HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 25 Ambulatory Care Services
SPONSOR(S): Health Market Reform Subcommittee, Stevenson
TIED BILLS: **IDEN./SIM. BILLS:** SB 1540

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Market Reform Subcommittee	9 Y, 3 N, As CS	Royal	Crosier
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Pursuant to s. 395.002(3), F.S., an ambulatory surgical center (ASC) is a facility that is not part of a hospital, the primary purpose of which is to provide elective surgical care, in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight. The bill changes the allowable length of stay in an ASC from less than one working day to no more than 48 hours. The bill also allows ASCs to provide advanced birth services such as planned low-risk cesarean deliveries, trial of labor after cesarean delivery for screened patients who qualify and vaginal deliveries for laboring patients from the beginning of the 37th week of gestation through the end of the 41st week of gestation if they meet certain quality standards.

The bill creates a new licensure category for a Recovery Care Center (RCC), defined as a facility the primary purpose of which is to provide recovery care services, to which a patient is admitted and discharged within 72 hours, and which is not part of a hospital. The bill defines recovery care services as:

- Postsurgical and post-diagnostic medical and general nursing care to patients for whom acute hospitalization is not required and an uncomplicated recovery is reasonably expected; and
- Postsurgical rehabilitation services.

Recovery care services do not include intensive care services, coronary care services, or critical care services.

The bill requires all patients to be certified as medically stable and not in need of acute hospitalization by their attending or referring physician prior to admission to a RCC. A patient may receive recovery care services in a RCC upon:

- Discharge from an ASC after surgery;
- Discharge from a hospital after surgery or other treatment; or
- Receiving out-patient medical treatment such as chemotherapy.

The new RCC license is modeled after the current licensing procedures for hospitals and ASCs, subjecting RCCs to similar regulatory standards, inspections, and rules. RCCs must have emergency care and transfer protocols, including transportation arrangements, and a referral or admission agreement with at least one hospital.

The bill has an indeterminate, but likely insignificant, fiscal impact on the Agency for Health Care Administration.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Ambulatory Surgical Centers (ASCs)

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

ASCs are licensed and regulated by the Agency for Health Care Administration (AHCA) under the same regulatory framework as hospitals.[2] Currently, there are 458 licensed ASCs in Florida.[3] Of the 308 licensed hospitals in the state, 210 report providing outpatient surgical services.[4]

In 2017, there were 1,636,976 visits to ASCs in Florida.[5] Visits occur at hospital-based outpatient facilities or freestanding ASCs. Hospital-based outpatient facilities accounted for 47 percent and freestanding ASCs accounted for 53 percent of the total number of visits.[6] Of the $44 billion in total charges for ambulatory procedures in 2017, hospital-based outpatient facilities accounted for 77 percent of the charges, while freestanding ASCs accounted for 23 percent.[7] The average charge at the hospital-based facilities, $23,951, was more than three times larger than the average charge at the freestanding ASCs, $6,208.[8]

In Florida, for 2017, the top five medical procedures, by total charges, at a freestanding ASC and hospital-based outpatient facility were:

- Esophagogastroduodenoscopy;
- Cataract surgery with IOL implant;
- Colonoscopy and biopsy;
- Diagnostic colonoscopy; and
- Colonoscopy with lesion removal.[9]

[1] S. 395.002(3), F.S.
[2] SS. 395.001-.1065, F.S., and Part II, Chapter 408, F.S.
[3] Agency for Health Care Administration, *Facility/Provider Locator, Ambulatory Surgical Center*, available at http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (last viewed January 11, 2019)
[4] Id.
[5] Agency for Health Care Administration, *Ambulatory (Outpatient) Surgery Query Results, available at* http://www.floridahealthfinder.gov/QueryTool/QTResults.aspx?T=O (last viewed December 11, 2018).
[6] Agency for Health Care Administration, *Ambulatory (Outpatient) Surgery Query Results, By Facility Type,* available at http://www.floridahealthfinder.gov/QueryTool/QTResults.aspx?T=O (last viewed December 11, 2018).
[7] Id.
[8] Id.
[9] Agency for Health Care Administration, *Ambulatory (Outpatient) Surgery Query Results; By Current Procedural Terminology Code and Facility Type,* available at http://www.floridahealthfinder.gov/QueryTool/QTResults.aspx?T=O (last viewed December 11, 2018).

The following chart shows the total number of visits for each of the top five medical procedures and the average charge for each procedure in 2017[10]:

Procedure	Total Visits	Average Charge
Esophagogastroduodenoscopy	254,537	$5,540
Cataract surgery with IOL implant	250,096	$4,829
Colonoscopy and biopsy	192,133	$4,836
Diagnostic colonoscopy	183,785	$3,605
Colonoscopy with lesion removal	166,185	$5,041

In 2017, payment for visits to freestanding ASCs and hospital-based outpatient facilities was made mainly by commercial insurance and regular Medicare. Commercial insurance paid $18 billion or 41 percent of charges, while Medicare paid $12 billion or 27 percent of charges.[11] The next three top payer groups, Medicare managed care, Medicaid managed care, and self-pay, accounted for a combined $10.8 billion or 24 percent of charges.[12]

Federal Requirements

Medicare

ASCs are required to have an agreement with the Centers for Medicare and Medicaid Services (CMS) to participate in Medicare. ASCs are also required to comply with specific conditions for coverage. CMS defines an "ASC" as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours[13] following an admission.[14]

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 that CMS determines provides reasonable assurance that the conditions are met.[15] All of the CMS conditions for coverage requirements are included in Chapter 59A-5, F.A.C., and apply to all ASCs.

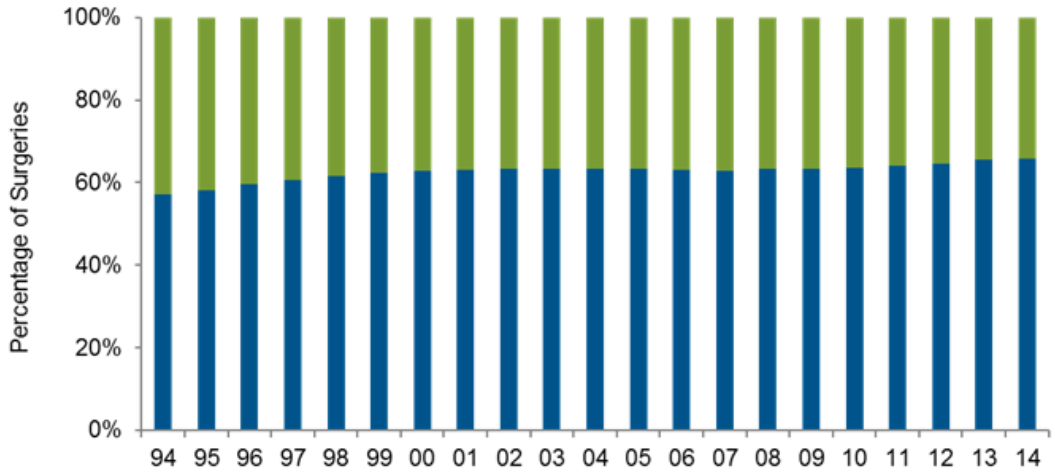
ASC Cost of Care and Quality Outcomes

There has been tremendous growth in the outpatient surgery segment of health care in the U.S., facilitated by advances in technology. From 1981 through 2005, the number of outpatient surgeries increased ten-fold.[16] Outpatient surgeries now account for more than 80 percent of all surgeries completed in the U.S.[17] Research shows that procedures in ASCs are 25 percent faster on average

[10] Id.
[11] Agency for Health Care Administration, *Ambulatory (Outpatient) Surgery Query Results; By Principal Payer* http://www.floridahealthfinder/gov/QueryTool/QTResults.aspx?T=O (last viewed December 11, 2018).
[12] Id.
[13] State Operations Manual Appendix L, *Guidance for Surveyors: Ambulatory Surgical Centers* (Rev. 137, 04-01-15), available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_l_ambulatory.pdf (last viewed February 5, 2017); Exceeding the 24-hour time frame is expected to be a rare occurrence and each rare occurrence is expected to be demonstrated to have been something which ordinarily could not have been foreseen. Not meeting this requirement constitutes condition-level noncompliance with regulations. In addition, review of the cases that exceed the time frame may also reveal noncompliance with conditions for coverage related to surgical services, patient admission and assessment, and quality assurance/performance improvement.
[14] 42 C.F.R. §416.2
[15] 42 C.F.R. §416.26(a)(1)
[16] Munnich E. and Parente S., *Procedures Take Less Time at Ambulatory Surgery Centers, Keeping Costs Down and Ability to Meet Demand Up*, Health Affairs 33;5: 764-69, 764 (2014).
[17] Munnich E. and Parente S., *Returns to Specialization: Evidence from the Outpatient Surgery Market*, pg. 1 (April 2014), available at https://louisville.edu/faculty/elmunn01/Munnich_Parente_ASC_Quality.pdf (last viewed December 11, 2018); Chart data is from an analysis of the American Hospital Association Annual Survey data from 2014 for community hospitals.

than hospital-based outpatient facilities, driven mainly by technological, system and process efficiencies in ASCs.[18]

Percentage of Inpatient vs. Outpatient Surgeries 1994-2014[19]



The increased use of outpatient surgery may help lower health care costs and meet increased patient demand for outpatient surgery, which is frequently more convenient for patients and their families and allows for less stressful recovery.

ASC Cost of Care

Despite the volume of outpatient surgeries today, there is little research on cost savings associated with ASCs.[20] The study that found procedures in ASCs were completed 25 percent faster than the same procedures in hospital-based outpatient facilities also found that ASC efficiency generated a savings of $363-$1,000 per outpatient case.[21]

In 2014, the Office of the Inspector General for the U.S. Department of Health and Human Services studied the cost efficiency associated with Medicare beneficiaries obtaining surgical services in an outpatient setting.[22] The OIG found that Medicare saved almost $7 billion during calendar years (CYs) 2007 through 2011 and could potentially save $12 billion from CYs 2012 through 2017 due primarily to the lower rates for surgical procedures done in ASCs.[23] The OIG also found that Medicare beneficiaries realized savings of $2 billion in the form of reduced co-payment obligations in the ASC setting.[24] In addition, Medicare could generate savings of as much as $15 billion for CYs 2012 through 2017 if CMS reduced hospital outpatient department payment rates for ASC-approved procedures to ASC payment levels.[25] Beneficiaries, in turn, would save $3 billion.[26]

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[18] Trentman T., et al, *Outpatient surgery performed in an ambulatory surgery center versus a hospital: comparison of perioperative time intervals*, Amer. J. Surgery 100;1: 64-67 (July 2010).
[19] Shapiro, M.D., slide 5, January 25, 2017 (on file with Health Innovation Subcommittee staff).
[20] Professor Elizabeth L. Munnich, University of Louisville, Louisville, Kentucky, Presentation on Measuring Cost and Quality in Ambulatory Surgical Centers-Health Innovation Subcommittee, slide 2, January 25, 2017 (on file with Health Innovation Subcommittee staff).
[21] Supra, FN 16 at pg. 767; The savings calculation is based on the estimated charges for operating room time, set at $29 to $80 per minute, not including surgeon and anesthesia provider fees. Macario A. *What does one minute of operating room time cost?* J Clin Anesth. 2010;22(4):233–6.
[22] U.S. Department of Health and Human Services, Office of Inspector General, *Medicare and Beneficiaries Could Save Billions If CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates*, Audit A-05-12-00020 (April 16, 2014).
[23] Id. at pg. i.
[24] Id. at pg. ii.
[25] Id.
[26] Id.

A review of commercial medical claims data found that U.S. healthcare costs are reduced by more than $38 billion per year due to the availability of ASCs for outpatient procedures.[27] More than $5 billion of the cost reduction accrued to the patient through lower deductible and coinsurance payments.[28] This cost reduction is driven by the fact that, in general, ASC prices are significantly lower than hospital outpatient department prices for the same procedure in all markets, regardless of payer. The study also looks at the potential savings that could be achieved if additional procedures were redirected to ASCs. As much as $55 billion could be saved annually depending on the percentage of procedures that migrate to ASCs and the mix of ASCs selected instead of HOPDs.[29]

An analysis by the Ambulatory Surgery Center Association of 2014 data from the Center for Medicaid and Medicare Services focused on the impact of Florida ASCs to Medicare. Specifically, the analysis found:

- Medicare saved more than $84 million on cataract procedures because beneficiaries elected to have those procedures performed in an ASC.
- Florida patients saved more than $23.4 million by having upper GI procedures in an ASC.
- Medicare saved an additional $42.6 million on colonoscopies performed in ASCs.[30]

ASC Quality Outcomes

The body of evidence shows that patients undergoing outpatient surgery in an ASC have the same or better outcomes as patients undergoing surgery at a hospital-based outpatient department.[31] Another study showed that patients who underwent a high volume procedure in an ASC were less likely than those treated in a hospital-based outpatient department to visit an ER or be admitted to the hospital following surgery.[32] The finding held true across timeframe since surgery and for low and high risk patients. Researchers concluded that ASCs provide high volume services more efficiently that hospital-based outpatient departments, but not at the expense of quality of care.[33]

One study found patient satisfaction with care received at ASCs across the country measured at 92 percent.[34]

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[27] Healthcare Bluebook and HealthSmart, *Commercial Insurance Cost Savings in Ambulatory Surgery Centers*, page 7 (June 2016), available at http://www.ascassociation.org/asca/communities/community-home/librarydocuments/viewdocument?DocumentKey=61197e80-d852-4004-860a-2424968b005b (last viewed December 13, 2018).
[28] Id.
[29] Id.
[30] Supra, FN 20, slide 8.
[31] Office of Program Policy and Government Accountability, Research Memorandum, *Ambulatory Surgical Centers and Recovery Care Centers*, January 19, 2016 (on file with Health Innovation Subcommittee staff). The OPPAGA research literature review found nine studies supporting the conclusion that ASCs provide more timely service to patients and have low rates of unexpected safety events. The review also found five studies concluding that the increase in patient volume to ASCs was not associated with an increase in hospital admissions or patient mortality. *Outpatient Surgery Performed in an Ambulatory Surgery Center Versus a Hospital: Comparison of Perioperative Time Intervals* (Trentman et al., 2010*); A Comparative Study of Quality Outcomes in Freestanding Ambulatory Surgery Centers and Hospital-Based Outpatient Departments: 1997-2004* (Chukmaitov et al., 2008); *Comparing Quality at an Ambulatory Surgery Center and a Hospital-Based Facility: Preliminary Findings* (Grisel and Arjmand, 2009); *Ambulatory Surgery Centers and Their Intended Effects on Outpatient Surgery* (Hollenbeck et al., 2015); *Changing Access to Emergency Care for Patients Undergoing Outpatient Procedures at Ambulatory Surgery Centers: Evidence From Florida* (Neuman et al., 2011); and *Hospital-Based, Acute Care After Ambulatory Surgery Center Discharge* (Fox et al., 2014).
[32] Supra, FN 18 at pgs. 26-29; Fleisher LA, Pasternak LR, Herbert R, Anderson GF. *Inpatient hospital admission and death after outpatient surgery in elderly patients: importance of patient and system characteristics and location of care*. Arch Surg. 2004 Jan;139(1):67-72.
[33] Supra, FN 20 at slide 8.
[34] *Press Ganey Outpatient Pulse Report 2008*. Represents the experiences of 1,039,289 patients treated at 1,218 facilities nationwide between January 1 and December 31, 2007.

Out-Hospital-Births

Out-of-hospital births have increased from 0.87% of U.S. births in 2004 to 1.36% of U.S. births in 2012, its highest level since 1975.[35] In 2012, 66% of out-of-hospital births occurred at home and 29% occurred in a freestanding birth center.[36]

Florida licenses birth centers, which is any facility, institution, or place, which is not an ambulatory surgical center, a hospital or in a hospital, in which births are planned to occur away from the mother's usual residence following a normal, uncomplicated, low-risk pregnancy.[37] Birth centers are licensed and regulated by the Agency for Health Care Administration (AHCA) under ch. 383. F.S., and part II of ch. 408, F.S.

A birth center may only accept those patients who are expected to have normal pregnancies and deliveries; and prior to being accepted for care, the patient must sign an informed consent form.[38] A mother and her infant must be discharged from a birth center within 24 hours after giving birth, except when:[39]

- The mother is in a deep sleep at the end of the 24-hour period; in which case, the mother must be discharged as soon after waking as feasible; or
- The 24-hour period is completed during the middle of the night.

A birth center must file a report with AHCA within 48 hours of the birth describing the circumstances and the reasons for the decision, if a mother or infant must remain in the birth center for longer than 24 hours after giving birth for a reason other than those listed above.[40]

Birth centers must ensure that its patients have adequate prenatal care and must maintain records of prenatal care for each client and must make the records available during labor and delivery.[41]

Birth centers may perform simple laboratory tests and collect specimens for tests that are requested pursuant to its protocol.[42]

Birth centers may perform surgical procedures that are normally performed during uncomplicated childbirths, such as episiotomies and repairs. Birth centers may not perform operative obstetrics or caesarean sections.[43]

Birth centers may not administer general and conduction anesthesia. Systemic analgesia and local anesthesia for pudendal block and episiotomy repair may be administered if procedures are outlined by the clinical staff and performed by personnel with statutory authority to do so.[44]

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[35] Marian F. MacDorman, Ph.D.; T.J. Mathews, M.S.; and Eugene Declercq, Ph.D, *Trends in Out-of-Hospital Births in the United States, 1990–2012*. NCHS Data Brief No. 144, March, 2014. Available at: https://www.cdc.gov/nchs/products/databriefs/db144.htm (Last visited January 12, 2017).
[36] Id.
[37] Section 383.302(2), F.S.; Section 383.302(8), F.S. defines "low-risk pregnancy" as a pregnancy which is expected to result in an uncomplicated birth, as determined through risk criteria developed by rule of the department, and which is accompanied by adequate prenatal care.
[38] Section 383.31, F.S. The informed consent form must advise the patient of the qualifications of the clinical staff, the risks related to out-of-hospital births, the benefits of out-of-hospital births, and the possibility of referral or transfer if complications arise during pregnancy or childbirth with additional costs for services rendered (r. 59A-11.010, F.A.C.)
[39] Section 383.318(1), F.S., and Rule 59A-11.016(6), F.A.C.
[40] Section 383.318(1), F.S.
[41] Section 383.312, F.S.
[42] Section 383.313, F.S.
[43] Id.
[44] Id.

Birth centers may not inhibit, simulate, or augment labor with chemical agents during the first or second stage of labor unless prescribed by personnel with the statutory authority to do so and in connection with and prior to an emergency transport.[45]

Birth centers must provide postpartum care and evaluation that includes physical examination of the infant, instillation of a prophylactic into the eyes of the infant within one hour after birth, metabolic screening tests, referral to pediatric care sources, maternal postpartum assessment, family planning, referral to secondary or tertiary care, and instruction in child care, including immunization, breastfeeding, safe sleep practices, and possible causes of Sudden Unexpected Infant Death.[46]

Birth centers must have the equipment necessary to provide low-risk maternity care and readily available equipment to initiate emergency procedures in life-threatening events to a mother and baby.[47] A birth center must transfer the patient to a hospital if unforeseen complications arise during labor.[48] Each facility must have an arrangement with a local ambulance service for the transport of emergency patients to a hospital, which must be documented in the facilities policy and procedures manual.[49]

Birth centers must have written consultation agreements with each consultant who has agreed to provide advice and services to the birth center.[50] A consultant must be a licensed medical doctor or licensed osteopathic physician who is either certified or eligible for certification by the American Board of Obstetrics and Gynecology, or has hospital obstetrical privileges.[51] Consultation may be provided onsite or by telephone.[52]

Birth centers must ensure their clients and their families are fully informed of the following policies and procedures of the birth center:

- The selection of clients.
- The expectation of self-help and family/client relationships.
- The qualifications of the clinical staff.
- The transfer to secondary or tertiary care.
- The philosophy of childbirth care and the scope of services.
- The customary length of stay after delivery.
- The clients shall be prepared for childbirth and childbearing by education in:
- The course of pregnancy and normal changes occurring during pregnancy.
- The need for prenatal care.
- Nutrition, including encouragement of breastfeeding.
- The effects of smoking and substance abuse.
- Labor and delivery.
- The care of the newborn to include safe sleep practices and the possible causes of Sudden Unexpected Infant Death.

Birth centers must ensure its clinical records include the following information:

- Identifying information.
- Risk assessments.
- Information relating to prenatal visits.
- Information relating to the course of labor and intrapartum care.

[45] Id.
[46] Section 383.318(3), F.S.
[47] Section 383.308(2)(a), F.S.
[48] Section 383.316, F.S.
[49] Id.
[50] Section 383.315(1), F.S.
[51] Section 383.302(4), F.S.
[52] Section 383.315(2), F.S.

- Information relating to consultation, referral, and transport to a hospital.
- Newborn assessment, APGAR score, treatments as required, and followup.
- Postpartum followup.

Birth centers must also make clinical records available at the time of admission, when transfer of care is necessary, and for inspection by AHCA. Birth centers must also audit clinical records no less than every 3 months to evaluate care outcomes and analyze at least semi-annually statistics on maternal and perinatal morbidity and mortality, maternal risk, consultant referrals, and transfers of care. Birth centers must make the results of such audits available for inspection by the public and AHCA.

Recovery Care Centers

Recovery care centers (RCCs) are entities that provide short-term nursing care, support, and pain control for patients that do not require acute hospitalization.[53] RCC patients are typically healthy persons that have had elective surgery. RCCs can be either freestanding or attached to an ASC or hospital. In practice, RCCs typically provide care to patients transferred from an ASC following surgery, which allows the ASC to perform more complex procedures.[54]

RCCs are not eligible for Medicare reimbursement.[55] However, RCCs may receive payments from Medicaid programs and commercial payers.

Three states, Arizona, Connecticut, and Illinois, have specific licenses for RCCs.[56] Other states license RCCs as nursing facilities or hospitals.[57] One study found that eighteen states allow RCCs to have stays over 24 hours, usually with a maximum stay of 72 hours.[58]

[53] Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare Payment for Post-Surgical Recovery Care Centers*, (2000), available at https://permanent.access.gpo.gov/lps20907/nov2000medpay.pdf (last viewed December 11, 2018).
[54] Id. at pg. 4.
[55] Supra, FN 53.
[56] Ariz. Rev. Stat. Ann.§§ 36-448.51-36-448.55; Conn. Conn. Agencies Regs § 19A-495-571; 210 Ill. Comp. Stat. Ann. 3/35. In 2009, Illinois limited the total number of RCCs to those centers holding a certificate of need for beds as of January 1, 2008. The five existing RCCs were grandfathered in and continue to be regulated under 77 Ill. Admin. Code 210.
[57] Sandra Lee Breisch, *Profits in Short Stays*, Am. Acad. of Orthopedic Surgeons Bulletin (June, 1999), available at http://www2.aaos.org/bulletin/jun99/asc.htm (last viewed December 11, 2018).
[58] Supra FN 53, at pg. 4 (citing Federated Ambulatory Surgery Association, Post-Surgical Recovery Care, (2000)).

Comparison of RCC Regulations in Arizona, Connecticut, and Illinois

Regulation	Arizona[59]	Connecticut[60]	Illinois[61]
Licensure Required	X	X	X
Written Policies	X	X	X
Maintain Medical Records	X	X	X
Patient's Bill of Rights	X	X	X
Allows Freestanding Facility or Attached	Not Addressed.	X	X
Length of Stay	Not Addressed.	Expected 3 days; maximum 21 days	Expected 48 hours; maximum 72 hrs
Emergency Care Transfer Agreement	For care not provided by the RCC.	With a hospital and an ambulance service.	With a hospital within 15 minutes travel time.
Prohibited Patients	Patients needing: • Intensive care • Coronary care • Critical care	Patients needing: • Intensive care • Coronary care • Critical care	• Patients with chronic infectious conditions • Children under age 3
Prohibited Services	• Surgical • Radiological • Pediatric • Obstetrical	• Surgical • Radiological • Pre-adolescent pediatric • Hospice • OB (over 24-week gestation) • IV-therapy (non-hospital RCC)	Blood administration (only blood products allowed)
Required Services	• Laboratory • Pharmaceutical • Food	• Pharmacy • Dietary • Personal care • Rehabilitation • Therapeutic • Social work	• Laboratory • Pharmaceutical • Food • Radiological
Bed Limit	Not Addressed.	Not Addressed.	20
Required Staff	• Governing authority • Administrator	• Governing body • Administrator	Consulting committee
Required Medical Personnel	• At least two physicians • Director of nursing	• Medical advisory board • Medical director • Director of nursing	• Medical director • Nursing supervisor
Required Personnel When Patients Are Present	• Director of nursing 40 hours per week • One RN • One other nurse	• Two persons for patient care	• One RN • One other nurse

[59] Ariz. Rev. Stat. Ann. §§ 36-448.51-36-448.55; Ariz. Admin. Code §§ R9-10-501-R9-10-518 (updated in 2013, formerly R9-10-1401-R9-10-1412).
[60] Conn. Agencies Regs. § 19A-495-571.
[61] 210 Ill. Comp. Stat. Ann. 3/35; Ill. Admin. Code tit. 77, §§ 210.2500 & 210.2800.

Effect of Proposed Changes

ASCs

Pursuant to s. 395.002(3), F.S., patients receiving services in an ASC must be discharged on the same working day that they were admitted and cannot stay overnight. Medicare reimbursement policy limits the length of stay in an ASC to 24 hours following admission. The bill amends s. 395.002(3), F.S., to permit a patient to stay at an ASC for no longer than 48 hours.

Advanced Birth Services

The bill allows ASCs to provide advanced birth services. The bill defines advanced birth services to include:

- Planned low-risk cesarean deliveries.
- Trial of labor after cesarean delivery for screened patients who qualify.
- Vaginal deliveries for laboring patients from the beginning of the 37th week of gestation through the end of the 41st week of gestation.

The bill allows ASCs that provide advanced birth services to also provide postpartum sterilization, circumcisions, and other surgical procedures normally performed during uncomplicated childbirths such as episiotomies and repairs.

ASCs must meet the following requirements in order to provide advanced birth services

- Be operated and staffed 24 hours per day, 7 days per week.
- Employ or maintain an agreement with at least one board-certified obstetrician that must be present in the center at all times during which a patient is in active labor in the center to attend deliveries, respond to emergencies and, when necessary, be available to perform cesarean deliveries.
- Employ a registered nurse who is present in the facility at all times and has the ability to stabilize and facilitate the transfer of patients and newborn infants when appropriate.
- Have at least one properly equipped, dedicated surgical suite for the performance of cesarean deliveries.
- Enter into a written agreement with a blood bank for emergency blood bank services.
- Have written protocols for the management of obstetrical hemorrhage that include provisions of emergency blood transfusions.
- Have a clinical laboratory on-site that is certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder.
- Make the transportation arrangements with a local ambulance service licensed under chapter 401 for the transport of emergency patients to a hospital.
- Must identify neonatal-specific transportation services, including ground and air ambulances.
- Enter into a written transfer agreement with a local hospital for the transfer and admission of emergency patients to the hospital or a written agreement with an obstetrician who has hospital privileges to provide coverage at all times and who has agreed to accept the transfer of the facility's patients.
- Ensure that a patient signs a client informed-consent form before being accepted for care that informs the client of the benefits and risks related to childbirth outside a hospital.
- Inform clients and their families of the policies and procedures of the facility.
- Provide postpartum care.
- Ensure that clients have adequate prenatal care as defined by agency rule.
- Maintain clinical records for patients and audit such records every 3 months to evaluate outcomes.

The bill requires ASCs that provide advanced birth services to discharge a mother and her infant from the facility within 48 hours after a vaginal delivery of the infant or within 72 hours after a delivery by cesarean section, except in unusual circumstances as defined by rule of the agency.

The bill requires ASCs that provide advanced birth services to have all general anesthesia administered by an anesthesiologist or a certified registered nurse anesthetist(CRNA). The bill requires that when general anesthesia is being administered, a physician or a CRNA be present in the facility during the anesthesia and post-anesthesia recovery period until the patient is fully alert.

The bill allows ASCs that provide advanced birth services to use chemical agents to induce labor. The bill allows for labor to be electively induced beginning at the 39th week of gestation for a patient with a documented Bishop score of 8 or greater.

The bill requires ASCs that provide advanced birth services to provide the same postpartum care and evaluation that birth centers are required to provide. The bill also requires ASCs that provide advanced birth services to inform their clients of the same policies and procedures that birth centers are required to provide to their clients. The bill also requires ASCs that provide advanced birth services to meet the same clinical record-keeping and audit requirements for birth centers.

RCCs

The bill creates a new license for a Recovery Care Center (RCC). The new RCC license is modeled after the current licensure program for hospitals and ASCs in Chapters 395 and 408, F.S. An applicant for RCC licensure must follow the general licensing procedures in Chapter 408, Part II. Additionally, the applicant will be subject to the license, inspection, safety, facility, and other requirements of Chapter 395, Part I.

The bill defines a RCC as a facility whose primary purpose is to provide recovery care services, to which the patient is admitted and discharged within 72 hours, and is not part of a hospital. The bill defines recovery care services as:

- Postsurgical and post-diagnostic medical and general nursing care to patients for whom acute hospitalization is not required and an uncomplicated recovery is reasonably expected; and
- Postsurgical rehabilitation services.

Recovery care services do not include intensive care services, coronary care services, or critical care services.

The bill requires all patients to be certified as medically stable and not in need of acute hospitalization by their attending or referring physician prior to admission to a RCC. A patient may receive recovery care services in a RCC upon:

- Discharge from an ASC after surgery;
- Discharge from a hospital after surgery or other treatment; or
- Receiving an out-patient medical treatment, such as chemotherapy.

A RCC must have emergency care and transfer protocols, including transportation arrangements, and a referral or admission agreement with at least one hospital. Further, AHCA is authorized to adopt rules regarding RCC admission and discharge procedures.

The bill authorizes AHCA to adopt, by rule, appropriate standards for RCCs pursuant to s. 395.1055, F.S. in the same categories for hospitals and ASCs:

- Staffing;
- Infection control;

- Housekeeping;
- Medical records;
- Emergency management;
- Inspections;
- Accreditation;
- Organization, including a governing body and organized medical staff;
- Departments and services;
- Quality assessment and improvement;
- Minimum space; and
- Equipment and furnishings.

In addition, the bill requires AHCA to adopt rules to set standards for dietetic departments, proper use of medications, and pharmacies in RCCs.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 395.001, F.S., related to legislative intent.
Section 2: Amends s. 395.002, F.S., related to definitions.
Section 3: Amends s. 395.003, F.S., related to licensure; denial, suspension, and revocation.
Section 4: Creates s. 395.0171, F.S., related to recovery care center admissions; emergency and transfer protocols; discharge planning and protocols.
Section 5: Amends s. 395.1055, F.S., related to rules and enforcement.
Section 6: Amends s. 395.10973, F.S., related to powers and duties of the agency.
Section 7: Amends s. 408.802, F.S., related to applicability.
Section 8: Amends s. 408.820, F.S., related to exemptions.
Section 9: Amends 385.211, F.S., related to refractory and intractable epilepsy treatment and research at recognized medical centers.
Section 10: Amends s. 394.4787, F.S., related to definitions.
Section 11: Amends s. 409.975, F.S., related to managed care plan accountability.
Section 12: Amends s. 627.64194, F.S., related to coverage requirements for services provided by nonparticipating providers; payment collection limitations.
Section 13: Provides an effective date of July 1, 2019.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Section 408.805, F.S., requires AHCA to set license fees that are reasonably calculated to cover the cost of regulation. HB 7083, which is linked to this bill, authorizes AHCA to set license fees for RCCs. Applicants for licensure as a RCC will be subject to the current Plans and Construction project review fee of $2,000 plus $100 per hour for building plan reviews, an application fee of at least $1,500, and a licensure inspection fee of $400.[62]

2. Expenditures:

The bill requires AHCA to regulate RCCs in accordance with Chapters 395 and 408, F.S., and any rules adopted by the agency. HB 7083, which is linked to this bill, authorizes AHCA to set license

[62]Agency for Health Care Administration, 2019 Agency Legislative Bill Analysis-HB 25, March 11, 2019 (on file with Health Market Reform Subcommittee staff).

fees for RCCs. The fees associated with the license are anticipated to cover the expense incurred by AHCA in enforcing and regulating the new license.

AHCA may incur costs associated with regulating ASCs that perform advanced birth services. AHCA has authority under current law to set fees for ASCs to cover the costs of regulating those facilities.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Individuals needing surgery may save money by being able to stay longer in an ASC or stay in a RCC rather than having the original procedure in a hospital and remaining in the hospital to recover merely because the recovery time will be longer than the ASC limit would allow.

Being able to keep patients longer may have a positive fiscal impact on the ASC by being able to perform more complex procedures.

Hospitals may experience a negative fiscal impact if more patients receive care in an ASC or RCC.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

There is sufficient rulemaking authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 13, 2019, the Health Market Reform Subcommittee adopted two amendments and reported HB 25 favorably as amended.

The amendments:

- Define advanced birth services to include planned low-risk cesarean deliveries, trial of labor after cesarean delivery for screened patients who qualify and vaginal deliveries for laboring patients from the beginning of the 37th week of gestation through the end of the 41st week of gestation.
- Allow ambulatory surgical centers to provide advanced birth services if they meet the following requirements:
    - Be operated and staffed 24 hours per day, 7 days per week.
    - Comply with minimum staffing requirements.
    - Have at least one properly equipped, dedicated surgical suite for the performance of cesarean deliveries.
    - Enter into agreements with blood banks for emergency transfusions.
    - Make arrangements with a local ambulance service and a hospital or physician with hospital privileges for the transfer of emergency patients.
    - Have a clinical laboratory on-site.
    - Comply with record-keeping requirements.
- Require an ambulatory surgical center that provides advanced birth services to discharge a mother and her infant from the facility within 48 hours after a vaginal delivery of the infant or within 72 hours after a delivery by cesarean section, except in unusual circumstances as defined by rule of the agency.
- Require an ambulatory surgical center that provides advanced birth services to provide prenatal and postpartum care.
- Require an ambulatory surgical center that provides advanced birth services to obtain the patient's informed consent and inform the patient of the facility's policies and protocols.
- Allow an ambulatory surgical center that provides advanced birth services to provide the following additional procedures:
    - Surgical procedures normally performed during uncomplicated childbirths such as episiotomies and repairs.
    - Postpartum sterilization.
    - Circumcisions.

The analysis is drafted to the bill as amended by the Health Market Reform Subcommittee.