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:	Senators Passidomo and Book
SUBJECT:	Neonatal Abstinence Syndrome Pilot Project
DATE:	November 6, 2017 REVISED: 11/7/2017

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Favorable**
2.			AHS	
3.			AP	

I. Summary:

SB 434 establishes a pilot project to license facilities specifically to treat neonatal abstinence syndrome (NAS) that, subject to specific appropriation, will begin on July 1, 2018, and expire on June 30, 2020. The bill requires the Agency for Health Care Administration (AHCA), in consultation with the Department of Children and Families (DCF), to establish a licensure program in AHCA region 8[1] for a community based care option to treat infants with NAS after they have been stabilized in a hospital. The bill also establishes minimum standards that a facility must meet in order to obtain a license and requires the Department of Health (DOH) to contract with a state university to study the risks, benefits, cost differentials, and transition to social services for infants treated at facilities licensed under the pilot project as well as the establishment of baseline data for long term studies on the neurodevelopmental outcomes for infants with NAS.

The bill's provisions take effect upon becoming law.

II. Present Situation:

Neonatal Abstinence Syndrome

NAS occurs in a newborn who was exposed to addictive opiate drugs while in the mother's womb. The most common opiate drugs that are associated with NAS are heroin, codeine, oxycodone (oxycontin), methadone and buprenorphine.[2] When a pregnant mother uses opiate drugs the fetus can become addicted to the drug in-utero. When the baby is born, since it is no longer receiving the opiate drug from its mother it may go into opiate withdrawal and show symptoms including: blotchy skin coloring (mottling), diarrhea, excessive crying or high-pitched

[1] AHCA region 8 includes Charlotte, Collier, DeSoto, Glades, Hendry, Lee, Monroe and Sarasota counties.

[2] DOH *Neonatal Abstinence Syndrome*, available at http://www.floridahealth.gov/diseases-and-conditions/neonatal-abstinence-syndrome/index.html, (last visited Oct. 31, 2017).

crying, excessive sucking, fever, hyperactive reflexes, increased muscle tone, irritability, jitteriness, poor feeding, rapid breathing, seizures, sleep problems, slow weight gain, stuffy nose, sneezing, sweating, trembling (tremors), and vomiting.[3] Most symptoms begin within 72 hours of birth, but some can appear right after birth or up to several weeks after birth. Symptoms can last between one week and 6 months.[4] Additional complications from NAS can include low birthweight, jaundice, requiring treatment in a neonatal intensive care unit (NICU), and needing treatment with medicine.[5]

In correlation with the general increase in the rate of opioid addiction, the rate of NAS is Florida has increased between 1998 and 2013 from approximately 66.7 to 69.2 infants per 10,000 live births. However, between 2013 and 2014 the rate increased significantly to 76.6 infants per 10,000 live births which is an increase of approximately 10 percent. The rate of NAS is substantially higher among non-Hispanic white infants (156.2) when compared to non-Hispanic black infants (26.6) and Hispanic infants (20.2).[6]

Non-hospital Based Treatment of Infants with NAS

Infants with NAS are at increased risk for admission to the neonatal intensive care unit, birth complications, the need for pharmacologic treatment, and a prolonged hospital stay, all of which are outcomes that separate the mother and her infant at a critical time for infant development and bonding. The average length of a hospital stay for infants with NAS is 17 days overall and 23 days for those requiring treatment. Prolonged hospitalization results in the use of a greater portion of health care resources for the care of infants with the NAS than for those without the syndrome.[7]

West Virginia has had success in reducing the length of hospital stays for newborns and infants with NAS through the use of a neonatal abstinence center called "Lily's Place." Lily's Place is a facility that provides a safe recovery environment for the infant, and offers parental education and makes referrals to addiction-recovery programs for caregivers when appropriate. The 7,500 square foot facility, previously a physician's office building, was donated and renovated by community volunteers and grant funded staff to serve as an outpatient neonatal abstinence center.[8]

After creation of Lily's Place, all inpatient newborns were admitted at birth to newborn nursery or NICU if comorbidities existed. When it was determined that medication was required for treatment of NAS, infants were moved to the neonatal therapeutic unit (NTU) or secondarily to NICU when beds were unavailable. After initial assessment and stabilization, neonates could be

[3] Supra n. 2
[4] The March of Dimes, *Neonatal Abstinence Syndrome (NAS)* (June 2017), *available at* https://www.marchofdimes.org/complications/neonatal-abstinence-syndrome-(nas).aspx, (last visited Oct. 31, 2017).
[5] Id.
[6] Department of Health, *Senate Bill 434 Analysis* (on file with the Senate Committee on Health Policy).
[7] Karen McQueen, R.N., Ph.D., and Jodie Murphy-Oikonen, M.S.W., Ph.D., *Neonatal Abstinence Syndrome* (December 22, 2016), the New England Journal of Medicine, *available at* http://www.nejm.org/doi/full/10.1056/NEJMra1600879#t=article, (last visited Nov. 1, 2017).
[8] S. Loudin, et. al., *A management strategy that reduces NICU admissions and decreases charges from the front line of the neonatal abstinence syndrome epidemic* (July 6, 2017) Journal of Perinatology, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5633652/, (last visited Nov. 1, 2017).

sent to Lily's Place when beds were available. Babies were preferentially transferred to Lily's Place who were considered to potentially benefit from private rooms with less external stimulation. The protocol for medication management of NAS was the same for the NICU, NTU and Lily's Place.[9]

A study from Cabell Huntington Hospital of the effectiveness Lily's Place found that it contributed to an overall decrease in the number of infants admitted to the NICU. This decrease relieved the strain of an increasing NAS population crowding the hospital's NICU and the study concluded that without [Lily's Place and the opening of the NTU] the NICU would be in a critical state of gridlock and diversion. Additionally, the study found that Lily's Place provided care to NAS infants at a significantly lower cost, charging only $17,688 on average versus $90,601 for an NAS infant in the NICU.[10]

Mandatory Reporting and DCF Investigations of Child Abuse

Section 39.201, F.S., requires any person who knows, or has reasonable cause to suspect, that a child is abused to report such knowledge or suspicion to the DCF. For the purposes of such reporting, "abuse" means any willful act or threatened act that results in any physical, mental, or sexual abuse, injury, or harm[11] and the definition of "harm" includes exposing a child to a controlled substance or alcohol. Exposure to a controlled substance or alcohol is established by:

- A test, administered at birth, which indicated that the child's blood, urine, or meconium contained any amount of alcohol or a controlled substance or metabolites of such substances, the presence of which was not the result of medical treatment administered to the mother or the newborn infant; or
- Evidence of extensive, abusive, and chronic use of a controlled substance or alcohol by a parent when the child is demonstrably adversely affected by such usage.[12]

Once reported, the DCF must commence an investigation immediately, if it appears that the immediate safety or well-being of a child is endangered, that the family may flee or the child will be unavailable for purposes of conducting a child protective investigation, or that the facts otherwise so warrant, or within 24 hours after receiving the report. If the investigation warrants, a child may be taken into custody by an authorized agent of the DCF if the agent has probable cause to support a finding that the child has been abused. After taking the child into custody the DCF must review the facts of the case and determine whether to file a shelter petition within 24 hours of taking custody.[13]

Authority of Health Care Workers to Detain a Child

Section 39.395, F.S., authorizes any person in charge of a hospital or similar institution, or any physician or licensed health care professional treating a child to detain that child without the consent of the parents, caregiver, or legal custodian, whether or not additional medical treatment is required, if the circumstances are such, or if the condition of the child is such that returning the

[9] Supra note 8
[10] Id.
[11] s. 39.01(2), F.S.
[12] s. 39.01(30)(g), F.S.
[13] s. 39.401, F.S.

child to the care or custody of the parents, caregiver, or legal custodian presents an imminent danger to the child's life or physical or mental health. After doing so, any such person detaining a child shall immediately notify the DCF, whereupon the DCF shall immediately begin a child protective investigation in accordance with the provisions of this chapter and shall make every reasonable effort to immediately notify the parents or legal custodian that such child has been detained. If the department determines, according to the criteria set forth in this chapter, that the child should be detained longer than 24 hours, it shall petition the court through the attorney representing the DCF as quickly as possible and not to exceed 24 hours, for an order authorizing such custody in the same manner as if the child were placed in a shelter.

III. Effect of Proposed Changes:

SB 434 creates s. 409.9134, F.S. to establish a pilot project to license facilities specifically to treat NAS that, subject to specific appropriation, will begin on July 1, 2018, and expire on June 30, 2020.

The bill defines the terms:

- "Infant" to include both the terms "newborn" and "infant" as defined in s. 383.145, F.S. As defined in that section "newborn" means an age range from birth to 29 days old and "infant" means an age range from 30 days to 12 months; and
- "Neonatal abstinence syndrome" to mean the postnatal opioid withdrawal experienced by an infant who is exposed in utero to opioids or agents used to treat maternal opioid addiction.

The bill requires the AHCA, in consultation with the DCF, to establish a pilot project in AHCA region 8[14] to license one or more facilities to treat infants who suffer from NAS by providing a community-based care option, rather than hospitalization, after an infant has been stabilized. The bill authorizes the AHCA to charge an initial licensure fee and biennial renewal fee of up to $1,000; applies the licensure standards of part II of ch. 408, F.S.;[15] exempts facilities licensed under this program from the requirement to obtain a certificate of need; and requires the AHCA, in consultation with the DCF, to adopt rules for minimum licensure standards including:

- Requirements for physical plant and maintenance of facilities;
- Compliance with local building and fire codes;
- The number, training, and qualifications of essential personnel employed by and working under contract with the facility;
- Staffing requirements intended to ensure adequate staffing to protect the safety of infants being treated in the facility;
- Sanitation requirements for the facility;
- Requirements for programs, basic services, and care provided to infants treated by the facility and their parents;
- Requirements for the maintenance of medical records, data, and other relevant information related to infants treated by the facility; and
- Requirements for application for initial licensure and licensure renewal.

[14] Supra note 1.
[15] Part II of ch. 408, F.S., contains the general provisions for health care facility licensing.

The bill also establishes minimum requirements that, in order to obtain a license and participate in the pilot project, each facility must:

- Be a private, not-for-profit Florida corporation;
- Be a Medicaid provider;[16]
- Have an on-call medical director;
- Demonstrate an ability to provide 24-hour nursing and nurturing care to infants with neonatal abstinence syndrome;
- Demonstrate an ability to provide for the medical needs of an infant being treated within the facility, including, but not limited to, pharmacotherapy and nutrition management;
- Maintain a transfer agreement with a nearby hospital that is not more than a 30-minute drive from the licensed facility;
- Demonstrate an ability to provide comfortable residential-type accommodations for an eligible mother to breastfeed her infant or to reside within the facility while her infant is being treated at that facility, if not contraindicated and if funding is available for residential services. The facility may request at any time that the mother's breast milk be tested for contaminants or that the mother submit to a drug test. The mother shall vacate the facility if she refuses to allow her breast milk to be tested or to consent to a drug test or if the facility determines that the mother poses a risk to her infant;
- Be able to provide or make available parenting education, breastfeeding education, counseling, and other resources to the parents of infants being treated at the facility including, if necessary, a referral for addiction treatment services;
- Contract and coordinate with Medicaid managed medical assistance plans as appropriate to ensure that services for both the infant and the parent or the infant's representative are timely and unduplicated;
- Identify, and refer parents to, social service providers, such as Healthy Start,[17] Early Steps,[18] and Head Start[19] programs, prior to discharge, if appropriate; and
- Adhere to all applicable standards established by the AHCA.

[16] The Medicaid program covered 63 percent of all births in Florida for SFY 2015-16.

[17] The Healthy Start program is available statewide for eligible Medicaid recipients and provides prenatal services, post-natal, and other child-birth related assistance to low income women and children up to 185 percent of the federal poverty level and to other pregnant women who are identified to be at risk for poor birth outcomes, poor health, and poor developmental outcomes. Substance using pregnant women and exposed newborns are priority populations for automatic inclusion in the Healthy Start program, and most medical providers and hospitals automatically refer them for Healthy Start services.

[18] Early Steps is Florida's early intervention program which offers services to eligible infants and toddlers (birth to age 36 months) who are identified with significant delays or conditions that are likely to result in a developmental delay. Most services are covered by insurance or Medicaid, if eligible, and are provided by local Early Steps offices. Currently, Early Steps policy does not consider NAS to be an established condition. This means that children with NAS may only be made eligible for Early Steps based on meeting a certain level of developmental delay. However, as of January 1, 2018 when new policies become effective, there will be an at-risk category of eligibility. NAS will be considered one of the at-risk conditions for Early Steps, meaning that a child with NAS will be eligible for Early Steps because NAS is known to create a risk of developmental delay. Written confirmation from a licensed physician is required to establish at-risk eligibility and must be in the child's Early Steps record. Services for such at-risk children will include: individualized family support planning, service coordination, developmental surveillance, and family support. (*See* DOH Senate Bill 434 Analysis) (on file with the Senate Committee on Health Policy).

[19] Head Start is a national school readiness program for low income families that provides comprehensive education, health, nutrition, and parent involvement services. The federal government awards grants to local public agencies, private and public not-for-profit organizations, school systems, and Indian Tribes to operate the programs in local communities.

Additionally, the bill mandates that the AHCA require level 2 background screening for facility personnel.[20]

Facilities licensed under this program may not accept an infant with a serious or life-threatening condition other than NAS and may not treat an infant for longer than 6 months.

The bill directs the DOH to contract with a state university to study the risks, benefits, cost differentials, and the transition of infants to social services providers for the treatment of infants with NAS in hospital settings and in facilities licensed under the pilot project. The DOH must report the study results and recommendations for the continuation or expansion of the pilot project to the Legislature by December 21, 2019. The contract with the state university must also require the establishment of baseline data for longitudinal studies on the neurodevelopmental outcomes of infants with NAS and the contract may require the evaluation of outcomes and length of stay in facilities for nonpharmacologic and pharmacologic treatment of NAS. Facilities licensed under the pilot project, hospitals that provide services to infants with NAS, and Medicaid medical assistance plans must provide data to the contracted university for its research and studies in compliance with the Health Insurance Portability and Accountability Act of 1996.

The bill's provisions take effect upon becoming law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

SB 434 may have a positive fiscal impact on families with infants with NAS who are able to use a facility licensed under the bill's provisions since a stay at such a facility may be less costly than an extended stay in a NICU.

[20] Pursuant to s. 408.809, F.S., and ch. 435, F.S.

C. Government Sector Impact:

The bill requires the DOH to contract with a state university to conduct research and a specified study. The DOH estimates the cost of such a contract at $210,000 over the course of the pilot project.

The pilot project established by the bill is subject to a specific appropriation. The amount of such appropriation is unknown at this time.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill creates a new license type and requires a Medicaid provider number in order to be licensed. However, typically, to obtain a Medicaid provider number a provider must submit a state license or authorization as part of provider enrollment and processing may take several months for a provider number to be issued. This "catch 22" is under discussion with the state Medicaid program for resolution.

VIII. Statutes Affected:

This bill creates section 409.9134 of the Florida Statutes.

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.