
Risk Management Back to the Basics

SANDRA JONES, CPHRM, CPHQM, CASC, FHFMA
CEO, AMBULATORY STRATEGIES INC.
SJONES@ABOUTASCS.COM

Why risk management?

- Manage the risk of harm to patients and staff by improving processes, training, and communication.

“If it’s not safe, it’s not care”
Institute for Healthcare Improvement

Regulations and Standards

- Code of Federal Regulations (CFR)
- Florida Statute and Florida Administrative Code

CMS Regulation

- 42 Code of Federal Regulations (CFR) 416
 - Medicare Conditions for Coverage, State Operations Manual, **Appendix L** – Guidance for Surveyors: Ambulatory Surgical Centers. July 21, 2023
 - 42 CFR 416.43 – Quality Assessment and Performance Improvement.

State Statutes and Rules for ASCs

- Florida Statute 395 and 408
- Florida Statute 395.0197
- Florida Administrative Code 59A-5
- Florida Administrative Code 59A-10
- Florida Administrative Code 59A-35

Florida Regulations: FS 408, Part II and FAC 59A-35

- **59A-35.115 Patient Safety Surveys**
- Health Care Licensing
- Facility license required, must be displayed
- Change of Ownership
- Fees required
- Background screening
- Application process

CMS and AHCA Risk Management

- CMS Appendix L, §416.43
- State of Florida
 - Florida Statute 395.0197
 - Florida Administrative Codes
 - 59A-5
 - 59A-10
 - 59A-35.115

CMS Appendix L, QAPI section, Page 57 FSASC Risk Management, 7th edition, Page 45

- Last CMS update released July 21, 2023
- Regulation requires that an ASC's QAPI program must improve both outcomes and safety. Must
 - Be ongoing
 - Use quality indicators or performance measures, consider frequency of problems, prevalence, severity
 - Identify and reduce medical errors/adverse patient events

CFR §416.43 (a) QAPI Program Scope

- (1) include an ongoing program, demonstrates improvement, 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 include care and services furnished in the ASC.

CMS §416.43(b) Program Data

- Program must incorporate quality indicator data, including patient care
- ASC must use the data collected to
 - Monitor the effectiveness and **safety** of its services and quality of its care
 - Identify opportunities that could lead to improvements and changes in its patient care.

CFR §416.43 (c) QAPI

- The ASC must set priorities for its performance improvement activities that
 - Focus on high **risk**, high volume, and problem-prone
 - Consider **incidence, prevalence and severity** of problems
 - Affect health **outcomes, patient safety**, quality of care

CMS examples: Quality metrics and infection control

§416.43(c) Program Activities

- Track **adverse patient events, examine their causes**, implement improvements, and ensure that improvements are sustained over time
- Implement preventive strategies to target **adverse events** and ensure all staff is familiar with these strategies.

Interpretive Guidelines 416.43(c)

- Active data collection
- Data analysis
- Implement improvements/preventive strategies
- Sustaining improvements
- Staff training

CMS surveyor will:

- Ask to see examples of **quality and adverse event data**
- Ask who is responsible for data collection and analysis
- What education and training equips staff to conduct analysis of data
- Provide examples where **data was used** to identify opportunities for improvement
- How is staff trained on prevention of adverse events
- Ask staff what they know about QAPI and risk activities

§416.43(e)

- Governing body responsibilities. The governing body must ensure that the QAPI program... is designed to establish clearly the expectations that **patient safety** is a priority, not only by tracking of all **adverse events**, but also by the processes for **analyzing** and **making changes** in ASC operations to **prevent** future such events.

CMS surveyor will look for:

- All essential elements included in program
- How governing body is involved in the QAPI program
- Meeting minutes show governing body review of all elements
- Example of how program improved performance
- Resources, staff time allocated, staff involvement

Florida Administrative Code 59A-5.019 (2) Quality Assessment and Improvement

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/improvement activities including laboratory and radiology services;
- h) Results of autopsies if needed.

59A-5.019(3) QAPI

- 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

QAPI “ongoing, high risk , high volume, problem prone”

AHCA surveyor will

- Interview the manager of QAPI and/or Risk Management about the QAPI program, action taken to correct problems identified, data collection, example of how QAPI findings and RM are integrated.
- Examine reports and minutes of meetings to determine if the ASC has documented the remedial action and its outcome.

State Statutes and Rules

- Florida Statute 395 and 408
- Florida Statute 395.0197
- Florida Administrative Code 59A-5
- Florida Administrative Code 59A-10
- Florida Administrative Code 59A-35.115

Florida Regulations

- Chapter 395, Part I, Florida Statute
 - Risk management: Chapter 395.0197
 - Duty to notify patients: Chapter 395.1051
 - Patient Safety: Chapter 395.1012
 - Patient Safety Surveys: Chapter 395.1012(4)
 - Other important sections of Chapter 395
 - Staff membership and clinical privileges: 395.0191
 - Peer review, disciplinary powers: 395.0193

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

- 395.0197(1) Every licensed facility shall, as part of its administrative functions, establish an internal risk management program that includes all of the following components.
- 59A-5.003(11) Each center licensed under chapter 395, FS, shall establish an internal risk management program pursuant to chapter 59A-10, FAC, as a part of its administrative function.

Definitions

- "Incident reporting" 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.

Definitions

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

Definitions

- "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.

395.0197(1)(a) Investigation and Analysis

- (1) Program must include
 - (a) Investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents to patients.

AHCA surveyor will

- Determine if the plan establishes incident categories
- Incidents and categories specific to the facility
- Review 6 monthly logs and 4 quarterly summary reports.

395.0197(1)(b) Develop Measures to Minimize Risk

(b) Development of appropriate measures to minimize risk

1. Education and training of all nonphysician personnel
 - a. At initial orientation and
 - b. At least one hour annually
2. Two people in recovery
3. Authorized persons only to assist or participate in surgical procedure
4. Procedure, protocols, systems to identify patients, planned procedure, correct site

AHCA surveyor will

- Review RM plan/program/policies for
 - Incident categories, trending logs and summary reports
 - Review past year's adverse incidents identified as risk reduction/process improvement opportunities
 - Interview RM or designee regarding role in risk reduction and risk prevention strategies
 - Verify strategies are systematic and implemented
 - What were results of actions to minimize risk?

Survey findings

- No evidence of development and implementation of risk reduction and risk prevention strategies.
- No evidence risk manager aware of QAPI activities, infection control surveillance, environment of care program.

395.0197(1)(b)(1) and 59A-10.0055(1)

- Education and training for all nonphysician **personnel** (including CRNAs, PRN, independent contractors) working in clinical areas and providing patient care
 - Initial orientation (within 30 days of employment)
 - Annually for one hour
- “Personnel” for purposes of this rule means any employee or independent contractor of a facility or member of a facility’s medical staff. 59A-10.002(26)

Personnel, 59A-10.002 (26)

- “Personnel” for purposes of this rule means any employee or independent contractor of a facility or member of a facility’s medical staff.

AHCA surveyor will

- Review policies regarding education that includes incident reporting, Code 15 and annual incident reporting requirements
- Look at records to verify new and contracted personnel educated within 30 days and annually.
- Ask a few employees about their training and their role in patient safety: what occurrences, events, near misses to report; their role in patient safety; knowledge to report sexual abuse of a patient

395.0197(1)(b)(2) Recovery Room Staffing

- Staffing the recovery room, authorized staff member
- At least one other person in recovery room
- Exceptions: Live visual observation, electronic observation or “other reasonable measure taken to ensure patient privacy and protection”.

Note: (1) the second person is not specified and can be the patient’s responsible adult companion and (2) 59A-5.0085(3)(d) “A registered professional nurse shall be present in the recovery area at all times when a patient is present.”

AHCA surveyor will

- Review staff schedule for recovery room
- Review P&P re: 2-person requirement
- Tour the recovery room
- Interview staff regarding staffing patterns

395.0197(1)(b)(3) Investigation & Analysis

- Prohibition of unlicensed person assisting or participating in any surgical procedure unless the facility has authorized the person to do so following a competency assessment. Assistance or participation must be under direct and immediate supervision of a licensed physician. Cannot be an activity that may only be performed by a licensed health care practitioner.

AHCA surveyor will

- Interview surgical staff
- Identify any unlicensed staff participating in surgical procedures
- Review unlicensed staff competencies and competency assessments
- Review for documentation of direct and immediate supervision
- Review competencies for private or contracted scrub individuals

AHCA surveyor will

- Check staff for
 - Circulating nurses for **every procedure** no matter where it is performed: pre-op pain blocks, procedure room, operating room
 - **CRNA cannot be administering anesthesia AND serve as circulating nurse**
 - Recovery nurse whenever patient present
 - Licensed staff must be giving medications
 - **Not techs**
 - **Not MA unless direct supervision by physician**

395.0197(1)(b)(4) Ongoing

- Development, implementation, and ongoing evaluation of procedures, protocols, and systems to accurately identify patients, planned procedures, correct site to minimize risk of wrong patient, wrong surgical procedure, wrong site.

AHCA surveyor will

- Review adverse incidents
- Review plan/policy documents to address identity of patient/procedure
- Verify there is a system to prevent wrong patient, wrong procedure, wrong site
- Protocols monitored for quality program purposes
- Review development, implementation, and ongoing evaluation process to prevent occurrences

64B-8-9.007 Standards of Practice for Medical Doctors

64B-8-9.007 (b): The physician(s) or *physician 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.

Note: CMS states that only physicians can perform procedures in an ASC. Physicians include MD, DO, DPM, DDS, chiropractors. A PA, APRN or a scrub tech cannot perform procedures.

395.0197 (1)(c) Risk Management Program

- (1) Program must include
 (c) Analysis of patient grievances that relate to care and quality

“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.

- Note: this definition is not the same used by CMS §416.50(d) or the American Society for Health Care Risk Management (ASHRM).

AHCA surveyor will

- Ask to see grievances relating to patient care and medical services
- Review analysis of grievance
- Check for evidence that resolution and corrective actions, when indicated, occurred
- Verify a plan to prevent further occurrences

395.0197 (1)(d) Patient Notification of Adverse Incidents

- (d) Informing patient when subject of an adverse incident. Such notice shall be given by an appropriately trained person designated by the licensed facility as soon as practicable to allow the patient an opportunity to minimize damage or injury.
- Note: 395.1051 also requires notification of patient and states this does not constitute an acknowledgement or admission of liability, nor can it be used as evidence.

AHCA surveyor will

- Review P&P on patient notification of adverse incident
- Review any training of person(s) conducting notification
- Review sample of incident reports for documentation of notification

Physician's Obligation to Report

- FS 456.0575: Practitioner
 - Every licensed health care practitioner shall inform each patient (or surrogate) in person about adverse incidents that result in serious harm to the patient.

395.0197(1)(e) Incident Reporting System

- (e) Development and implementation of reporting system based upon the affirmative duty of all health care providers and all agents and employees to report adverse incidents

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

- Reporting system shall include reporting within 3 calendar days to risk manager or designee
- Form to report shall contain
 - Patient's name, locating information, admission diagnosis, admission date, age and sex
 - Clear and concise description of incident including date, time, exact location and elements needed for annual report based on ICD-10-CM

AHCA surveyor will look for

- Policies and procedures
- Dates of events and dates of review
- Form contains fields for all information required
- Interview a sample of staff:
 - What is the reporting system?
 - What is the time frame for reporting?
 - Does staff know who are risk manager and designee?

59A-10.0055(2) (c)-(e) Reports

- Whether or not a physician was notified of incident and, if so, a brief statement of any medical treatment directives
- A list of all persons involved directly and witnesses along with locating information for each
- Name, signature, and position of person completing the report and date and time report completed.

395.0197 (2) Responsibility of Governing Board and Risk Manager

- RM program is responsibility of governing board, have risk manager responsible for implementation and oversight and who demonstrates competence through education or experience in all the following:

395.0197(2) Education or Experience

- 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.

59A-10.002(29) Risk Manager Designee

- “Risk Manager Designee” means any person appointed by the facility to work with the health care risk manager or to act as his representative in carrying out risk management activities. This appointment must be in writing.

AHCA surveyor will

- Verify there is a Risk Manager
- Review the job description re responsibilities
- Is there a RM designee? What are designee’s responsibilities?
- What education or experience does the risk manager and the designee have?

Definitions in 59A-5 and 59A-10

- “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.
- “Accident prevention” means those risk management techniques that seek to reduce the frequency and/or severity of incidents

Definitions in 59A-5 and 59A-10

- "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.
- "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.

395.0197(4) RM Access to Records

- Person responsible for risk management shall have free access to all medical records.
- “Incident reports are part of the workpapers of the attorney defending ... and are subject to discovery, but are not admissible as evidence in court.”

397.0197(4) Continued: Development of Corrective Procedures

- Incident reports shall be used to develop categories of incidents which identify problem areas.
- Procedures shall be adjusted to correct the problem areas.

Chapter 395. 0197(5) and (7) FS and 59A-10.0065 F.A.C.: 15 Day Reports

- For purposes of reporting to the agency, the term “adverse incident” means an event over which health care personnel **could exercise control...**
- See page 10, FSASC RM white paper, 7th edition

AHCA surveyor will

- Ask about any Code 15 reports
- Timeliness of reporting within 15 days
- Review P&P about reporting Code 15 reports
- Review any re-admissions after being discharged
- Review records of any patients who expired in ASC
- Review records of transfers to higher level of care

395.0197(9) Sexual Misconduct

- RM shall investigate allegations
- Report every allegation to the administrator
- Notify the family or guardian of the victim of allegation
- Report to DOH every allegation of misconduct by a licensed practitioner

395.0197(10) Sexual Abuse Reporting

- Any witness or anyone possessing actual knowledge of act shall
 - (10) (a) Notify local police
 - (10) (b) Notify the risk manager and administrator

AHCA surveyor will

- Review any incident reports related to allegations of sexual misconduct
- Review P&P regarding investigation and reporting
- If allegation confirmed, what action was taken?
- Was family/guardian notified? DOH notified?
- Interview staff: do they know what to do if they hear allegation?

AHCA surveyor will

- Review any incident involving alleged sexual abuse
- Review P&P
- Ascertain if and when police were notified
- Determine if staff know what to do
- Ascertain knowledge of reporting requirements
- Is facility promoting safe culture and awareness?

59A-10.0055(3) RM review of incident reports

- The RM is responsible for
 - Reviewing all incident reports to identify trends or patterns
 - Develop recommendations for corrective actions, prevention education and training
- **Summary data** systematically maintained for **3** years

Note: retention of the incident reports is not specified

59A-10.055(3)(a) Summary Report to GB

- At least quarterly, RM shall provide a summary report to the governing body, which includes information about activities of RM

AHCA surveyor will

- Review report contents and who presents it
- Review GB agenda/minutes for RM reporting of summaries, safety issues, and reporting of current status of corrective actions and follow up

395.0197 Annual Report of Judgments

- (3) Each facility shall annually report to AHCA and DOH the name and judgments entered against each health care practitioner for which it assumes liability.
- (6) (a) Annual report summarizing incident reports.
 - Total number of adverse incidents
 - List of types of operations, procedures causing injuries
 - Types of injuries caused
 - Code number of licensee
 - Description of malpractice claims

395-0197(13) Agency Access to Records 59A-10.0055(13)

- AHCA has access to all records necessary to carry out review. Records are not available to the public except disciplinary proceedings by a licensing board if they occur.
- AHCA has access to all incident reporting and analysis, summary reports, evidence of corrective actions.

395.0197(9) Unlawful Coercion of Reporting Obligation

- Unlawful for any person to coerce, intimidate or preclude a risk manager from lawfully executing his or her reporting obligations.

Has you ever been afraid to report?

395.1012(1) Patient Safety Plan

- 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.

Note: 42 C.F.R. part 482.21 is QAPI for hospitals; same as 416.43 for surgery centers. See page 45+ in FSASC RM and Related Regulations white paper, 7th edition

AHCA surveyor will

- Review patient safety plan/QAPI plan
- Was plan implemented? If not, surveyor is to contact AHCA field office for further guidance.
 - Required evidence of QAPI activity
- Is information gathered used for QAPI and patient safety?

395.1012(2) Patient Safety Officer and Committee

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

AHCA surveyor will

- Confirm appointment of patient safety officer and committee
- Confirm one member is not employed or contracted
- Interview patient safety officer regarding role and responsibility
- Review composition of committee
- Review committee agenda and minutes
- Review committee involvement in evaluation of measures implemented

FS 395.1012(4) and 59A-35.115 F.A.C. Patient Safety Surveys

- Conduct Patient Safety Culture Surveys (PSCS).
- Conduct within 2 years of effective date of rule
- And, thereafter, every 2 years
- Report data to AHCA between June 1 and August 31 every two years. First report of data due in 2025

Patient Safety Culture Survey

- Anonymous responses
- All “staff members”: physicians, advanced practice/allied health staff, all employed staff including PRN who have been staff member for at least 6 months.
- AHCA Form 3130-8016
- Data Submission via “data entry tool” uploaded
- AHCA to publish survey data findings. All or part?

PSCS Results Related to RM and QI

- Communication among team and ability to speak up
- Team members express ideas and make suggestions
- Have time, training, and help when needed
- Processes are changed to improve care
- Management provides resources

Patient Safety Culture Surveys Resources

- AHCA Patient Safety Culture Survey System User Guide
 - https://ahca.myflorida.com/content/download/22052/file/PSCS_System_Guide_2022.pdf
- AHRQ: Agency for Healthcare Research and Quality
 - <https://www.ahrq.gov/sops/index.html>

Summary

- CMS Appendix L
- 395, Part I, Florida Statutes,
especially 395.0197 and 395.1012
- 59A-5 Florida Administrative Code
- 59A-10 Florida Administrative Code
- 59A-35.115 Florida Administrative Code

Q&A

sjones@aboutascscs.com



Ambulatory
Strategies Inc.

We Bring the Pieces Together

