendix E: Chapter 59A-5 Ambulatory Surgical Center Licensure

59A-5.002	Definitions
59A-5.003	Licensure Procedure
59A-5.004	Validation, Licensure, & Life Safety
Inspections and	Complaint Investigations
59A-5.005	Governing Board
59A-5.0065	Patient Rights
59A-5.007	Organized Medical Staff
59A-5.0085	Departments and Services
59A-5.011	Surveillance, Prevention, and Control of Infection
59A-5.012	Medical Records
59A-5.016	Physical Plant Maintenance
59A-5.017	Fire Control
59A-5.018	Comprehensive Emergency Management Plan
59A-5.019	Quality Assessment and Improvement
59A-5.021	Plans Submission and Fee Requirements
59A-5.022	Physical Plant Requirements for Ambulatory Surgical Centers

## 59A-5.002 Definitions.

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 Chapter 458 or 459, F.S., and who has completed an approved residency in the field of anesthesiology.

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

(5) “Center” means an ambulatory surgical center.

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

(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 Chapter 458 or 459, F.S.

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

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

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

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

*Rulemaking Authority 395.1055 FS. Law Implemented 395.1055 FS. History—New 6-14-78, Formerly 10D-30.02, Amended 2-3-88, 5-5-92, Formerly 10D-30.002, Amended 11-13-95, 9-17-14.*

### 59A-5.003 Licensure Procedure.

(1) In addition to the licensure requirements contained in Chapters 395, Part I and 408, Part II, F.S., all centers shall comply with the following:

(2) All persons requesting licensure for the operation of a center under the provisions of Chapter 395, F.S., shall make application to the Agency on Health Care Licensing Application, Ambulatory Surgical Centers, AHCA Form 3130-2001 July 2014, which is incorporated by reference. The form is available at: <http://www.flrules.org/Gateway/reference.asp?No=Ref-04452> and available from the Agency for Health Care Administration, 2727 Mahan Drive, Mail Stop 31, Tallahassee, Florida 32308, or at the web address at: <http://ahca.myflorida.com/HQAlicensureforms>. The center must obtain a standard license prior to the acceptance of patients for care or treatment.

(3) Each center applying for a license shall be designated by a distinctive name, and the name shall not be changed without first notifying the Agency and receiving approval in writing. Duplication of an existing center's name is prohibited.

(4) In addition to the requirements found in Chapter 408, Part II, F.S., the following documents shall accompany the initial application:

(a) Proof of fictitious name registration if applicable;

(b) Articles of Incorporation or similarly titled document registered by the applicant with the Florida Department of State; and

(c) The center's Zoning Certificate or proof of compliance with zoning requirements.

(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.

(6) In addition to the requirements found in Chapter

408, Part II, F.S., all applications for a change of ownership shall include;

(a) A signed agreement with the Agency to correct physical plant deficiencies listed in the most recent licensure inspection that conforms to Florida Building Code;

(b) A copy of the closing documents, which must include an effective date and the signatures of both the buyer and the seller;

(c) Articles of Incorporation or similarly titled document registered by the applicant with the Florida Department of State;

(d) Proof of fictitious name registration if applicable;

(e) Evidence of payment of, or arrangement to pay, any liability to the state pursuant to Section 395.003(3), F.S.

(7) A license fee of \$1,679.82 for the operation of a center as established by Chapter 395, F.S., shall accompany an application for an initial, renewal or change of ownership license. The license fee shall be made payable to the Agency for Health Care Administration. No license shall be issued without payment of the requisite fee.

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

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

(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.

(12) Upon receipt of the required information in subsections (1) through (4) above, the Agency shall conduct a licensure inspection to determine compliance with Chapter 395, Part I, F.S., and Rules 59A-5.002 through 59A-5.022, F.A.C.

(13) When a center is in compliance with Chapters 395, Part I and 408, Part II, F.S., and Rules 59A-5.002 through 59A-5.022, F.A.C., and has received all approvals required by law, the Agency shall issue, a single license which identifies the licensee and the name and location of the center.

(14) Separate licenses shall not be required for separate buildings on the same grounds when used by the same center.

(15) A license issued to a center shall be revoked or denied by the Agency in any case where the Agency finds there has been substantial failure to comply with provisions of Chapter 395, Part I, F.S., or Chapter 59A-5, F.A.C.

(16) 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.

*Rulemaking Authority 395.1055, 408.819 FS. Law Implemented 395.003, 395.004, 395.0161, 395.1055, 408.806, 408.809, 408.811 FS. History—New 6-14-78, Formerly 10D-30.03, Amended 2-3-88, Formerly 10D-30.003, Amended 11-13-95, 9-17-14.*

### **59A-5.004 Validation, Licensure, & Life Safety Inspections and Complaint Investigations.**

(1) Inspections. The Agency shall conduct periodic inspections of ambulatory surgical centers in order to ensure compliance with all licensure requirements in accordance with Section 395.0161, F.S.

(2) Non-accredited ambulatory surgical centers. Centers which are not accredited by an accrediting organization shall be subject to a scheduled licensure inspection. The fee for conducting a licensure inspection shall be \$400.00.

(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.

(a) Upon receipt of the accrediting organization's report, the Agency will review the findings to determine if the center is in compliance with state licensure requirements.

(b) The Agency shall notify the center within 60 days of the receipt of the accrediting organization's report regarding the Agency's determination of the center's compliance or non-compliance with state licensure requirements.

(c) Accredited centers shall be subject to a licensure inspection under the following circumstances:

1. The center has been denied accreditation or has received a provisional or conditional accreditation from an accrediting organization on its most recent

accreditation report, and has not submitted an acceptable plan of correction to the accrediting organization.

2. The center has received full accreditation, but has not authorized the release of the report to the Agency or has not ensured that the Agency received the accrediting organization's report prior to the Agency's scheduled inspection.

(d) The fee for a licensure inspection shall be \$400.00 for any accredited center subject to inspection pursuant to paragraph (c).

(4) Life safety inspection fee. A separate fee of \$40.00 shall be assessed for a life-safety inspection, except when conducted as part of a licensure or a Centers for Medicare and Medicaid Services certification inspection.

(5) Validation inspection. Each year, the Agency shall conduct validation inspections on a minimum of five percent of those centers that have undergone an accreditation inspection from an accrediting organization, to determine ongoing compliance with state licensure requirements.

(a) Upon completion of a validation inspection, the Agency will send a copy of its findings to the center. For those centers determined not to be in compliance with state licensure requirements the notification will include a statement of deficiencies.

(b) If the Agency determines, based on the results of validation inspection findings, that an accredited center is not in compliance with licensure requirements, the Agency shall report its findings to the accrediting organization and shall conduct a full licensure inspection on that center during the following year.

(c) The fee for conducting a licensure validation inspection shall be \$400.00. A separate fee for a validation inspection will not be assessed when conducted in conjunction with a Centers for Medicare and Medicaid Services certification inspection.

(6) Complaint investigations. The Agency shall conduct investigations of complaints regarding violations of licensure, and life-safety standards in accordance with Sections 395.0161 and 408.811, F.S. Complaint investigations will be unannounced. An entrance conference shall be conducted upon arrival, by Agency personnel investigating the complaint, to inform the center's administrator about the nature of the complaint investigation and to answer questions from the center's staff. An exit conference shall be provided at the conclusion of the onsite investigation to inform the center of the scope of the



investigation and to receive any additional information that the center wishes to furnish.

(a) Upon receipt of a complaint, the Agency shall review the complaint for allegations of non-compliance with licensure requirements, and shall take the following actions:

1. Complaints involving any center shall be reviewed and sent to the appropriate Agency local office for investigation, if it is determined that the allegations could constitute a violation of state licensure or federal certification;
2. If allegations are more appropriately addressed by another state agency or entity, the complaint will be referred accordingly.

(b) Upon a determination that investigation of a complaint is warranted, the Agency shall conduct an investigation.

(7) Conformance with accreditation standards. In all centers where the Agency does not conduct a licensure inspection, by reason of the center's accreditation status, the center shall continue to conform to the standards of accreditation throughout the term of accreditation, or shall notify the Agency of the areas of non-conformance. Where the Agency is notified of non-conformance, it shall take appropriate action as specified under subsection (3).

(8) Sanctions. The Agency shall impose penalties pursuant to Section 395.1065, F.S., on those centers which fail to submit an acceptable plan of correction or implement actions to correct deficiencies identified by the Agency or an accrediting organization which are specified in an approved plan of correction or as identified as a result of a complaint investigation.

*Rulemaking Authority 395.1055, 395.0161, 48.819 FS. Law Implemented 395.003, 395.0161, 395.1065, 408.811 FS. History—New 6-14-78, Formerly 10D-30.04, 10D-30.004, Amended 11-13-95, 9-17-14, 3-19-17.*

### **59A-5.005 Governing Board.**

(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.

(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.

(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.

*Rulemaking Authority 395.1055 FS. Law Implemented 393.0191, 395.1055 FS. History—New 6-14-78, Amended 3-3-80, Formerly 10D-30.05, 10D-30.005, Amended 11-13-95, 9-17-14.*

### **59A-5.0065 Patient Rights.**

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.

*Rulemaking Authority 395.1055 FS. Law Implemented 395.301, 395.1055, 395.3025 FS. History—New 11-13-95, Amended 2-23-16.*

### **59A-5.007 Organized Medical Staff.**

(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.

(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 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.

*Rulemaking Authority 395.1055 FS. Law Implemented 395.0191, 395.0193, 395.1055 FS. History—New 6-14-78, Formerly 10D-30.07, Amended 2-3-88, Formerly 10D-30.007, Amended 11-13-95, 2-23-16.*

### **59A-5.0085 Departments and Services.**

(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.

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

(b) 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.

(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.

(e) 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.

(f) 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.

(2) 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.

(a) 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.

(b) 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.

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

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

(e) 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.

(f) 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 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.

(3) 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.

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

(b) 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.

(c) 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.

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

(e) 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.

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

(g) 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.

(4) 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.

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

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

(b) New installations of radiological equipment, and subsequent inspections for the identification of radiation hazards shall be made as required by in Chapter 64E-5, F.A.C.

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

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.
2. A technologist shall be on duty or on call at all times when there are patients within the center.
3. The use of all radiological apparatus shall be limited to appropriately licensed personnel; and use of fluoroscopes shall be limited to appropriately licensed, credentialed and privileged personnel.

(d) 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.

(6) 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.

*Rulemaking Authority 395.1055 FS. Law Implemented 395.009, 395.1055, 395.1011 FS. History—New 12-12-96, Amended 9-28-14.*

### **59A-5.011 Surveillance, Prevention, and Control of Infection.**

(1) 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.

(2) 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.

(3) 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.

(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;

(4) The individuals involved in the infection control program shall meet at least quarterly, shall maintain written minutes of all meetings, and shall make a report at least annually to the quality assurance committee and the governing board.

(5) 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.

*Rulemaking Authority 395.1055 FS. Law Implemented 395.1055 FS. History—New 6-14-78, Formerly 10D-30.11, Amended 2-3-88, Formerly 10D-30.011, Amended 11-13-95, 2-23-16.*

### **59A-5.012 Medical Records.**

(1) 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;

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

(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.

(5) 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;
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.

*Rulemaking Authority 395.1055 FS. Law Implemented 395.1055, 395.3025 FS. History—New 6-14-78, Formerly 10D-30.12, 10D-30.012, Amended 11-13-95, 9-17-14.*

### **59A-5.016 Physical Plant Maintenance.**

(1) 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.

(2) All mechanical and electrical equipment shall be

maintained in working order, and shall be accessible for cleaning and inspection.

*Rulemaking Authority 395.1055 FS. Law Implemented 395.001, 395.1055 FS. History—New 6-14-78, Formerly 10D-30.16, 10D-30.016, Amended 11-13-95.*

### **59A-5.017 Fire Control.**

(1) Each ambulatory surgical center shall provide fire protection through the elimination of fire hazards; the installation of necessary safeguards such as extinguishers, sprinkling devices, and fire and smoke barriers as described in Rule 59A-5.022, F.A.C., to insure rapid and effective fire control; and the adoption of written fire control plans rehearsed four (4) times a year by all personnel. To safeguard patients, the ambulatory surgical center shall have:

(a) Written evidence of regular inspection by local fire control agencies.

(b) Stairwells kept closed by fire doors equipped with self-closing devices.

(c) Annual check of fire extinguishers for type, replacement, and renewal dates.

(d) "No Smoking" signs prominently displayed in those areas where smoking is not permitted.

(e) Fire regulations and evacuation route prominently posted for each floor and department.

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

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

*Rulemaking Authority 395.1055 FS. Law Implemented 395.001, 395.1055 FS. History—New 6-14-78, Formerly 10D-30.17, Amended 2-3-88, Formerly 10D-30.017, Amended 11-13-95.*

### **59A-5.018 Comprehensive Emergency Management Plan.**

(1) 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 at:

[http://ahca.myflorida.com/MCHQ/Health\\_Facility\\_Regulation/Hospital\\_Outpatient/forms/ASC\\_CEMP\\_Reconstructed\\_122104.pdf](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;
- (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.

(4) 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.

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

(6) If a center evacuates during or after an emergency, the center shall not be reoccupied until a determination is made by the center’s administrator that the center can meet the needs of the patients. A center with significant structural

damage shall not be reoccupied until approval is received from the Agency's Office of Plans and Construction that the center can be safely occupied as required by the Florida Building Code.

(7) A center that must evacuate the premises due to a disaster or an emergency condition, shall report the evacuation to the Agency's local area health facility regulation office within 24 hours or as soon as practical. The names and destination of patients relocated shall be provided to the county emergency management agency or its designee having responsibility for tracking the population at large. The licensee shall inform the Agency's local area office of a contact person who will be available 24 hours a day, seven days a week, until the center is reoccupied.

*Rulemaking Authority 395.1055 FS. Law Implemented 395.1055 FS. History—New 6-14-78, Formerly 10D-30.18, 10D-30.018, Amended 12-28-94, 9-17-14.*

### **59A-5.019 Quality Assessment and Improvement.**

(1) 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.

(2) 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.

(3) 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.
- (4) Each center shall have a process to incorporate quality assessment and improvement activities in existing ambulatory surgical center processes and procedures.

*Rulemaking Authority 395.1055 FS. Law Implemented 395.1055 FS. History—New 11-13-95, Amended 2-23-16.*

### **59A-5.021 Plans Submission and Fee Requirements.**

(1) No construction work, including demolition, shall be started until prior written approval has been given by the Office of Plans and Construction. This includes all construction of new facilities and any and all additions, modifications, renovations, or refurbishment of the site, building, equipment or systems of all existing facilities. Approval to start construction will be granted by the Agency when the design complies with all applicable codes and standards as evidenced by a thorough examination of the documents submitted to the Agency as required for Stage III construction documents.

- (2) Approval to start construction limited to



demolition, site work, foundation, and building structural frame may be obtained prior to the approval of Stage III construction documents when the following is submitted for review and approval:

(a) A Preliminary Stage II approval letter from the Office of Plans and Construction granted by the Agency when the design complies with applicable life safety code requirements, flood requirements and the layout will accommodate all required functional spaces as evidenced by a thorough examination of the documents submitted to the Agency as required in this rule for Stage II preliminary plans.

(b) Construction documents, specifications and construction details for all work to be undertaken.

(c) A letter from the facility holding the agency harmless for any changes that may occur to the project as a result of the final construction document review.

(d) An infection control risk assessment (ICRA) and a life safety plan indicating temporary egress and detailed phasing plans indicating how the area(s) to be demolished or constructed is to be separated from all occupied areas shall be submitted when demolition or construction in and around occupied buildings is to be undertaken. Submissions that fail to provide an ICRA or depict the safety measures prescribed by the ICRA will not be approved.

(3) Construction must commence within 12 months of receiving approval from the Office of Plans and Construction to begin construction. Once construction begins construction activities should be continuous until the completion of the project. Failure to commence construction within 12 months of plan approval or periods of construction inactivity exceeding 12 months following commencement of construction will result in termination of the project. Restarting a terminated project will require resubmission of the construction documents accompanied by a new plan review application and will be subject to all fees prescribed by Section 395.0163, F.S. Projects which have not received approval to begin construction will be considered abandoned following 12 months of inactivity and the project will be terminated.

(4) When construction is planned, either for new buildings or additions, alterations or renovations to existing buildings, the plans and specifications shall be prepared and submitted to the Office of Plans and Construction for approval by the appropriate Florida-registered design professionals as required by the Florida Building Code, Chapters 471, and 481, F.S. All architecture or engineering firms not practicing as a sole proprietor shall also be registered as an architecture or engineering firm with

the Florida Department of Business and Professional Regulation.

(5) The initial submission of plans to the Office of Plans and Construction for any new project shall include a completed Application for Plan Review, AHCA Form 3500-0011, June 2014, incorporated by reference and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-05456>, and a valid Certificate of Need if required by the agency. This information shall accompany the initial submission. Projects requiring a Certificate of Need will not be approved to begin construction without a valid Certificate of Need. Applications for Plan Review are available from the Agency for Health Care Administration, Office of Plans and Construction, 2727 Mahan Drive, Mail Stop #24, Tallahassee, Florida 32308, or at the web address at: <http://ahca.myflorida.com/MCHQ/HQALicensureForms/index.shtml>

(6) Plans and specifications submitted for review shall be subject to plan review fees prescribed by Section 395.0163, F.S. All fees shall be payable to the Agency for Health Care Administration and shall annotate the Office of Plans and Construction and the facility log number. Fees are not refundable.

(7) Plans and specifications may be submitted for review at any of the three stages of development described in this rule.

(8) For each stage of submission, a program or scope of work shall be submitted. It shall consist of a detailed written description of all contemplated work and any required phasing and shall identify the types of medical services to be provided.

(9) For projects involving only equipment changes or system renovations, only Stage III, construction documents will be accepted. These documents shall include the following:

(a) Life safety plans showing the fire/smoke compartments in the area of renovation.

(b) Detailed phasing plans indicating how the new work will be separated from all occupied areas.

(c) Engineering plans and specifications for all of the required work.

(10) Stage I, Schematic Plans.

(a) The following shall be incorporated into the schematic plans:

1. Single-line drawings of each floor that indicates the relationship of the various activities or services to each other and the room arrangement in each.

2. The function of each room or space shall be noted in or near the room or space.
3. The proposed roads and walkways, service and entrance courts, parking, and orientation shown on either a small plot plan or on the first floor plan.
4. A simple cross-section diagram showing the anticipated construction.
5. A schematic life safety plan showing smoke and fire compartments, exits, exit passageways and gross areas of required smoke and fire compartments.
6. Indicate which areas are sprinklered, both new and existing.

(b) If the proposed construction is an addition or is otherwise related to existing buildings on the site, the schematic plans shall show the facilities and general arrangement of those buildings.

(c) If the project involves increasing, decreasing, relocating or transferring licensed beds, a schedule showing the total number of beds, types of bedrooms and types of ancillary spaces must be provided.

(11) Stage II, Preliminary Plans.

The following shall be incorporated into the preliminary plans.

(a) A Vicinity Map. For new ambulatory surgery center construction, provide a vicinity map showing the major local highway intersections.

(b) Site Development Plans.

(c) Plans depicting existing grades and proposed improvements.

(d) Building location dimensions.

(e) Location of the fire protection services water source to the building.

(f) Architectural Plans.

1. Floor plans, 1/8-inch scale minimum, showing door swings, windows, case work and mill work, fixed equipment and plumbing fixtures. Indicate the function of each space.
2. Typical large-scale interior and exterior wall sections to include typical rated fire and fire/smoke partitions and a typical corridor partition.
3. All exterior building elevations.

(g) Equipment which is not included in the construction contract that requires mechanical or electrical service connections or construction modifications shall be identified to assure coordination with the architectural, mechanical and electrical phases of construction.

(h) If the project is located in an occupied facility, preliminary phasing plans indicating how the project is to be separated from all occupied areas.

(i) Life Safety Plans.

1. Life safety plans must include the following:

a. Single-sheet floor plans depicting required fire and smoke compartmentation, all means of egress and all exit signs. If smoke compartmentation is required, depict and provide the dimension for the longest path of travel in each smoke compartment to the door(s) accessing the nearest adjoining smoke compartment, calculate the total area of the smoke compartment in square feet, and tabulate exit inches.

b. All sprinklered areas.

c. All fire extinguishers.

d. All fire alarm devices and pull station locations.

1. If the project is an addition, or conversion of an existing building, fully developed life safety plans must be submitted.
2. If the project is a renovation in an existing building, life safety plans of the floor being renovated and the required exit egress floor(s) must be submitted.
3. When demolition or construction in and around occupied buildings will be undertaken, a life safety plan indicating temporary egress, and detailed phasing plans indicating how the area(s) to be demolished or constructed will be separated from all occupied areas must be submitted.

(j) Mechanical Engineering Plans.

1. Single-sheet floor plans with a one-line diagram of the ventilating system with relative pressures of each space. Provide a written description and drawings of the anticipated smoke control system, passive or active, and a sequence of operation correlated with the life safety plans.
2. The general location of all fire and smoke dampers, all duct smoke detectors and fire stats.
3. If the building is equipped with fire sprinklers, indicate the location of the sprinkler system risers and the point of connection for the fire sprinkler system. State the method of design for the existing and new fire sprinkler systems.
4. The locations of all plumbing fixtures and other items of equipment requiring plumbing services and/or gas services.
5. The locations of any fume, radiological or chemical hoods.

6. The locations of all medical gas outlets, piping distribution risers, terminals, alarm panel(s), low pressure emergency oxygen connection, isolation/zone valve(s), and gas source location(s).
7. The locations and relative size of major items of mechanical equipment such as chillers, air handling units, fire pumps, medical gas storage, boilers, vacuum pumps, air compressors and fuel storage vessels.
8. The locations of hazardous areas and the volume of products to be contained therein.
9. The location of fire pump, stand pipes, and sprinkler riser(s).

(k) Electrical Engineering Drawings.

1. A one-line diagram of normal and essential electrical power systems showing service transformers and entrances, switchboards, transfer switches, distribution feeders and over-current devices, panel boards and step-down transformers. The diagram shall include a preliminary listing and description of new and existing, normal and emergency loads, preliminary estimates of available short-circuit current at all new equipment and existing equipment serving any new equipment, short-circuit and withstand ratings of existing equipment serving new loads and any new or revised grounding requirements.
2. Show fire alarm zones and correlate with the life safety plan.

(l) Outline Specifications. Outline specifications must include a general description of the construction, including construction classification and ratings of components, interior finishes, general types and locations of acoustical material, floor coverings, ventilating equipment, plumbing fixtures, fire protection equipment, medical gas equipment and electrical equipment.

(m) Whenever an existing building is to be converted to a health care facility, the general layout of spaces of the existing structure shall be submitted with the preliminary plans for the proposed facility.

(n) Whenever an addition, alteration, renovation or remodeling to an existing facility is proposed, the general layout of spaces of the existing facility shall be submitted with the preliminary plans.

(12) Stage III, Construction Documents.

The Stage III, construction documents shall be an extension of the Stage II, preliminary plan submission and shall provide a complete description of the contemplated

construction. Construction documents shall be signed, sealed and dated and submitted for written approval to the Office of Plans and Construction by a Florida-registered architect and Florida-registered professional engineer. These documents shall consist of work related to civil, structural, mechanical, and electrical engineering, fire protection, lightning protection, landscape architecture and all architectural work. In addition to the requirements for Stage II submission, the following shall be incorporated into the construction documents:

(a) Site and civil engineering plans indicating building and site elevations, site utilities, paving plans, grading and drainage plans and details, locations of the two fire hydrants utilized to perform the water supply flow test, and landscaping plans.

(b) Life safety plans for the entire project. Projects located on floors above or below the exit discharge level must also include life safety plans for the exit discharge serving the project area.

(c) Architectural Plans.

1. Typical large-scale details of all typical interior and exterior walls and smoke walls, horizontal exits and exit passageways.
2. Comprehensive ceiling plans that show all utilities, lighting fixtures, smoke detectors, ventilation devices, sprinkler head locations and fire-rated ceiling suspension member locations where applicable.
3. Floor/ceiling and roof/ceiling assembly descriptions for all conditions.
4. Details and other instructions to the contractor on the construction documents describing the techniques to be used to seal floor construction penetrations necessary to prevent smoke migration from floor to floor during a fire.

(d) Structural engineering plans, schedules and details.

(e) Mechanical engineering plans including fire and smoke control plans. Include all equipment that requires mechanical utilities. Provide a clear and concise narrative control sequence of operations for each item of mechanical equipment including but not limited to air conditioning, heating, ventilation, medical gas, plumbing, and fire protection and any interconnection of the equipment of the systems. Mechanical engineering drawings shall depict completely the systems to be utilized, whether new or existing, from the point of system origination to termination. Provide a tabular schedule giving the required air flow (as computed from the information contained on the ventilation rate table) in cubic feet per minute (cfm) for

supply, return, exhaust, outdoor, and ventilation air for each space, as applicable, shown on the architectural documents. The schedule shall also contain the HVAC system design air flow rates and the resulting space relative pressures. The schedule or portion of the schedule as applicable shall be placed on each floor plan drawing sheet containing the spaces depicted on the drawing.

(f) Fire protection system layout documents as defined by the Department of Business and Professional Regulation in Rule 61G15-32.002, F.A.C., where applicable, that shall include the existing system as necessary to define the new work. These documents shall be signed and sealed by a Florida-registered professional engineer.

(g) Electrical engineering plans describing complete power, lighting, alarm, communications and lightning protection systems and power system study.

(h) A power study that shall include a fault study complete with calculations to demonstrate that over-current devices, transfer switches, switchboards, panel boards, motor controls, transformers and feeders are adequately sized to safely withstand available phase-to-phase and phase-to-ground faults. The study shall also include an analysis of generator performance under fault conditions and a coordination study resulting in the tabulation of settings for all over-current device adjustable trips, time delays, relays and ground fault coordination. This must be provided for all new equipment and existing equipment serving any new equipment. Power studies for renovations of existing distribution systems shall include only new equipment and existing equipment upstream to the normal and emergency sources of the new equipment. Renovations involving only branch circuit panel boards without modifications to the feeder do not require a full power study; instead, the power study shall be limited to the calculation of new and existing loads of the branch circuit panel.

(13) A complete set of specifications for all work to be undertaken.

(a) All project required contractor supplied testing and/or certification reports shall be submitted in writing, on standard forms, reviewed and accepted by the Engineer of Record prior to presenting to the agency for review.

(b) The specifications shall require a performance verification test and balance air quantity values report with the specified air filters installed for each air handling unit system operating in the minimum pressure drop condition (clean filter state) and at the maximum pressure drop condition (dirty filter state).

(14) All construction documents shall be coordinated to provide consistency of design intent throughout the

documents and phasing plans shall be clear and provide continuity of required services. It is specifically required that in the case of additions to existing institutions, the mechanical and electrical, especially existing essential electrical systems and all other pertinent conditions shall be a part of this submission.

(a) All subsequent addenda, change orders, field orders and other documents altering the above shall also be signed, sealed and dated and submitted in advance to the Office of Plans and Construction for review. The Agency will either approve or disapprove the submission based on compliance with all applicable codes and standards and shall provide a listing of deficiencies in writing.

(b) All submissions will be acted upon by the agency within 60 days of the receipt of properly executed construction documents and the initial payment of the plan review fee. The Agency will either approve or disapprove the submission and shall provide a listing of deficiencies in writing. All deficiencies noted by the agency must be satisfactorily corrected before final approval will be provided from the Agency.

(15) Additions or revisions that increase the scope of the project work greater than fifty percent or change the original scope of the project more than fifty percent will be required to be submitted as a new project.

(16) Record Drawings. Within 60 days after final approval of the project has been obtained from the agency, the Office of Plans and Construction shall be provided with a complete set of legible record drawings showing all of the construction, fixed equipment and the mechanical and electrical systems as installed. These drawings shall include the life safety plans. Record drawings may be submitted electronically in Portable Document Format (PDF). If record drawings are not received within this time frame specified in this section, only the construction document and project file will be retained.

*Rulemaking Authority 395.1055 FS. Law Implemented 395.0163, 471.025, 481.221, 553.73, 633.033 FS. History—New 6-14-78, Formerly 10D-30.21, Amended 2-3-88, 5-6-92, Formerly 10D-30.021, Amended 11-12-96, 7-9-15.*

### **59A-5.022 Physical Plant Requirements for Ambulatory Surgical Centers.**

(1) The Agency provides technical assistance to the Florida Building Commission and the State Fire Marshal in developing and maintaining standards for the design and construction of ambulatory surgery centers. These standards are included in the following:

(a) The building codes in Rule 61G20-1.001, F.A.C.; as adopted by the Florida Building Commission.

(b) The fire codes in Chapter 69A-60, F.A.C.; as adopted by the State Fire Marshal.

(c) The handicap accessibility standards in Chapter 553, Part V, F.S. and Rule 61G20-4.002, F.A.C.; as adopted by the Florida Building Commission.

(2) No building shall be converted to a licensed ambulatory surgery center unless it complies with the standards and codes in effect when the building is converted.

(3) Local codes which set more stringent standards or add additional requirements shall take precedence over these standards and requirements as set forth in this section. Contact the Office of Plans and Construction when conflicts occur.

*Rulemaking Authority 395.1055 FS. Law Implemented 395.1055 FS. History—New 6-14-78, Formerly 10D-30.22, Amended 2-3-88, Formerly 10D-30.022, Amended 6-11-97, 7-9-15.*

### **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 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.

(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.

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

(a) A description of the individual charges from each department or service area by date, as prescribed in subsection 395.301(1)(d), F.S.;

(b) Contact information for health care practitioners or medical practice groups that are expected to bill separately based on services provided; and,

(c) The center's contact information for billing questions and disputes.

*Rulemaking Authority 395.301 FS. Law Implemented 395.301 FS. History—New 2-19-18.*

# Appendix F: Chapter 59A-10 Internal Risk Management Program

59A-10.002	Definitions
59A-10.0055	Incident Reporting System
59A-10.0065	Fifteen Day Reports (Repealed)
59A-10.031	Purpose (Repealed)
59A-10.032	Definitions (Repealed)
59A-10.033	General Licensure Qualifications for Health Care Risk Managers (Repealed)
59A-10.034	Qualification by Completion of a Training Program (Repealed)
59A-10.035	Qualification by College Level Studies (Repealed)
59A-10.036	Qualification by Practical Experience (Repealed)
59A-10.037	Educational Programs (Repealed)

## **59A-10.002 Definitions.**

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 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 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.

(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.

*Rulemaking Authority 395.0197, 395.1073 FS. Law Implemented 395.0197 FS. History—New 8-28-79, Formerly 10D-75.02, Amended 3-25-86, 12-28-89, Formerly 10D-75.002, Amended 9-16-92, 8-2-16.*

### **59A-10.0055 Incident Reporting System.**

(1) Incident Reporting. An incident reporting system shall be established for each facility. Procedures shall be detailed in writing and disseminated to all employees of the facility. All new employees, within 30 days of employment, shall be instructed about the operation of the system and responsibilities of it. At least annually all nonphysician personnel of the facility working in clinical areas and providing patient care shall receive 1 hour risk management and risk prevention education and training including the importance of accurate and timely incident reporting.

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

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

(b) A clear and concise description of the incident including time, date, exact location; and elements as needed for the annual report based on ICD-10-CM;

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

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

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

(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.

(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.

(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.

*Rulemaking Authority 395.0197 FS. Law Implemented 395.0197 FS. History—New 1-2-97.*

#### **59A-10.0065 Fifteen Day Reports.**

*Rulemaking Authority 395.0197 FS. Law Implemented 395.0197 FS. History—New 3-25-86, Amended 12-28-89, Formerly 10D-75.0065, Amended 9-16-92, 2-12-96, Repealed 11-28-18.*

#### **59A-10.031 Purpose.**

*Rulemaking Authority 395.10973(1) FS. Law Implemented 395.10974 FS. History—New 7-9-86, Formerly 4-65.001, 4-217.010, Repealed 5-14-12.*

#### **59A-10.032 Definitions.**

*Rulemaking Authority 395.10973 FS. Law Implemented 395.10974 FS. History—New 7-9-86, Formerly 4-65.002, 4-217.015, Amended 4-4-01, Repealed 12-4-16.*

#### **59A-10.033 General Licensure Qualifications for Health Care Risk Managers.**

*Rulemaking Authority 395.10973(1), 408.819 FS. Law Implemented 395.10974, 408.805, 408.806, 408.809, 408.810 FS. History—New 7-9-86, Formerly 4-65.003, 4-217.020, Amended 5-4-15, Repealed 7-1-18.*

#### **59A-10.034 Qualification by Completion of a Training Program.**

*Rulemaking Authority 395.10973(1) FS. Law Implemented 395.10974 FS. History—New 7-9-86, Formerly 4-65.004, 4-217.025, Repealed 7-1-18.*

#### **59A-10.035 Qualification by College Level Studies.**

*Rulemaking Authority 395.10973(1) FS. Law Implemented 395.10974 FS. History—New 7-9-86, Formerly 4-65.005, 4-217.030, Repealed 7-1-18.*

#### **59A-10.036 Qualification by Practical Experience.**

*Rulemaking Authority 395.10973(1) FS. Law Implemented 395.10974 FS. History—New 7-9-86, Formerly 4-65.006, 4-217.035, Amended 8-2-16, Repealed 7-1-18.*

#### **59A-10.037 Educational Programs.**

*Rulemaking Authority 395.10973(1) FS. Law Implemented 395.10974 FS. History—New 7-9-86, Formerly 4-65.007, 4-217.040, Amended 8-2-16, Repealed 7-1-18.*

# Appendix G: Chapter 64B-8-9.007 Standards of Practice for Medical Doctors

## **64B8-9.007 Standards of Practice.**

The Board of Medicine interprets the standard of care requirement of Section 458.331(1)(t), F.S., and the delegation of duties restrictions of Section 458.331(1)(w), F.S., with regard to surgery as follows:

(1) The ultimate responsibility for diagnosing and treating medical and surgical problems is that of the licensed doctor of medicine or osteopathy who is to perform the procedure. In addition, it is the responsibility of the treating physician or an equivalently trained doctor of medicine or osteopathy or a physician practicing within a Board approved postgraduate training program to explain the procedure to and obtain the informed consent of the patient. It is not necessary, however, that the treating physician obtain or witness the signature of the patient on the written form evidencing informed consent.

(2) This rule is intended to prevent wrong site, wrong side, wrong patient and wrong surgeries/procedures by requiring the team to pause prior to the initiation of the surgery/procedure to confirm the side, site, patient identity, and surgery/procedure.

(a) Definition of Surgery/Procedure. As used herein, “surgery/procedure” means the removal, incision or curettage of tissue or an organ, insertion of natural or artificial implants, electro-convulsive therapy, endoscopic procedure or other procedure requiring the administration of anesthesia or an anesthetic agent. Minor surgeries/procedures such as excision of skin lesions, moles, warts, cysts, lipomas and repair of lacerations or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient are exempt from the following requirements. Paracentesis, thoracentesis, ocular surgery, liposuction, lipoplasty, and Mohs, are not minor surgeries/procedures.

(b) Except in life-threatening emergencies requiring immediate resuscitative measures, once the patient has been prepared for the elective surgery/procedure and the team has been gathered and immediately prior to the initiation of any procedure, the team will pause and the physician(s) or physican assistant(s) performing the procedure will verbally confirm the patient’s identification, the intended procedure and the correct surgical/procedure site. The

operating physician shall not make any incision or perform any surgery or procedure prior to performing this required confirmation. If the surgery/procedure is performed in a facility licensed pursuant to Chapter 395, F.S., or a level II or III surgery/procedure is performed in an office surgery setting, the physician(s) or physican assistant(s) performing the procedure and another Florida licensed health care practitioner shall verbally and simultaneously confirm the patient’s identification, the intended procedure and the correct surgical/procedure site prior to making any incision or initiating the procedure. The medical record shall specifically reflect when this confirmation procedure was completed and which personnel on the team confirmed each item.

(c) Confirmation of the patient’s identity shall be made by using two or more of the following corroborating patient identifiers:

1. Name.
2. Assigned identification number.
3. Telephone number.
4. Date of Birth.
5. Social security number.
6. Address.
7. Photograph.

(d) The provisions of paragraph (b) shall be applicable to anesthesia providers licensed pursuant to Chapter 458, F.S., prior to administering anesthesia or anesthetic agents, or performing regional blocks at any time both within or outside a surgery setting.

(e) At the time after the pause is completed, but before the procedure is initiated, if the physician(s) or physican assistant(s) leave(s) the room where the procedure is being performed, upon his or her return, the pause set forth in subsection (b) above must be performed again.

(3) Management of postsurgical care is the responsibility of the operating surgeon.

(4) The operating surgeon can delegate discretionary postoperative activities to equivalently trained licensed doctors of medicine or osteopathy or to physicians practicing within Board approved postgraduate training programs. Delegation to any health care practitioner is permitted only if the other practitioner is supervised by the

operating surgeon or an equivalently trained licensed doctor of medicine or osteopathy or a physician practicing within a Board approved postgraduate training program.

*Rulemaking Authority 458.309, 458.331(1)(v) FS. Law Implemented 458.331(1)(v) FS. History—New 11-28-91, Formerly 21M-20.015, 21M-27.007, 61F6-27.007, 59R-9.007, Amended 2-18-04, 9-18-05, 4-25-06, 5-6-08, 1-29-13(2)(a), 1-29-13(2)(b), (c), (e), 5-15-14.*

# Appendix H: CFR 416.43 Condition for Coverage: Quality Assessment and Performance Improvement

## Q-0080

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

### §416.43 Condition for Coverage: Quality Assessment and Performance Improvement

**The ASC must develop, implement and maintain an ongoing, data-driven quality assessment and performance improvement (QAPI) program.**

#### Interpretive Guidelines: §416.43

The QAPI CfC requires an ASC to take a proactive, comprehensive and ongoing approach to improving the quality and safety of the surgical services it delivers. The QAPI CfC presumes that ASCs employ a systems approach to evaluating their systems and processes, identifying problems that have occurred or that potentially might result from the ASC's practices and getting to root causes of problems rather than just superficially addressing one problem at a time.

From a survey perspective, the focus of the QAPI condition is not on whether an ASC has any deficient practices, but rather on whether it has an effective, ongoing system in place for identifying problematic events, policies, or practices and taking actions to remedy them, and then following up on these remedial actions to determine if they were effective in improving performance and quality. QAPI programs work best in an environment that fixes problems rather than assigning blame.

For surveyors this can sometimes pose difficult challenges, because it requires a balancing act. ASCs are not relieved of their obligation to comply with all Medicare CfCs, and surveyors are obligated when they find evidence of violations of a CfC to cite accordingly. However, surveyors generally should avoid using the ASC's own QAPI program data and analyses as evidence of violations of other CfCs. For example, an ASC that identifies problems with infection control through its QAPI program and takes effective actions to reduce the potential for transmission of infection would be taking actions consistent with the QAPI CfC. Absent evidence independently collected by the surveyors

of current noncompliance with the infection control CfC, it would not be appropriate for surveyors to use the infection control information in the ASC's QAPI program as evidence of violations of the infection control CfC. There can be egregious cases under investigation where it might be appropriate to use QAPI program information as evidence of a deficiency, but these cases should be the exception rather than the rule.

CMS does not prescribe a particular QAPI program; it provides each ASC with the flexibility to develop its own program. Each program must, however, satisfy the regulatory criteria:

- Ongoing – i.e., the program is a continuing one, not just a one-time effort. Evidence of this would include, but is not limited to, things like collection by the ASC of quality data at regular intervals; analysis of the updated data at regular intervals; and updated records of actions taken to address quality problems identified in the analyses, as well as new data collection to determine if the corrective actions were effective.
- Data-driven – i.e., the program must identify in a systematic manner what data it will collect to measure various aspects of quality of care; the frequency of data collection; how the data will be collected and analyzed; and evidence that the program uses the data collected to assess quality and stimulate performance improvement.

#### Survey Procedures: §416.43

When there is a team surveying the ASC, survey of the QAPI Condition should be coordinated by one surveyor.

## Q-0081

(Rev.56, Issued: 12-30-09, Effective/

Implementation: 12-30-09)

### §416.43(a) & §416.43(c)(1)

#### §416.43(a) Standard: Program Scope

1. **The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.**
2. **The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.**

#### §416.43(c) Standard: Program Activities

(1) **The ASC must set priorities for its performance improvement activities that –**

- (i) **Focus on high risk, high volume, and problem-prone areas.**
- (ii) **Consider incidence, prevalence and severity of problems in those areas.**
- (iii) **Affect health outcomes, patient safety and quality of care.**

#### **Interpretive Guidelines: §416.43(a) & §416.43(c)(1)**

There are a variety of types of indicators that are currently in use for measuring and improving quality of healthcare. This is also a rapidly changing field, as interest and research in patient safety and healthcare quality measurement grows. As a result of a recommendation of a 1998 Presidential Advisory Commission, the National Quality Forum (NQF), a public-private not-for-profit membership organization, was created in 1999 to develop and implement a national strategy for healthcare quality measurement and reporting. Since then NQF has developed detailed recommendations for ways to promote and measure quality and patient safety, including in ASCs. The federal Agency for Healthcare Quality and Research (AHRQ) supports research assessing

the effectiveness of care practices and procedures. A number of other organizations are also active in the field of healthcare quality improvement and patient safety. As a result, ASCs have many choices of indicators to use.

Indicators can be broken down into several types:

- **Outcomes Indicators** measure results of care; typical outcomes measures include risk-adjusted mortality rates, complication rates, healthcare-associated infection rates, length of stay, readmission rates, etc. In the ASC setting, outcomes measures might focus on things like complication rates, healthcare-associated infection rates, cases exceeding 24 hours, transfers to hospitals, wrong site surgeries, etc.
- **Process of Care Indicators** measure how often the standard of care was met for patients with a diagnosis related to that standard. For example, in the ASC setting, measures might focus on the administration and time of prophylactic antibiotics.
- **Patient Perception Indicators** measure a patient's experience of the care he/she received in the ASC. AHRQ sponsored development of one patient experience of care instrument, H-CAHPS, that CMS now uses in reporting on hospital quality. There may be similar patient survey instruments that could be used in the ASC setting.

The regulation at §416.43(a) requires that an ASC's QAPI program must improve both patient health outcomes and patient safety in the ASC. In order to achieve these goals, the ASC's QAPI program must:

1. Be ongoing – i.e., the program is a continuing one, not just a one-time effort or occasional effort. Evidence that the ASC's program is ongoing would include, for example, collection by the ASC of quality data at regular intervals; analysis of the updated data at regular intervals; and updated records of actions taken to address quality problems identified in the analyses, as well as new data collection to determine if the corrective actions were effective.
2. Use quality indicators or performance measures associated with improved health outcomes in a surgical setting. The quality and safety indicators available differ in terms of the weight and type of evidence for their effectiveness in measuring quality. For some indicators there is compelling peer-reviewed research of an association with improved health outcomes. For others, typically process of care indicators, con-

sensus among experts in the field suggests a strong association with improved quality of care. Indicators also differ in terms of how the data is collected, and how frequently the data should be collected.

For example, measures of how quickly an ASC produces error-free billing claims, while relevant to the ASC's financial performance and of interest to ASC governing bodies, have no direct relationship to the quality of care the ASC provides. On the other hand, a measure of the frequency with which the ASC administers antibiotic prophylaxis consistent with generally accepted standards of care would be related to improved health outcomes, i.e., prevention of surgical site infections. Likewise, an ASC could choose to collect data measuring its compliance with applicable National Quality Forum Safe Practices, or with applicable Centers for Disease Control and Prevention (CDC) infection control guidelines, or with guidelines issued by national professional societies, such as the American College of Surgeons, or with recommended practices developed by national accreditation organizations or other organizations specializing in healthcare quality improvement, such as the Institute for Healthcare Improvement. CMS does not prescribe a certain set of indicators/measures for ASCs to use, but ASCs must be able to demonstrate that the indicators they are tracking will enable them to improve outcomes for ASC patients.

The regulations at §416.43(c)(1) also require the ASC to set priorities in choosing its quality indicators/measures, because what is measured will determine where the ASC focuses its efforts to make changes that improve performance. For example, if the ASC does not track measures related to infection control, it will not be in a position to determine whether or not its infection control program is working well or poorly, and thus will not be in a position to improve it.

The ASC is required to focus on high risk, high volume, and problem-prone areas. It is required to consider, when selecting the measures/indicators that will shape its improvement activities in these areas, the following:

- The incidence, i.e., the rate or frequency at which problems occur in the ASC related to area measured by the indicator. "Incidence" is a technical term used in epidemiology, referring to the frequency with which something, such as a disease,

appears in a particular population or area. In disease epidemiology, the incidence is the number of newly diagnosed cases during a specific time period. Applying this concept in the ASC setting, as an example, the annual incidence of surgical site infections in an ASC would be the rate that results when dividing the number of such infections that occurred in a calendar year by the total number of surgical cases in the ASC during that same year. Likewise, the annual incidence of emergency transfers to a hospital would be the rate that results when dividing the number of such transfers by the total number of surgical cases during the same year;

- The prevalence, i.e., how widespread something is in an ASC at a given point in time. "Prevalence" is also a technical term used in epidemiology, and is a statistical concept referring to the number of cases of a disease that are present in a particular population at a given time. In an ASC setting, for example, it would make little sense to employ measures related to prevalence of pressure ulcers among ASC patients, since the limited amount of time a patient typically spends in an ASC makes it unlikely that the ASC's care processes contributes to pressure ulcers. On the other hand a more appropriate measure might be periodic observation of the hand hygiene practices of all staff providing direct patient care, in order to assess the prevalence of good versus deficient practices; and
- The severity of problems. For example, any single instance of a transfer of a patient to a hospital represents a serious adverse, unplanned outcome of the surgical procedure, and it would be appropriate for an ASC to track and evaluate all such cases, due to their severity, even if they are low volume incidents.

Once having identified the quality indicators it will use, the ASC must collect and analyze data on these indicators.

3. Identify and reduce medical errors/adverse patient events. Although there is no single, standard definition of a medical error or adverse event, the Institute of Medicine created a series of definitions (P. 28, *To Err is Human*, Institute of Medicine, November, 1999.) related to patient safety that are helpful in understanding the regulatory requirement:

“An **error** is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).”

“An **adverse event** is an injury caused by medical management rather than the underlying condition of the patient.”

“An adverse event attributable to error is a **preventable adverse event**.”

Using these definitions, if an ASC performing orthopedic procedures operates on the right shoulder of a patient with a left shoulder rotator cuff injury requiring surgery, then the ASC has committed an error. The patient suffered an adverse event – i.e., the harm to the patient of undergoing surgery on the wrong shoulder, and presumably having to undergo yet another surgery on the correct shoulder. Because the ASC’s error resulted in the adverse event, it is a preventable adverse event that could and should have been avoided.

Not every adverse event is the result of an error. For example, the standard of practice might call for use of a particular medication when certain indications are present. A patient might have an allergy to that medication that is unknown to the patient and the patient’s physicians. The patient develops an allergic reaction to the medication, requiring further medical intervention to counteract the reaction. Due to the unknown nature of the patient’s allergy, there was no error, even though there was an injury resulting from medical management. On the other hand, if the allergy had been documented in the patient’s medical record and the medication had been administered anyway, this would constitute an error.

Not every error results in an adverse event; for example, an ASC with two operating rooms might mix up the records of two ASC patients scheduled to have the same orthopedic procedure, e.g., foot surgery, on the same date, but on the opposite feet. This is an error. But the ASC employs a time-out procedure to verify the identity of the patients and site of the surgery and recognizes the error before surgery begins.

The error did not result in an adverse event, but it was a near miss.

ASCs must track all patient adverse events, in order to determine through subsequent analysis whether they were the result of errors that should have been preventable, to reduce the likelihood of such events in the future. ASCs are also expected to identify errors that result in near misses, since such errors have the potential to cause future adverse events.

ASCs seeking initial enrollment in the Medicare program are unlikely to have collected extensive data for their QAPI program indicators, since they likely have been in operation for a relatively brief period of time. Nevertheless, these initial applicants must have a QAPI program in place, and must be able to describe how the program functions, including which indicators/measures are being tracked, at what intervals, and how the information will be used by the ASC to improve quality and safety.

#### **Examples of ASC Quality/Patient Safety Indicators**

The following information is based on the National Quality Forum’s (NQF) consensus standards for ASCs, and is provided only as an illustration of several types of measures an ASC might choose to include in its QAPI program. An ASC is free to use different measures, so long as the measures it chooses meets the regulatory criteria. ASCs are also expected to develop additional measures related to infection control, for example to enable it to comply with the requirement at §416.51(b)(2) for its infection control program to be integrated into its QAPI program, and at §416.44(a)(3) to have a program to identify healthcare associated infections and report diseases as required under State law. Depending on the individual characteristics of the ASC, including problems it had experienced in the past, it may be necessary to track other additional indicators as well.

More information on these and other NQF ASC measures is available at: <http://www.qualityforum.org/pdf/ambulatory/tbAMBALLMeasuresendorsed%2012-10-07.pdf>.<sup>1</sup>

---

<sup>1</sup> The web address listed in the April 2015 edition of the CMS Appendix L publication is not active. To learn more and see examples of quality measures, please go to the ASC Quality Collaboration at [www.ascquality.org](http://www.ascquality.org) which has measures applicable to ASCs, including those CMS requires ASCs to report, or to the National Quality Forum at [www.qualityforum.org](http://www.qualityforum.org) which covers various healthcare settings.

- **Patient Burn** – Percentage of ASC admissions experiencing a burn prior to discharge. Approximately 100 surgical fires occur each year nationally, in all surgical settings, with about 20 resulting in serious injuries to patients.
- **Prophylactic Intravenous Antibiotic Timing** – Percentage of ASC patients who received appropriate antibiotics ordered for surgical site infection prophylaxis on time.
- **Hospital Transfer/Admission** – Percentage of ASC admissions requiring a hospital transfer or hospital admission prior to being discharged from the ASC.
- **Patient Fall** – Percentage of ASC admissions experiencing a fall in the ASC.
- **Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant** - Percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant.

**Survey Procedures: §416.43(a)**

- Ask the ASC's leadership to describe the QAPI program, including staff responsibilities for QAPI and the quality/safety indicators being tracked.
- Ask what the rationale is for the particular indicators that the ASC has chosen to track. Are they based on nationally-recognized recommendations? If not, what evidence does the ASC have that the indicators it has chosen are associated with improvement in patient health outcomes and safety?
  - o At a minimum, do the indicators include cases of patients transferred from the ASC to a hospital?
  - o At a minimum, do the indicators include measures appropriate for surgery and infection control measures?
  - o At a minimum, does the ASC have a system for tracking adverse patient events?
- Ask the staff responsible for QAPI what the method and frequency is for data collection for each QAPI program indicator.

**Q-0082**

(Rev. 56, Issued: 12-30-09, Effective Implementation: 12-30-09)

**§416.43(b) and §416.43(c)(2) & (3)**

**§416.43(b) Standard: Program Data**

- (1) **The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.**
- (2) **The ASC must use the data collected to –**
  - (i) **Monitor the effectiveness and safety of its services, and quality of its care.**
  - (ii) **Identify opportunities that could lead to improvements and changes in its patient care.**

**§416.43(c) Standard: Program Activities**

- (3) **Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.**
- (4) **The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.**

**Interpretive Guidelines: §416.43(b) & §416.43(c)(2) & (3)**

**Active Data Collection**

The ASC must not only have identified a number of indicators or measures of quality and patient safety, but it must actively collect data related to those measures at the intervals called for by its QAPI program. Staff responsible for collection of the data should be trained in appropriate techniques to collect and maintain the data.

**Data Analysis**

Once having collected the data, the ASC must analyze it to monitor ASC performance, i.e., to determine what the data suggests about the ASC's quality of care and the effectiveness and safety of its services. Analysis must take place at regular intervals, in order to avoid too much time elapsing before the ASC is able to detect problem areas. In the case of data related to adverse events, the ASC must use



the data to analyze the cause(s) of the adverse events. Data collection and analysis must be conducted by personnel with appropriate qualifications to collect and interpret quantitative data. CMS does not expect ASCs to engage in sophisticated statistical modeling of data, but calculation of incidence rates should be within the skill set of individual(s) conducting the analysis. On the other hand, CMS does expect ASCs to conduct thorough analyses that focus on systemic issues. For example, if the ASC's adverse event tracking system identifies a medication error that resulted in serious injury to a patient, the ASC would not be taking the type of systems approach mandated under the QAPI regulations if it states that the event was caused by the staff member who administered the medication incorrectly, and that its method for improving performance was to fire that staff member. An acceptable analysis would look at the root causes that facilitated the error by the staff member: Were medications stored in a manner that increased the possibility of error? Were the physician's orders clearly written? Was the staff member appropriately trained? Is there any evidence of similar errors made by other staff members, including errors that did not result in adverse events? There are probably additional issues that should be investigated in order to fully understand the causes of the adverse event. Once there is a thorough analysis of these causes, the ASC would then be in a better position to identify improvement strategies that are appropriately designed to address the underlying causes.

The ASC may choose to use contractors for technical aspects of the QAPI program, including analysis of data, but the ASC is also expected to actively involve ASC staff in the program and the ASC's leadership retains the responsibility for the ongoing management of the program, even when a contractor is used.

Analysis of the monitoring data must be used to identify areas where there is room for improvement in the ASC's performance, as well as follow-up actions taken to improve performance. A good monitoring system, even in a good ASC surgical program, is likely to always find some areas of performance that are weaker than others. These identified areas of weakness present opportunities for the ASC to make changes in its systems, policies or procedures that result in improved patient care.

#### **Implement Improvements/Preventive Strategies**

Once the ASC's analysis of its data has identified opportunities for improvement, the ASC must develop specific changes in its policies, procedures, equipment, etc., as applicable, to accomplish improvements in the identified areas of weakness. In particular, an ASC must implement

preventive strategies designed to reduce the likelihood of adverse events throughout the ASC. For example, if an ASC has three operating or procedure rooms, and it has an adverse event in a case in one of these rooms that is attributable in part to a confusing storage of emergency medications, the ASC should review the set up in each of the rooms to ensure that the same problem does not occur elsewhere.

#### **Sustaining Improvements**

The ASC must also have a method to ensure that the improvements it makes are sustained over time. For example, if an ASC's QAPI program identifies problems with hand hygiene in ASC staff providing care to patients, the ASC must be able to demonstrate that whatever solution it adopted to address this problem continues to work over time. Generally this means that the ASC must collect data on indicators that measure staff hand hygiene on an ongoing basis.

#### **Staff Training**

The ASC is required to make all staff aware of the strategies it has adopted for prevention of adverse events. For example, all staff who are involved in the preparation of a patient for the surgical procedure, as well as in the conduct of the surgical procedure, must be familiar with the ASC's strategies for avoiding wrong patient, wrong site, wrong side, wrong procedure, wrong implant, and adverse surgical events. All staff involved in the preparation and administration of injectable medications should be aware of standard safe injection practices designed to avoid the transmission of infectious disease. Staff should be encouraged to ask questions when they observe a practice, or receive an order, etc. that they believe might compromise patient safety or quality of care in the ASC.

#### **Prospective ASC's Applying for Initial Certification in Medicare**

A facility seeking initial certification as an ASC may not have been in operation long enough to demonstrate extensive data collection or the identification of opportunities for improvement based on the monitoring data. However, it must be able to show that it has an active data collection and analysis infrastructure in place as well as to indicate when it expects to have sufficient data to begin analysis and what procedures it has put in place to consider the results of QAPI program analyses.

#### **Survey Procedures: §416.43(b)**

- Ask the ASC to show you examples of quality and adverse event data it is collecting. Is the ASC

collecting data on all of the indicators/measures it identified for its QAPI program? Is it collecting the data at the frequency specified in its QAPI program?

- Ask the ASC who is responsible for the data collection and analysis, and what their qualifications are? In particular, ask the ASC how it determines the causes of adverse events – does the ASC stop with the immediate cause (staff error, equipment failure, etc.) or does it probe to discover the underlying root causes of the adverse events?
- If ASC staff handle these duties, do they have education or training that equips them to conduct analyses of the data?
- Ask the ASC to provide examples of instances where it used QAPI data to identify opportunities for improving processes for providing care. Ask how it evaluated whether the improvements were effective a
- Ask the ASC how it trains staff on ways to prevent adverse events from occurring.
- Ask ASC staff what they know about the ASC's QAPI program, focusing in particular on staff awareness of policies and procedures for preventing adverse events.

## Q-0083

(Rev.56, Issued: 12-30-09, Effective/

Implementation: 12-30-09)

### §416.43(d) Standard: Performance Improvement Projects.

- (1) **The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.**
- (2) **The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results.**

#### Interpretive Guidelines: §416.43(d)

Every ASC must undertake one or more specific quality improvement projects each year. Larger ASCs with multiple

ORs or procedure rooms, multiple types of surgical procedures offered, or high volume of cases are expected to undertake more or more complex projects. Furthermore, a highly complex improvement project might be of such scope that it could reasonably be the only project an ASC undertakes in a given year.

CMS does not specify particular projects that each ASC must undertake, but instead expects the projects to be based on the types of services the ASC furnishes, as well as other aspects of the ASC's operations. The requirement for annual projects does not mean that an ASC may not undertake a complex project that is expected to require more than 1 year in order to be completed.

The ASC must keep records on its performance improvement projects. Each project must, at a minimum, include an explanation of why the project was undertaken. The explanation must indicate what data collected in the ASC or based on recommendations of nationally recognized organizations leads the ASC to believe that the project's activities will actually result in improvements in patient health outcomes and safety in the ASC. For projects that are still underway, the ASC must be able to explain what activities the project entails, and how the impact of the project is being monitored. Unless the project has just begun, the ASC must be able to provide evidence that it is collecting data that will enable it to assess the project's effectiveness. For projects that are completed, the ASC must be able to show documentation that explains what the results of the project were, and what actions, if any, the ASC took in response to those results.

#### Survey Procedures: §416.43(d)

- Ask the ASC to show you documentation for performance improvement projects currently underway, as well as those completed in the prior year.
- If a large, complex, or high volume ASC has only one project underway, is the scope of that project such that it is likely to have a significant impact on the ASC's quality of care or patient safety?
- Does the ASC's documentation indicate the rationale for undertaking each project? Does the ASC have data indicating it had a problem in the area targeted for improvement, or could the ASC point to recommendations from a nationally recognized expert organization suggesting the activities?
- Does the documentation for the completed project(s) include the project's results? If a project was unsuccessful, ask the ASC what actions it took

as a result of that information. If the project was successful, ask the ASC how it is sustaining the improvement.

## Q-0084

(Rev.56, Issued: 12-30-09, Effective/  
Implementation: 12-30-09)

### §416.43(e) Governing body responsibilities.

#### The governing body must ensure that the QAPI program –

- (1) Is defined, implemented, and maintained by the ASC.
- (2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness.
- (3) Specifies data collection methods, frequency, and details.
- (4) Clearly establishes its expectations for safety.
- (5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.

#### Interpretive Guidelines: §416.43(e)

An ongoing, successful QAPI program requires the support and direction of the ASC's leadership. This regulation makes clear CMS' expectations that the ASC's governing body must assume responsibility for all aspects of the design and implementation of every phase of the QAPI program. The governing body must assure that the ASC's QAPI program:

- Is defined, in writing, for example in the minutes of a meeting where the governing body established the program;
- Is actually implemented, with written evidence of this implementation, as well as evidence of knowledge of the program by the ASC's staff;
- Is implemented on an ongoing basis;
- Employs quality and patient safety indicators that reflect appropriate prioritization, as required by §416.43(c);
- Describes in detail the indicator data to be collected, how it will be collected, how frequently it will be collected;
- Uses the data collected and analyzed to improve the ASC's performance;

- Evaluates changes designed to improve the ASC's performance to determine whether they are effective, and takes appropriate actions to make further changes as needed;
- Is designed to establish clearly the governing body's expectations that patient safety is a priority, not only by the tracking of all adverse events, but also by the program's processes for analyzing and making changes in ASC operations to prevent future such events; and
- Has sufficient resources, i.e., the ASC's governing body must allocate sufficient and qualified staff (including consultants), staff time, information systems and training to support the program. Given the great variety in size and complexity among ASCs, the extent of resources required will vary as well. However, the resources dedicated to the QAPI program must be commensurate with the ASC's overall scope and complexity. The ASC must also be able to identify in detail the resources that it dedicates to the QAPI program.

#### Survey Procedures: §416.43(e)

- Does the ASC's QAPI program include all of the essential elements described above?
- Ask the ASC's leadership to explain how the governing body is involved in the QAPI program. Does the ASC's leadership display ready knowledge of the program's structure and activities. If a contractor is used for some portions of the program, does the ASC's leadership monitor closely the contractor's activities?
- Is there evidence of a governing body review of all elements of the QAPI program, e.g., meeting minutes?
- Ask the ASC's leadership how it uses the program to improve performance. Ask for evidence of changes made as a result of QAPI program activities.
- Ask the ASC's leadership for documentation of the details of the resources that are dedicated to the QAPI program. Is there evidence that these resources were actually made available as planned? For example, interview staff identified as having a role in the QAPI program to determine whether they actually perform QAPI functions, and for what percentage of their time. Is there evidence that planned data collections and analyses actually took place?



**The mission** of the Florida Society of Ambulatory Surgical Centers (FSASC) is to advance the ambulatory surgical center industry through community awareness and government advocacy and to promote the professionalism of its members through education, networking and the exchange of information.

**In Florida**, FSASC is the only organization that maintains close contact with state agencies to monitor and impact regulations that govern ASCs. Members are provided with a steady flow of vital information to enable centers to operate with state-of-the-art surgical, technical and administrative procedures. FSASC hosts an annual trade show and provides educational offerings, a quarterly newsletter and timely email broadcasts on industry specific items.

**FSASC is focused** on the advancement of the ambulatory surgical center industry through legislative and regulatory advocacy. The Society maintains an active presence in Tallahassee with full time staff and lobbyist. On a national level, the Society works with the Ambulatory Surgery Center Association. This cooperation allows FSASC members to add their influence to activities at the Federal level.

FSASC is able to diligently work on behalf of surgery centers in Florida because of our members. To join and show your support for FSASC's advocacy efforts, contact FSASC using the information below.

## **Florida Society of Ambulatory Surgical Centers**

1400 Village Square Blvd, #3-175  
Tallahassee, FL 32312  
Phone: (850) 222-3000  
Fax: (850) 907-1288  
[www.fsasc.org](http://www.fsasc.org)



1400 Village Square Blvd, #3-175  
Tallahassee, FL 32312  
Phone: (850) 222-3000  
Fax: (850) 907-1288  
[www.fsasc.org](http://www.fsasc.org)