

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: SB 434

INTRODUCER: Senator Harrell

SUBJECT: Ambulatory Surgical Centers

DATE: February 18, 2019

REVISED: _____

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|----|---------|----------------|-----------|--------------------|
| 1. | Looke | Brown | HP | Pre-meeting |
| 2. | _____ | _____ | AHS | _____ |
| 3. | _____ | _____ | AP | _____ |

I. Summary:

SB 434 amends s. 395.002, F.S., to allow a patient to stay in an ambulatory surgical center (ASC) for 24 hours, rather than requiring that a patient be admitted and discharged on the same working day.

The bill also amends s. 395.1005, F.S., to require the Agency for Health Care Administration (AHCA) in consultation with the Board of Medicine (BOM) and the Board of Osteopathic (BOOM) Medicine, to adopt rules for practitioners and facilities to ensure the safe and effective delivery of surgical care to children in ambulatory surgical centers. The bill specifies that an ASC may provide surgical care that requires a length of stay past midnight to children younger than 18 years of age only after the AHCA authorizes such procedures in rule.

The bill provides an effective date of July 1, 2019.

II. Present Situation:

Ambulatory Surgical Centers

An ASC is a facility that is not a part of a hospital and which has the primary purpose of providing elective surgical care in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight.¹

In Florida, ambulatory procedures are performed in two settings, hospital-based outpatient facilities and freestanding ASCs. As of January 2019, there are 458 ASCs and 308 licensed

¹ Section 395.002(3), F.S.

hospitals in Florida. Of the 308 licensed hospitals, 212 report providing hospital-based outpatient surgical services.²

Between April 2017 and March 2018, there were 3,049,558 visits to ASCs in Florida.³ Hospital outpatient facilities accounted for 1,419,020 visits (46.5 percent) and freestanding ASCs accounted for 1,622,013 visits (53.5 percent). Freestanding ASC average charges range from \$3,516 to \$9,347 and hospital-based ASC average charges range from \$10,522 to \$34,291 for the same time period.⁴ According to 2017 utilization data submitted to the AHCA, less than 5 percent of all outpatient surgical visits at hospitals and ASCs were for pediatric patients (age 0 to 17 years).⁵

| Age Group | Visits | % of Visits |
|------------------------------|-----------|-------------|
| Age 0 (Less than 1 year old) | 10,348 | 0.34% |
| 1 – 4 years | 48,802 | 1.60% |
| 5 – 9 years | 37,398 | 1.22% |
| 10 – 14 years | 25,958 | 0.85% |
| 15 – 17 years | 24,992 | 0.82% |
| Total Pediatrics | 147,498 | 4.83% |
| Total All Ages | 3,056,789 | 100% |

ASC Licensure

ASCs are licensed and regulated by the AHCA under the same regulatory framework as hospitals.⁶ Applicants for ASC licensure must submit certain information to the AHCA prior to accepting patients for care or treatment, including:

- An affidavit of compliance with fictitious name;
- Registration of articles of incorporation; and
- The applicant’s zoning certificate or proof of compliance with zoning requirements.⁷

Upon receipt of an initial ASC application, the AHCA is required to conduct a survey to determine compliance with all laws and rules. Applicants are required to provide certain information during the initial inspection, including:

- Governing body bylaws, rules, and regulations;
- A roster of registered nurses and licensed practical nurses with current license numbers;
- A fire plan; and
- A comprehensive emergency management plan.⁸

² Agency for Health Care Administration, *Senate Bill 434 Analysis* (Jan. 24, 2019) (on file with the Senate Committee on Health Policy).

³ Agency for Health Care Administration, *Florida Health Finder*, <http://www.floridahealthfinder.gov/CompareCare/CompareFacilities.aspx> (last viewed Feb. 14, 2017).

⁴ Id.

⁵ Id. note 4

⁶ Sections 395.001-395.1065, F.S., and part II, ch. 408, F.S.

⁷ Rule 59A-5.003(4), F.A.C.

⁸ Rule 59A-5.003(5), F.A.C.

Rules for ASCs

Pursuant to s. 395.1055, F.S., the AHCA is authorized to adopt rules for hospitals and ASCs. Separate standards may be provided for general and specialty hospitals, ASCs, mobile surgical facilities, and statutory rural hospitals, but the rules for all hospitals and ASCs must include minimum standards for ensuring that:

- A sufficient number of qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care;
- Infection control, housekeeping, sanitary conditions, and medical record procedures are established and implemented to adequately protect patients;
- A comprehensive emergency management plan is prepared and updated annually;
- Licensed facilities are established, organized, and operated consistent with established standards and rules; and
- Licensed facility beds conform to minimum space, equipment, and furnishing standards.

Rule 59A-5 of the Florida Administrative Code implements the minimum standards for ASCs. Those rules require policies and procedures to ensure the protection of patient rights.

Staff and Personnel Rules

ASCs are required to have written policies and procedures for surgical services, anesthesia services, nursing services, pharmaceutical services, laboratory services, and radiologic services. In providing these services, ACSs are required to have certain professional staff available, including:

- A qualified person responsible for the daily functioning and maintenance of the surgical suite;
- 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, who must be in the center during the anesthesia and post-anesthesia recovery period until all patients are cleared for discharge;
- A registered professional nurse who is responsible for coordinating and supervising all nursing services;
- A registered professional circulating nurse for a patient during that patient's surgical procedure; and
- A registered professional nurse who must be in the recovery area at all times when a patient is present.⁹

Infection Control Rules

ASCs are required to establish an infection control program involving members of the medical, nursing, and administrative staff. The program must include written policies and procedures reflecting the scope of the infection control program. The written policies and procedures must be reviewed at least every two years by the infection control program members. The infection control program must include:

- Surveillance, prevention, and control of infection among patients and personnel;
- A system for identifying, reporting, evaluating, and maintaining records of infections;

⁹ Rule 59A-5.0085, F.A.C.

- Ongoing review and evaluation of aseptic, isolation, and sanitation techniques employed by the ASC; and
- Development and coordination of training programs in infection control for all personnel.¹⁰

Emergency Management Plan Rules

ASCs are required to develop and adopt a written comprehensive emergency management plan for emergency care during an internal or external disaster or emergency. The ASC must review the plan and update it annually.¹¹

Accreditation

ASCs may seek voluntary accreditation by an accrediting organization whose standards are determined by the AHCA to be comparable to state licensure requirements. The AHCA is required to conduct a licensure inspection survey for non-accredited ASCs. The AHCA is authorized to accept survey reports of accredited ASCs from accrediting organizations if the standards included in the survey report are determined to document that the ASC is in substantial compliance with state licensure requirements. The AHCA is required to conduct annual validation inspections on a minimum of five percent of the ASCs which were inspected by an accreditation organization.¹²

The AHCA is required to conduct annual life safety inspections of all ASCs to ensure compliance with life safety codes and disaster preparedness requirements. However, the life-safety inspection may be waived if an accreditation inspection was conducted on an ASC by a certified life safety inspector and the ASC was found to be in compliance with the life safety requirements.¹³

Medicare Requirements

ASCs are required to have an agreement with the federal Centers for Medicare & Medicaid Services (CMS) to participate in Medicare. ASCs are also required to comply with specific conditions for coverage. The CMS defines “ASC” as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and for whom the expected duration of services would not exceed 24 hours following an admission.¹⁴

The CMS may deem an ASC to be in compliance with all of the conditions for coverage if the ASC is accredited by a national accrediting body or licensed by a state agency and if the CMS determines that such accreditation or licensure provides reasonable assurance that the conditions for coverage are met.¹⁵ All of the CMS conditions for coverage requirements are specifically required in Rule 59A-5 of the Florida Administrative Code, and apply to all ASCs in Florida. The conditions for coverage require ASCs to have a:

¹⁰ Rule 59A-5.011, F.A.C.

¹¹ Rule 59A-5.018, F.A.C.

¹² Rule 59A-5.004, F.A.C.

¹³ Id.

¹⁴ 42 C.F.R. s. 416.2

¹⁵ 42 C.F.R. s. 416.26(a)(1)

- Governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation;
- Quality assessment and performance improvement program;
- Transfer agreement with one or more acute care general hospitals, which will admit any patient referred who requires continuing care;
- Disaster preparedness plan;
- Organized medical staff;
- Fire control plan;
- Sanitary environment;
- Infection control program; and
- Procedure for patient admission, assessment and discharge.

American College of Surgeons: Optimal Resources for Children's Surgical Care v. 1

The American College of Surgeons (ACS) was founded in 1913 on the basic principles of improving the care of surgical patients and strengthening the education of surgeons. With these principles in mind, the ACS Children's Surgery Verification Committee was created in 2015 to continue, on a permanent basis within the ACS, the work of the ad hoc Task Force for Children's Surgical Care. This group was first convened in 2012. The recommendations of this task force are contained in the document *Optimal Resources for Children's Surgical Care v. 1*.¹⁶

Specific to ASCs, the report found that:

Children's ambulatory surgical centers must have treatment protocols for resuscitation, transfer protocols, and data reporting and must participate in systems for performance improvement. Children's ambulatory centers must have good working relationships and be fully integrated with a Level I, II, or III inpatient children's surgical center¹⁷ to be verified in this program... It is essential for the children's ambulatory surgical center to have the involvement of one or more committed and appropriately trained pediatric health care providers to provide leadership and sustain the integration with other relevant components of an integrated children's health care system.¹⁸

¹⁶ American College of Surgeons, *Optimal Resources for Children's Surgical Care v.1*, available at https://www.facs.org/~media/files/quality%20programs/csv/acs%20csv_standardsmanual.ashx, (last visited on Feb. 14, 2019).

¹⁷ The report details such relationship on page 19. "*Ideally, one hospital, typically a Level I center, would be looked upon as the resource leader within a given region. This hospital would serve as a resource to all other hospitals within the system. Outside major population centers, a Level II center may serve as the lead hospital for extended geographic areas. In some rural areas, where population densities are low and distances great, a Level III center may be the only resource for miles. Ambulatory surgical centers are considered separately but in any system will have clearly identified relationships and demonstrable integration with one or more verified Level I, II, or III children's inpatient facilities.*" Id.

¹⁸ Id.

III. Effect of Proposed Changes:

SB 434 amends s. 395.002, F.S., to allow a patient to stay in an ASC for 24 hours, rather than requiring that a patient be admitted and discharged on the same working day. This change complies with federal CMS requirements for an ASC.¹⁹

The bill also amends s. 395.1005, F.S., to require the AHCA to, in consultation with the BOM and the BOOM, adopt rules for practitioners and facilities to ensure the safe and effective delivery of surgical care to children in ambulatory surgical centers. The bill requires the rules to establish minimum standards for pediatric patient care treatment practices including, but not limited to, requirements for:

- Surgical risk assessment;
- Anesthetic care;
- Resuscitation;
- Transfer agreements; and
- Training and certification requirements for pediatric health care providers.

The rules must also be consistent with the American College of Surgeons' 2015 standards document entitled "Optimal Resources for Children's Surgical Care." The bill specifies that an ASC may provide surgical care that requires a length of stay past midnight to children younger than 18 years of age only after the AHCA authorizes such procedures in rule.

The bill provides an effective date of July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

¹⁹ 42 C.F.R. s. 416.2.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

SB 434 may have an indeterminate positive fiscal impact on patients seeking surgical services if such patients are able to obtain the surgical services at an ASC for lower costs than the costs of receiving comparable services at a hospital.

The bill may have an indeterminate negative fiscal impact on hospitals if more patients choose to have their surgical procedures performed in an ASC.

C. Government Sector Impact:

The bill has an indeterminate fiscal impact on the Florida Medicaid program.

ASCs are reimbursed by Medicaid through an outpatient prospective payment reimbursement methodology called Enhanced Ambulatory Patient Groups (EAPGs). EAPGs categorize outpatient services and procedures into groups for payment based on clinical information present on an outpatient claim. ASCs are not currently reimbursed for an overnight stay. If ASCs are allowed to bill for an overnight stay through the EAPG system, there could potentially be an increase in the volume of ASC claims and there is the potential for an increase in ASC expenditures. However, these potential increased claim volumes and expenditures may be offset due to a decrease in claims and expenditures for services provided in the outpatient or inpatient hospital setting.²⁰

VI. Technical Deficiencies:

None.

VII. Related Issues:

SB 434 requires that the AHCA, in consultation with the BOM and the BOOM, adopt rules that establish requirements for practitioners to ensure the safe and effective delivery of surgical care to children in ASCs. In general, regulatory authority and rulemaking related to practitioner standards is delegated by the Florida Statutes to the Department of Health (DOH) and the various regulatory boards housed within the DOH²¹ while the AHCA has rulemaking authority over facility regulation and licensure.²² As such, it may be more appropriate to require the DOH, or the BOM and the BOOM, to adopt rules for practitioner standards related to pediatric surgical care in ASCs and to limit the AHCA's rulemaking authority to facility standards for pediatric care in ASCs.

²⁰ *Supra* note 2

²¹ See s. 20.43(1)(g), F.S.

²² See s. 20.42(3), F.S.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 395.002 and 395.1055.

IX. Additional Information:

A. **Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. **Amendments:**

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
